Assessing Quality in Health Care: An Evaluation: Report of a Study (1976)

Pages
157

Size
8.5 x 11

ISBN
0309026113

Institute of Medicine

INSTITUTE OF MEDICINE

ASSESSING QUALITY IN HEALTH CARE: AN EVALUATION

Final Report

November 1976

Supported by U.S. Department of Health, Education,
and Welfare Contract No. 282-75-0437 PM

National Academy of Sciences

Washington, D.C.

NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE
WASHINGTON, D. C. 20418

INSTITUTE OF MEDICINE
OFFICE OF THE PRESIDENT

September 30, 1976

The Honorable Harley O. Staggers
Chairman
Committee on Interstate and Foreign Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I am pleased to present to the Committee on Interstate and Foreign Commerce the final report of a study conducted by the Institute of Medicine, National Academy of Sciences, pursuant to Section 4 of the Health Maintenance Organization Act of 1973 (P.L. 93-222). That provision requested the Secretary of Health, Education, and Welfare to arrange for a comprehensive study of health care quality assurance programs.

The Institute of Medicine was asked to conduct a limited version of that study which had the following objectives: the description and assessment of the effect of operational quality review programs, based on existing information and supplemented by observations and data obtained in selected site visits; and a more detailed examination of several topics, designated "priority areas" because of their importance in determining the effectiveness of quality assurance programs. These areas include outcome-oriented approaches to quality assurance, quality assurance for ambulatory care, quality assurance for long-term care, methods for changing behavior patterns of health care providers, and patient and consumer involvement in quality assurance programs. The findings and recommendations for both objectives are presented in this volume.

An additional study objective, requested by the Department of Health, Education, and Welfare, required an assessment of the reliability of hospital utilization information generated by private abstracting services and based on abstracts of the hospital medical record. The purpose was to determine the usefulness of such information for evaluating the impact of Professional Standards Review Organizations. That study will be reported in a separate volume.

We shall be pleased to discuss this report in greater detail with the members and staff of your committee.

Sincerely yours,

David A. Hamburg, M.D.
President

Enclosure

NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE
WASHINGTON, D. C. 20418

INSTITUTE OF MEDICINE
OFFICE OF THE PRESIDENT

September 30, 1976

The Honorable Harrison A. Williams, Jr.
Chairman
Committee on Labor and Public Welfare
United States Senate
Washington, D.C. 20501

Dear Mr. Chairman:

I am pleased to present to the Committee on Labor and Public Welfare the final report of a study conducted by the Institute of Medicine, National Academy of Sciences, pursuant to Section 4 of the Health Maintenance Organization Act of 1973 (P.L. 93-222). That provision requested the Secretary of Health, Education, and Welfare to arrange for a comprehensive study of health care quality assurance programs.

The Institute of Medicine was asked to conduct a limited version of that study which had the following objectives: the description and assessment of the effect of operational quality review programs, based on existing information and supplemented by observations and data obtained in selected site visits; and a more detailed examination of several topics, designated "priority areas" because of their importance in determining the effectiveness of quality assurance programs. These areas include outcome-oriented approaches to quality assurance, quality assurance for ambulatory care, quality assurance for long-term care, methods for changing behavior patterns of health care providers, and patient and consumer involvement in quality assurance programs. The findings and recommendations for both objectives are presented in this volume.

An additional study objective, requested by the Department of Health, Education, and Welfare, required an assessment of the reliability of hospital utilization information generated by private abstracting services and based on abstracts of the hospital medical record. The purpose was to determine the usefulness of such information for evaluating the impact of Professional Standards Review Organizations. That study will be reported in a separate volume.

We shall be pleased to discuss this report in greater detail with the members and staff of your committee.

Sincerely yours,

David A. Hamburg, M.D.
President

Enclosure

INSTITUTE OF MEDICINE

ASSESSING QUALITY IN HEALTH CARE: AN EVALUATION

Steering Committee

Chairman

Robert J. HAGGERTY, M.D., Roger I. Lee Professor of Public Health, Harvard School of Public Health, Boston, Massachusetts

Members

*Carl EISDORFER, Ph.D., M.D., Professor and Chairman, Department of Psychiatry and Behavioral Sciences, School of Medicine, University of Washington, Seattle, Washington

Jacob J. FELDMAN, Ph.D., Associate Director for Analysis, National Center for Health Statistics, Rockville, Maryland

John R. GAMBLE, M.D., Chairman, Department of Medicine, Pacific Medical Center, San Francisco, California

Melvin A. GLASSER, LL.D., Director, Social Security Department, United Auto Workers, International Union, Detroit, Michigan

Sidney KATZ, M.D., Professor and Director, Office of Health Services Education and Research, College of Human Medicine, Michigan State University, E. Lansing, Michigan

*B. Harvey MINCHEW, M.D., Internist, Ellicott City, Maryland

Alan R. NELSON, M.D., Internist, Salt Lake City, Utah

Howard N. NEWMAN, J.D., President, Dartmouth-Hitchcock Medical Center, Hanover, New Hampshire

Donald C. RIEDEL, Ph.D., Chairman of the Center for the Study of Health Services, Yale University, New Haven, Connecticut

*Marc J. ROBERTS, Ph.D., Professor of Political Economy and Health Policy, Academic Director of the Executive Programs in Health Policies and Management, Harvard University, Boston, Massachusetts

Sam SHAPIRO, B.S., Director, Health Services Research and Development Center, Professor of Health Care Organization, Department of Health Services Administration, The Johns Hopkins University, Baltimore, Maryland

Barbara STARFIELD, M.D., Professor and Division Head, Health Care Organization and Associate Professor of Pediatrics, The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland

*Participation was limited to the planning phases of the study.

INSTITUTE OF MEDICINE

ASSESSING QUALITY IN HEALTH CARE: AN EVALUATION

Consultants and Reviewers

Basic Study

Don E. DETMER, M.D., Assistant Professor of Surgery and Preventive Medicine, University of Wisconsin, Madison, Wisconsin

Frederick C. LANE, M.D., Chief of Surgery, Kings County Hospital, Brooklyn, New York

James P. LOGERFO, M.D., Assistant Professor, Department of Health Services and Medicine, University of Washington, Seattle, Washington

Dale N. SCHUMACHER, M.D., Post Doctoral Fellow, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Maryland; Medical Resident, St. Agnes Hospital, Baltimore, Maryland

Issues of Cost and Cost Effectiveness

William C. L. HSIAO, Ph.D., Associate Professor of Economics, Harvard University, School of Public Health, Boston, Massachusetts

Beverlee A. MYERS, Lecturer, Department of Medical Care Organization School of Public Health, University of Michigan, Ann Arbor, Michigan

Alan C. MONHEIT, Ph.D., Research Associate in Health Economics, Health Policy Center, Boston University, Boston, Massachusetts

Howard N. NEWMAN, J.D., President, Dartmouth-Hitchcock Medical Center, Hanover, New Hampshire

Charles E. PHELPS, Ph.D., Research Staff, The RAND Corporation, Santa Monica, California

David S. SALKEVER, Ph.D., Associate Professor, Health Services Administration, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Maryland

Assessment of Health Outcomes

Robert H. BROOK, M.D., Research Staff, The RAND Corporation, Santa Monica, California

Don E. DETMER, M.D., Assistant Professor of Surgery and Preventive Medicine, University of Wisconsin, Madison, Wisconsin

Jacob J. FELDMAN, Ph.D., Associate Director for Analysis, National Center for Health Statistics, Rockville, Maryland

Sidney KATZ, M.D., Professor and Director, Office of Health Services Education and Research, College of Human Medicine, Michigan State University, East Lansing, Michigan

Alan R. NELSON, M.D., Internist, Salt Lake City, Utah

Quality Assurance in Ambulatory Care

Paul B. BATALDEN, M.D., Project Director, Quality Assurance Programs, St. Louis Park Medical Center, Minneapolis, Minnesota

Richard J. GREENE, M.D., Harvard School of Public Health, Boston, Massachusetts

Robert R. HUNTLEY, M.D., Professor and Chairman, Department of Community Medicine and International Health, Georgetown University School of Medicine, Washington, D.C.

James P. LOGERFO, M.D., Assistant Professor, Department of Health Services and Medicine, University of Washington, Seattle, Washington

John J. McCORD, President, Systemetrics, Inc., Santa Barbara, California

R. Heather PALMER, M.D., Instructor in Maternal and Child Health, Department of Health Services, Harvard School of Public Health, Boston, Massachusetts

Sam SHAPIRO, B.S., Director, Health Services Research and Development Center, Professor of Health Care Organization, Department of Health Services Administration, The Johns Hopkins University, Baltimore, Maryland

Barbara STARFIELD, M.D., Professor and Division Head, Health Care Organization and Associate Professor of Pediatrics, The Johns Hopkins University, School of Public Health, Baltimore, Maryland

Barbara P. WASSERMAN, M.D., Assistant Director for Clinical Services, Health Center, University of Maryland, College Park, Maryland

Quality Assurance in Long Term Care

Sidney KATZ, M.D., Professor and Director, Office of Health Services Education and Research, College of Human Medicine, Michigan State University, East Lansing, Michigan

Abraham KOSTICK, Executive Director, Levindale Hebrew Geriatric Center and Hospital, Baltimore, Maryland

T. Franklin WILLIAMS, M.D., Medical Director, Monroe Community Hospital, Rochester, New York

Implications of Quality Assurance for Provider Performance

William C. FELCH, M.D., Internist, The Rye Medical Group, Rye, New York

Robert J. HAGGERTY, M.D., Roger I. Lee Professor of Public Health, Harvard School of Public Health, Boston, Massachusetts

Christine McGUIRE, Associate Director for Research and Development, Center for Educational Development, University of Illinois at the Medical Center, Chicago, Illinois

R. Heather PALMER, M.D., Instructor in Maternal and Child Health, Department of Health Services, Harvard School of Public Health, Boston, Massachusetts

George C. STONE, Ph.D., Professor of Medical Psychology in Residence, Langley Porter Neuropsychiatric Institute, University of California, San Francisco, California

Consumer Involvement in Quality Assurance

Thomas L. DELBANCO, M.D., Medical Director of Ambulatory Care, Beth Israel Hospital, Boston, Massachusetts

Lawrence W. GREEN, Ph.D., Associate Professor, Head of Division of Health Education, School of Hygiene and Public Health, The Johns Hopkins University, Baltimore, Maryland

Alan R. NELSON, M.D., Internist, Salt Lake City, Utah

Sam SHAPIRO, B.S., Director, Health Services Research and Development Center, Professor of Health Care Organization, Department of Health Services Administration, The Johns Hopkins University, Baltimore, Maryland

Barbara STARFIELD, M.D., Professor and Division Head, Health Care Organization and Associate Professor of Pediatrics, The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland

Donald M. VICKERY, M.D., Department Staff, Mitre Corporation, McLean, Virginia

Assessment of the Reliability of Abstracted Hospital Utilization Data

Faye BROWN, R.R.A., Director, Medical Information Service, St. Helena Hospital and Health Center, Deer Park, California

Jacob J. FELDMAN, Ph.D., Associate Director for Analysis, National Center for Health Statistics, Rockville, Maryland

Donald C. RIEDEL, Ph.D., Chairman of the Center for the Study of Health Services, Yale University, New Haven, Connecticut

Joseph STEINBERG, President, Survey Design, Inc., Silver Spring, Maryland

INSTITUTE OF MEDICINE

DAVID A. HAMBURG, M.D., President

ASSESSING QUALITY IN HEALTH CARE: AN EVALUATION

IOM Study Staff

Linda K. DEMLO, Ph.D., Study Director

Marilyn Sue BOGNER, Ph.D.

Paul M. CAMPBELL

Carol Rubin LASKIN

Lupi Phillips ROBINSON

David SCHENKER

Juliana V. GOLDBERG, Editor

CONTENTS

FOREWORD

Assuring the quality of medical care is a major innovation in the delivery of health services in the United States. Indeed, no other nation has embarked upon such a large scale effort to review the quality of health services. Professional Standards Review Organizations are the vehicles through which this country is currently attempting to monitor the quality of services provided to beneficiaries of the Medicare, Medicaid, and Maternal and Child Health programs. It is much too early to make a definitive evaluation of the success of this massive effort. Nevertheless, the United States Congress, the Institute of Medicine, and other groups throughout the country are deeply involved in these evolving mechanisms for assuring quality of care, as well as alternative methods and approaches.

The complexities of quality assurance were noted in the Institute of Medicine's 1974 policy statement, "Advancing the Quality of Health Care," which outlined the state-of-the-art at that time. When Congress requested a study of health care quality assurance programs as part of the Health Maintenance Organization Act of 1973, it was natural that those charged with implementing the Congressional mandate should turn to the Institute of Medicine for assistance in conducting a limited version of the requested study. The report that follows assesses the current state of quality assurance by reviewing ongoing programs and existing literature. Recommendations are made for future directions in quality assurance.

As is customary for Institute of Medicine reports, a steering committee was appointed, consisting of both Institute members and non-members expert in the field. The steering committee guided and approved the conduct of the study and the final report, which was reviewed by the Council of the Institute of Medicine and the National Academy of Sciences. It was my privilege to work with a dedicated and competent staff and a stimulating steering committee throughout the study.

The report is not the final statement on quality assurance programs, for they will continue to change rapidly. Nevertheless, we trust that it will further the development of this major national effort to improve health and health care.

Robert J. Haggerty, M.D.
Chairman, Steering Committee

Chapter 1

SUMMARY AND RECOMMENDATIONS

The concept of quality in medical care historically has been a part of the ethos of the medical profession. In recent years, public interest in health care quality and cost has been heightened by the increase in public expenditures for health care. One congressional reflection of that interest was the enactment in 1972 of legislation that authorized the establishment of Professional Standards Review Organizations (PSROs) [1] to monitor the appropriateness of health services financed by the Medicare, Medicaid, and Maternal and Child Health programs. The following year, Congress requested a major study of alternative mechanisms for health care quality assurance, a request that was included in the Health Maintenance Organization Act of 1973. [2]

A limited version of that study was contracted to the Institute of Medicine by the Department of Health, Education, and Welfare. The study, reported in this document, had the following objectives:

- The description and assessment of the effect of operational quality review programs, based on existing written information and supplemented by observations and data obtained in selected site visits;
- A detailed literature review of several topics, designated as "priority areas" because of their importance in determining the effectiveness of quality assurance programs and the absence of reviews that integrate and analyze relevant information;
- A delineation of areas in which additional research and evaluation are required.

The purpose of the study was not to evaluate the PSRO program--a relatively recent, large-scale undertaking not yet organizationally complete. Nevertheless, some quality assessment programs reviewed were PSROs, and some recommendations refer specifically to the PSRO program.

In limiting the scope of the study, the steering committee established criteria for selecting quality assurance programs for detailed review. Because the concept of quality is multidimensional and complex, a single definition of quality was not used. Instead, components of quality that have been

identified and emphasized by existing programs were accepted within the focus of this study. Particular attention was given to programs with the stated purpose of improving the health status and satisfaction of patients. The committee did specify characteristics of an ideal quality assurance system: the existence of an organizational entity for assessing quality; the establishment of standards or criteria against which quality is assessed; a routine system for gathering information; assurance that such information is based on a representative sample of the total population of patients or potential patients; a process for providing the results of review to patients, the public, providers, and sponsoring organizations; and methods for instituting corrective actions.

A survey of existing programs, including many of those reviewed in detail in this study, makes apparent the fact that most programs do not meet all of the characteristics of an ideal system specified above. Most concentrate on the assessment of the medical care process, rather than the assurance of improved quality of health care. Few programs routinely provide review information to patients and providers, impose corrective actions, or determine through reassessment whether the quality of care has improved. Thus, one might more realistically describe the programs as quality assessment activities, rather than quality assurance. However, the term "quality assurance" is so prevalent that it is unlikely to be obliterated because of this distinction. Both terms are used in this report.

Several timely health policy issues that influence the quality of care were excluded from this report. For example, malpractice and the existence of fraud in federally financed health programs were not considered. Existing quality assessment programs do not emphasize the detection of fraudulent practices and may not be capable of doing so. Other mechanisms are being developed to deal with malpractice. Similarly, many factors in the financing and delivery of health care that influence quality were not studied in detail. These include the organizational arrangements through which care is provided, insurance or reimbursement programs that specify reimbursable methods of treatments, health professional education, the numbers and distribution of physicians and non-physicians geographically and among specialities, provisions for licensing and certification of individual health care providers and facilities, and the recording, storage, and retrieval of information about patients.

Thus, the study is not an exhaustive review of all factors in the health care sector that influence the quality of care. Rather, it is an examination of existing quality review programs. The primary purpose is to describe the manner in which they function and their reported effectiveness in improving health status or patient satisfaction and conserving resources. Additional issues relating to quality assurance are reviewed in the priority areas: outcome-oriented approaches to quality assurance, quality assurance for ambulatory care, quality assurance for long-term care, methods for changing behavior patterns of health care providers, and patient and consumer involvement in quality assurance programs.

Determining the effectiveness of quality review programs is particularly difficult--in part because of methodological problems, but also because of the

absence of valid and reliable information. The effect of review on quality of care usually is described anecdotally because of limitations in current measures of health status or outcome. Although improvements in quality attributed by program officials to review may be impressive, there is no current method for relating the individual anecdotes to the total review effort in a manner which would facilitate the determination of cost effectiveness. Because of the close link between quality and utilization of services, the relative ease of measuring utilization, and its associated relationship to cost control, effectiveness is frequently measured in terms of utilization, as expressed in costs. However, the measures customarily used are frequently inadequate and difficult to interpret. This is discussed in detail in the body of the report. Variations among review programs limit one's ability to compare program effectiveness. The relative effect of different types of review mechanisms might be assessed by comparing programs according to the magnitude of changes within them, assuming all other influences could be held constant. However, adequate baseline data are not available to permit before-and-after measurements. A period of time must be allowed for program development and refinement before effectiveness can realistically be expected.

DESCRIPTION OF QUALITY ASSESSMENT PROGRAMS

The 18 quality assessment programs reviewed in detail represent what have been regarded as the "better" programs. Most have benefitted from considerable financial support and extensive experience, as compared with programs not included in the study. The programs reviewed cannot be regarded as a representative national sample. Many of them were pioneers in the field of quality assurance and have created models that have been adapted elsewhere. Their accomplishments, however, were not made without difficulties, and these may be equally instructive. To draw conclusions from the experiences of these programs perhaps would be to pass judgment prematurely on programs that have had insufficient time to work on a very complex problem. The information presented here, therefore, is intended to assist in re-examining and, possibly, redirecting current efforts before they become so established in custom as to make modification difficult.

A majority of the programs visited can be characterized as follows:

- The stated goals are to ensure high quality medical care at a reasonable cost. But the goals are not expressed in terms that permit measurement of the degree to which they are achieved. The margin by which quality might be improved is not known. Even rough estimates of the magnitude of currently inappropriate care were unavailable. Without such measures, it becomes difficult to determine whether a program is achieving its objectives and whether the resultant improvement is sufficient to justify program expenditures.

- Programs are oriented toward users of health services, rather than people who do not use services, and with a few exceptions, do not consider

access to care and under-utilization of services.

- Compliance with PSRO review requirements is the major concern of most hospital programs. PSRO review components include: concurrent review--intended to assure that individual hospital admissions and continued stays are medically necessary; medical care evaluations (MCEs) or medical audits--a detailed, frequently retrospective review of the quality of care given to groups of patients; and profile analysis--a retrospective analysis of patterns of care that may concentrate on particular diagnoses, patients, or physicians and identify areas for special attention by either concurrent review or MCEs.

- Most hospital review programs place primary emphasis on concurrent review activities. There is considerable variation among programs in the timing, depth, and frequency of review. Similarly, the degree to which review coordinators and physician advisors are trained and supervised varies by program.

- Less emphasis is placed on medical care evaluation studies. Common problems have been encountered in conducting MCEs: the incompatibility between requirements of the Joint Commission on Accreditation of Hospitals (JCAH) and PSRO; the difficulty of selecting audit topics which result in the identification of significant problems so that improvements can be made; the difficulty of developing criteria that are relevant for all patients without becoming too general; and the difficulty of achieving change, once deficiencies in patient care have been identified. Innovative efforts which address these problems are underway.

- Profile analysis, the third component of PSRO review, is the least developed.

- Integration of the three review components is seldom achieved within hospitals or within PSRO administrative staffs.

- The most common type of quality assessment for ambulatory care is based on a review of claim forms submitted by physicians to fiscal intermediaries for reimbursement purposes. Alternatives to claims review should permit greater emphasis on quality by reviewing the provision of medical care over time and assessing access to care and health outcomes. However, they require further refinement and evaluation before being widely implemented.

- There is difficulty in achieving improvements after deficiencies in patient care have been documented. Most programs rely on educational methods for encouraging improved performance. Some internal appraisals of the effects of review have been made, but no program has established a formal mechanism for self-assessment. Some have been evaluated by external groups, however.

EFFECTIVENESS OF QUALITY ASSESSMENT PROGRAMS

The steering committee believes that the widespread interest in quality assurance activities and the intellectual stimulation and professional re-examination that occur as programs are initiated and standards for care are established should eventually improve the general quality of medical practice. The committee found impressive examples of stated improvements in quality and changes in utilization of health care services in the programs reviewed. Assessing the broader impact, however, requires consideration of the total magnitude of the effort, not merely isolated examples.

The difficulty of measuring the quality of care and the effectiveness of quality review systems was noted at the outset. Information on cost and effectiveness, in particular, covers a relatively short time span and reflects whatever information was readily available rather than what could be collected in a carefully designed effort at evaluation. These limitations notwithstanding, the steering committee was able to reach some preliminary conclusions about the current effectiveness of programs visited:

- Existing information does not substantiate the effectiveness of MCEs. MCEs or medical audits have been required for accreditation and reimbursement purposes for several years. Yet, there is no reliable source of data to reflect the numbers, topics, and associated costs of currently performed MCEs, the identified deficiencies in patient care, the remedial actions proposed and taken, or the extent and duration of improvements in patient care. MCEs may have caused improvements in quality, but reliable, generalizable assessments are not available.

- Evidence is not yet available for a conclusion that hospital concurrent review programs are effective. Although changes in utilization patterns have been noted, the reasons are not adequately understood. The costs of conducting concurrent review vary widely. Assertions of cost savings are exaggerated, because they assume that total per diem cost will be saved for each day of care denied and do not adequately take into account fixed hospital costs or the cost of alternative care.

- Most ambulatory care claims review programs considered in this study yield dollar reductions in submitted claims that are more than adequate to pay the costs of review, and some improvements in quality have been noted. At least for the fiscal intermediary, claims review is cost effective. A claim denied or reduced, however, is not necessarily a claim unpaid--some providers are persistent in recovering some portion of their fee, which may be eventually paid by the patient, other fiscal intermediaries, or society. Furthermore, most savings come from administrative reviews of patient eligibility for insurance coverage, the range of reimbursable benefits, or the amount of reimbursement claimed. These savings would be realized under most claims review systems and generally are unrelated to considerations of either quality or appropriateness of care. The additional benefits from the medical peer review component of claims review are not well documented.

The reasons for lack of demonstrated effectiveness of quality review programs are difficult to isolate. Whether they are due to faulty conceptualization of the nature of quality or to defects in program design is not clear. At the very least, it is evident that the objectives of current programs are not well specified and include a mixture of goals: cost control alone, utilization control (a desire to increase the potential benefits of care by controlling the types and quality of resources used, which also generate costs), and increased effectiveness of medical care (improved quality in terms of greater patient satisfaction and better health outcome). Though these objectives may be conceptually interrelated, it is not clear that a single review program can address these and possibly other objectives simultaneously.

These uncertainties notwithstanding, the steering committee believes that some monitoring, perhaps on a sample basis, of the quality of medical care provided to all patients--not just those for whom the federal government has financial responsibility--is essential. At the level of quality assurance expenditures anticipated for FY 1977, the total cost for hospital and ambulatory review could exceed $1,250,000,000 annually if extrapolated for the entire U.S. population. There is a need for less expensive methods to achieve better results. It should be possible to increase the efficiency of existing quality assessment techniques while also developing new strategies for areas which do not now receive adequate attention.

The steering committee identified a number of actions that could be taken to achieve these goals. The committee's recommendations are divided into two sections. General recommendations stem primarily from the site visits and are not confined to any specific priority area. They are mainly actions which should be taken by national policymakers, although other national policy recommendations in the priority areas are properly cited under those headings, which follow the general recommendations.

Both general and priority area recommendations are categorized into those which should be implemented immediately and long-term recommendations which require further research and evaluation. Many of the long-term recommendations emphasize the need to develop more refined techniques for conducting quality assurance activities, with particular concentration in two areas: research to develop more reliable and valid assessment tools to measure the levels of quality; and research to foster the improvement or assurance of quality, which involves the development of better methods for altering the behavior of both health care providers and consumers. Thus, many of the recommendations for the priority areas constitute a long-range research agenda.

GENERAL POLICY RECOMMENDATIONS

Immediate

1. Review techniques should be refined to facilitate a more concentrated (targeted) examination of diagnoses, patients, or providers associated

with questionable patterns of care, as an alternative to the current practice of reviewing all cases. A targeted review should enable more frequent identification of truly inappropriate care and less frequent review of appropriate care, which should increase the efficiency of review. Cases excepted from routine review should be monitored periodically to assure that more frequent review is not warranted. Profile analysis must be further developed to provide the information to identify patients or providers who require more concentrated review.

2. Criteria for excepting cases from review should be clearly specified. The new Medicare and Medicaid utilization review regulations, which permit each hospital independently to specify cases that will not be routinely reviewed and do not include adequate provisions for monitoring, may reduce the likelihood of identifying inappropriate care.

3. Within PSROs, a conscious effort is needed to integrate the three types of review. The common practice of delegating responsibility to hospitals for conducting MCEs independent of concurrent review should be discontinued because it encourages fragmentation. Within hospitals, PSRO review activities should be better integrated with prior utilization review and other quality assurance activities.

4. Intensified efforts should begin immediately to evaluate both federal and privately sponsored health care quality assurance systems by comparing the quality of care in geographic areas with and without quality review programs, or in areas of otherwise similar characteristics but different types of review. This should have been accomplished before a uniform national quality assurance program was required by the PSRO legislation. Nevertheless, the committee believes that planned experimentation should still be possible in order to determine the relative effects of alternative review mechanisms on health status, utilization and cost of services, and other measures of quality.

5. There should be fewer, better designed, and better evaluated MCEs. The JCAH and PSRO requirements for MCEs should be compatible in content, as well as numerical requirements. Hospitals should be permitted to count re-audits of completed audits in fulfilling MCE numerical requirements.

6. Criteria should be developed for categorizing successful and unsuccessful MCEs and isolating factors associated with success, so that more effective MCEs may evolve. Data bases must be developed to describe current MCEs, so that a more definitive, future assessment of effectiveness can be made. Since there currently is no "good" model of a MCE, a wide range of innovation and evaluation should be encouraged. The effectiveness of concurrent and prospective MCEs, that permit direct intervention in the process of care where warranted, should be tested. The relative merits of areawide MCEs, as opposed to individual hospital MCEs, should be assessed.

7. Uniform data elements, but not necessarily data formats, should be required in all health care settings to facilitate quality assurance activities, as well as program management, planning, and evaluation. Requirements for

the Uniform Hospital Discharge Data Set as modified for PSROs should be enforced. The Mininum Ambulatory and Long-Term Care Data Sets should be implemented. Methods for linking information from the Medicare Part B supplementary insurance program with Part A hospital information should be devised. More general methods are needed to integrate hospital and ambulatory patient care information using a common identification number. Better "denominator" data must be generated to define the population eligible for care and to provide the basis for monitoring utilization of services. Important confidentiality issues must be resolved to protect individual privacy and the public right to information.

8. Both nationally and locally, PSROs and Health Systems Agencies (HSAs) should establish mutually beneficial working relationships, beginning with an exchange of data. HSAs have information on the population eligible for care, which is needed by PSROs. PSROs can document variations in the use of services, which may suggest problems in access and under-utilization that should be addressed by both HSAs and PSROs.

9. Quality assurance programs should further specify their objectives and establish internal self-assessment units for program evaluation. The Department of Health, Education, and Welfare should provide technical assistance involving both trained researchers and persons experienced in peer review. Appropriate links with health services research centers should be established. Additional support is required for research training programs to develop the necessary cadre of skilled personnel.

10. Policy mandates for quality assurance should impose comparable levels of stringency on all health care delivery arrangements, even though the manner in which requirements are met may vary. The greater ease of conducting quality assessment activities in larger, formally organized health care programs, such as Health Maintenance Organizations, should not lead to the imposition of more rigorous requirements on such organizations.

GENERAL POLICY RECOMMENDATIONS

Long-Term

1. Better evaluative measures are needed to identify and aggregate the effects on health status that result from the provision of medical care, and to assess the impact of quality assurance programs, continuing education, and other activities designed to improve the quality of care.

2. Better techniques are needed to determine the effect of quality assurance programs on utilization and cost of medical care. Data should be adjusted to enable comparisons among facilities with different patient and provider characteristics. Measures should assess the effect of review on the total community, rather than individual facilities, and should take into account the costs of alternative care. Additional research is needed to determine the conditions under which hospital costs vary according to occupancy rate in both short and long-term situations. Adjustments for fixed costs and the cost of alternative care should be included in estimates of cost savings resulting from utilization review.

3. The assumption that hospitals have incentives to conduct meaningful utilization review programs should be examined. Current reimbursement mechanisms provide little incentive for hospital administrators to reduce variable costs associated with lower hospital utilization. Therefore, actual savings may be minimal.

4. The indices of quality currently used by quality assurance programs should be expanded. Access to care and potential under-utilization should be assessed. This requires attention to the availability of health care providers and facilities, appropriate links between levels of care, and policies (such as on-call arrangements) to assure that services are easily accessible. Benefit packages and reimbursement policies should be examined to determine their impact on the quality of care, particularly with respect to coverage of long-term care, both institutional and non-institutional. Greater efforts should be made to link the separate programs, which currently address only care provided to specific patients by specific providers or facilities, into an integrated program which assesses the quality of care provided by the total health system.

5. A systematic accumulation of data is needed to describe current patterns of medical care in all settings. Special attention should be given to unusual departures from customary practice, the extremes of under- and over-utilization, and the reasons for such variation. This information should provide a better estimate of the margin by which quality and utilization of services might be improved, which in turn, would help to determine the magnitude of the required quality assurance effort and identify areas of achievable gain for special attention.

6. The curricula for health professionals should include courses in health care evaluation and assessment designed to be relevant in routine practice and implemented throughout one's professional career. Quality assurance activities should be applied in facilities where physicians-in-training provide care.

RECOMMENDATIONS FOR ASSESSING HEALTH OUTCOMES

Immediate

1. Additional research is needed to develop substitute or short-term outcome measures which occur closer in time to the provision of care than final end-result measures. The relationship between such measures and process and final outcome measures should be established.

Long-Term

1. The steering committee believes that health care should be assessed on the basis of health outcome, despite the limitations of current measures and uncertainties about the contribution of medical care to health status. Patient satisfaction must be recognized as one indicator of outcome.

Research is needed to develop better measures of patient satisfaction and health status. In addition to the use of short-term outcome measures, greater reliance should be placed on existing instruments for assessing functional status and the growing body of knowledge of the natural history of disease--particularly for assessing the progress of the chronically ill.

2. In the same sense that process measures of quality are currently required of PSROs, limited post-discharge outcome information should be gathered. The cost and utility of outcome studies should be carefully monitored. Outcome data should assist in identifying patients and providers for whom the process of care should be more thoroughly assessed and in isolating areas in which efficacy studies are required. The accumulated data should lead to a better understanding of the natural course of illness. Over time, sufficient knowledge should be accumulated so that if patients of a particular provider have not progressed as expected, the provider's treatment methods could be questioned or the patient referred elsewhere for evaluation and consultation.

3. Individual practitioners should be encouraged to join with their patients in establishing outcome objectives for patient care and examining reasons for failure to meet them.

4. Additional research is needed to establish the natural history of diseases and the efficacy of medical procedures and therapies. For research findings to be useful in assessing the quality of care, determinations of efficacy should be made under average as well as ideal treatment situations at various points in time and should include a broad range of outcome measures. The Department of Health, Education, and Welfare should further specify the responsibilities of its component agencies in this area and increase the level of funding.

RECOMMENDATIONS FOR AMBULATORY QUALITY ASSURANCE

Immediate

1. Ambulatory claims review should be more widely implemented in an experimental manner while more appropriate ambulatory quality assurance techniques are being developed. Despite the limitations of claims review, it will permit the detection of the most serious deficiencies. Governmental agencies and other purchasers of health care should be encouraged to require more stringent claims review by their fiscal intermediaries. Careful evaluation of these programs should be required.

2. Closer monitoring should begin immediately of pharmacy services, small clinical laboratories, and free-standing radiological units. Monitoring techniques using pre-identified specimens should be more widely applied to determine the accuracy of judgments within labs and radiology services.

Long-Term

1. Intensified research and development is needed for ambulatory quality assessment methods. Primary ambulatory care is different from secondary and tertiary care and requires different quality assessment techniques. Many ambulatory review programs rely on a diagnostic-specific review of the medical record, but the bulk of primary ambulatory care consists of signs and symptoms that cannot readily be assigned to diagnostic categories. Classification schemes to record patient-reported symptoms are being developed and could form the basis of an experimental quality assurance project. Another approach might focus on the basic skills or tasks which constitute primary ambulatory care, such as the elicitation of signs and symptoms and their history, performance of a physical exam, the synthesis of this information into recommendations for care, and determination of the appropriate point for referral. Much of the success of primary care depends on the extent to which the practitioner coordinates care provided over a relatively long period of time. Very little of this information is found in the medical record, and other recording and assessment methods must be devised.

2. Additional work is needed to devise means for supplementing information recorded on the claim form. The Minimum Ambulatory Care Data Set should be the basis on which such work proceeds. In addition, the value of diagnostic, patient, and laboratory registries to facilitate problem identification and provide information over time should be explored. Probability sampling techniques must be developed for claims review to focus on patients and providers who fall at the extremes of distributions of care patterns and at the same time give estimates of the broader spectrum of care provided to the total population.

3. A single approach to quality assurance will not accommodate the diversity of functions and personnel included within the ambulatory care sector; further research is required before a range of proved alternative methods can emerge. The widest possible range of review techniques should be included in the ambulatory demonstration projects to be funded by the Bureau of Quality Assurance. Recipients of awards should not necessarily be limited to PSROs. The budget for these activities should be increased.

RECOMMENDATIONS FOR LONG-TERM CARE

Immediate

1. Existing standards to protect residents of long-term care facilities should be enforced, while more appropriate quality assurance mechanisms for long-term care are being developed.

2. The certification and licensure process for long-term care providers should be reconsidered. The Department of Health, Education, and Welfare study, scheduled to begin in April of 1977, should go beyond a review of existing structural standards to address more fundamental issues of quality and analyze the financial and other ramifications of forced compliance with standards.

Long-Term

1. Quality assurance programs for long-term care should be designed to address the unique needs of the chronically ill. The etiology of many chronic conditions remains obscure; many individuals, particularly the aged, have several chronic conditions. Thus, an assessment of quality based on diagnostic-specific criteria is often inappropriate, and functional status is a more relevant measure. Furthermore, because of the long-term nature of the patient's condition and frequent fluctuations in physical and mental states, treatment requirements vary. Patients may require differing levels of care within a relatively short time period, ranging from intensive hospital care, skilled nursing services, custodial care, or home health services, to periodic office visits. Methods for assessing the quality of care should include all sources of care and should consider the impact of care on the patient's expected and actual ability to function in daily life.

2. The responsibility for quality assurance in long-term care belongs at the community level so that an integrated review of the total range of services can occur. Anything less will be based on evaluation of care from the fragmented view of individual facilities or programs and will perpetuate the inefficient and costly services which currently exist. Steps should be taken to develop community-level organizations to include a broad range of providers, facilities, professional groups, consumers, and representatives from planning and certifying agencies. The community organization should consider such issues as access to care, appropriateness of placement, scope of available services, and the accumulation of uniform data. Assessment of the technical components of care could be delegated to PSROs and other groups of health care providers. Demonstrations should be initiated to test the feasibility of such an approach in terms of both cost and effectiveness. Evaluation should occur after prototype organizations have passed the developmental phase.

3. State and federal reimbursement policies for long-term care should be reformed. State and federal regulations for reimbursement and accounting should be made compatible and redesigned to enhance their influence on the quality of care. The levels of reimbursement should not be so inadequate as to lead to poor quality. Experimental reimbursement projects should examine the effect of capitation, which would permit the individual to move from one level of care to another without being penalized. Similarly, experimentation with facility reimbursement rates based on the customary mix of patients, rather than specific patients, might permit patients to be moved from one level of care to another, depending on their conditions.

4. Support of existing programs to train personnel for work in long-term care should be continued and expanded. Program content should focus on the unique characteristics of long-term care, the multiplicity of skills which are required to meet patient needs, and the necessity of a team approach.

5. The long-term care quality assurance demonstration projects to be funded by the Bureau of Quality Assurance should represent a wide variety of alternative

approaches to review and should not be limited to PSROs. The budget for these activities should be protected and expanded.

RECOMMENDATIONS FOR IMPROVING PROVIDER PERFORMANCE

Immediate

1. There should be no mandated provisions for any specific technique for improving provider performance in the immediate future, including continuing medical education. Existing evidence of effectiveness is inadequate.

2. Because of the limitations of education in improving individual provider performance, alternative methods should be explored. In particular, the influence of the organization of health care resources on quality needs immediate attention.

Long-Term

1. Research is needed to devise methods for encouraging improvements in patient care, once deficiencies are identified. Relevant literature from the social sciences, as well as from medical education, should be utilized. Existing quality deficiencies should be categorized to assist in determining the reasons for their occurrence and the design of appropriate corrective actions. All methods for improvement should be carefully evaluated to determine the extent to which they result in lasting behavior change.

2. Studies are needed of the effectiveness of various methods for informing a physician that he is providing inadequate care, including presentation of information describing his practice patterns compared with his peers, structuring the information to emphasize particular deficiencies, or providing incentives for review and change. Reasons for failure to change should be explored.

3. For instances in which clearly inappropriate care is identified and behavior does not change, sanctions which are less drastic than permanent loss of licensure may be more readily applied. Experimentation is needed with intermediate sanctions, including curtailment of privileges, licensing with restrictions on specified areas of practice, mandatory supervision of medical practice, or remedial education. Demonstrations should test the effectiveness of equipping PSROs with a wider range of sanctions for clearly inappropriate behavior, including more direct links with licensing bodies or authorizing the PSRO to remove a license with due cause. State legislative bodies should waive or amend existing statutes, if necessary, to permit such experimentation.

4. The feasibility and effectiveness of publicizing instances of persistently poor quality care by individual practitioners in public media should be explored.

RECOMMENDATIONS FOR CONSUMER INVOLVEMENT

Immediate

1. Health care consumers, both individually and collectively, should be educated to accept greater responsibility for their own health and should be involved in decisions regarding the provision and evaluation of health care. One immediate step for furthering this concept would be the inclusion of representatives of the public as members of the National Professional Standards Review Council. This may require a legislative amendment.

Long-Term

1. The steering committee believes that consumer involvement in the planning, management, and evaluation of health care programs should be encouraged and expanded. A better public understanding of the determinants of health, the limitations of health care, the resources required to provide it, and the necessity to work in partnership with professionals to create a system of health care should result in improvements in the quality and appropriateness of health services and a healthier public. The objective is clear, but the methods for achieving it are not. Research and experimentation are required.

2. More information is needed to identify aspects of health care that are important to the consumer, which can then be incorporated into valid and reliable instruments for assessing patient expectations and satisfaction. Additional information also is needed to relate expectations and satisfaction to compliance with medical instructions and to health outcome. Once the measures are adequate, the feasibility of implementing them in formal quality assurance programs can be better tested.

3. Although some health education programs have been effective in changing patient behavior, additional research is needed to identify factors associated with effectiveness. Attention should be given to the effect of alternative media, differing levels of patient and family involvement, the duration of behavior change and whether reinforcement is needed, the potential contribution of motivational research, and patient factors which may influence effectiveness, such as emotional state, demographic characteristics, and health status. Different approaches may be required for different patient conditions, ranging from preventive care to acute illnesses and chronic conditions.

4. When patient education is known to be essential, quality assessment criteria should require that education activities be performed. To the extent that process-oriented criteria are used to monitor care, current efforts to include educational components (such as dietary instruction for diabetics) should be encouraged. If changes in the process of care or delivery setting are anticipated, the acceptance of such changes will be increased if information is provided to patients in advance.

5. On an experimental basis, quality assurance programs should include consumer or patient boards to hear patient complaints and evaluate their validity. The use of patient questionnaires in assessing quality should be tested, as well as the effect of asking patients to review their own medical records. Patient expectations upon seeking care might be determined and used as the basis for providing patient education and instituting treatment; the influence of expectations on compliance and outcome could then be determined. A more direct involvement of consumers with providers in assessing the quality of care should be tested; each group may learn from the other.

6. Existing laws should be exploited whenever possible to further health education. Informed consent requirements, for instance, provide a unique opportunity to educate the patient, rather than simply to obtain an unthinking agreement to treatment.

7. The consumer's role in governance and policymaking requires careful documentation and analysis to facilitate more responsible, comfortable, and effective relationships with health care professionals.

FOOTNOTES

Chapter 1

1
U.S. Congress, House of Representatives, Social Security Amendments of 1972, Pub. L. 92-603, 92d Cong., 2d sess., 1972, H.R.1.

2
U.S. Congress, Senate, Health Maintenance Organization Act of 1973, Pub. L. 93-222, 93d Cong., 1st sess., 1973, S. 14.

Chapter 2

BACKGROUND AND METHODS

A great increase in federal spending for medical care programs over the past decade has more recently been accompanied by congressional concern about the cost and quality of that care. More specific interest in the effectiveness of methods for monitoring the quality of care led to a provision in the Health Maintenance Organization Act of 1973 (Public Law 93-222), which called for a comprehensive study of health care quality assurance programs. [1] The study was to include an analysis of the strengths, weaknesses, and costs of quality assurance prototypes; identification of research needs; design of prospective methods for evaluating quality assurance programs; and the development of specifications for an effective health care quality assurance system.

Although the study conducted by the Institute of Medicine and reported here stems from this legislative mandate, it is more limited in scope. Its general objective is "to provide an explication and synthesis of current knowledge about the study and development" of health care quality assurance systems, based primarily on existing documentation. [2] The study is not intended to evaluate Professional Standards Review Organizations (PSROs). [3] The PSRO program is a relatively recent, large-scale undertaking which is incomplete at this time. Nevertheless, some quality assurance programs reviewed were PSROs, and some recommendations refer specifically to the PSRO program.

SPECIFIC STUDY OBJECTIVES

Specific study objectives were:

- To describe and assess the impact of operational quality review programs, based on existing literature and supplemented by observations and data from site visits;
- To review seven topics (discussed below) designated as "priority areas" because of their importance in determining the effectiveness of quality assurance programs and the absence of reviews to integrate and analyze relevant information;
- To delineate areas in which additional research and evaluation are required; and

- To assess the reliability of hospital utilization information generated by private abstracting services and based on abstracts of the hospital medical record.

Study findings related to the first three objectives are included in this report. Study methods are discussed below. Descriptive comparisons of quality assurance programs and an analysis of what is known about their effectiveness are in Chapters 3 and 4. Reviews of the priority areas are summarized in Chapter 5. Research recommendations are presented at the end of each chapter and consolidated in Appendix A. Chapter 1 is a review of the findings and recommendations of the steering committee.

The fourth objective was intended to determine whether hospital utilization information processed by private abstracting services is sufficiently reliable to be used as baseline information for assessing the impact of PSROs over time. This activity required extensive field work and the analysis of primary data. Although it was conducted under the direction of the steering committee, it was a separate activity and is reported in a separate volume. [4]

CONCEPTS OF QUALITY

To limit the scope of the study, considerable attention was devoted to clarifying the concepts of "quality" and "systems" for quality assessment. Many definitions of quality have been proposed, ranging from statements of the ideal to minimal standards. Clearly, the definition of quality is multidimensional and complex. Quality may be viewed in relation to a total system for health care delivery, components of the system, or particular attributes of components. The type of care that an individual considers ideal may be unrealistic from a national perspective. The criteria and information base for assessing quality and the range of options for responding to inappropriate or unacceptable care may vary, depending on the patient or health care provider being assessed and the person or program making the evaluation. It is unlikely that any single definition or approach to quality assessment can satisfy the many needs of all who are concerned with the quality of care.

Because of these complexities, the steering committee adopted a pragmatic view of quality. Components of quality that have been identified and emphasized by existing programs were accepted within the focus of this study. However, particular attention was given to programs with the stated purpose of improving the health status and satisfaction of patients. This broad categorization was limited further by a more detailed specification of the kinds of systems to be considered.

Characteristics of an ideal quality assurance system were specified: the existence of an organizational entity created for assessing quality, the establishment of standards or criteria against which quality is assessed, a routine system for gathering information, assurance that such information is based on the total population or representative sample of patients or potential patients, a process for providing the results of review to patients, the public, providers, and sponsoring organizations, and methods for instituting corrective actions.

SELECTION OF PROGRAMS

Within the broad view of quality assurance systems, programs for detailed study were selected to include different approaches to quality assurance which might influence program effectiveness and be applied in other settings. Similarities among programs usually were more striking than differences. Nevertheless, some distinguishing characteristics were important.

One important factor was the portion of the medical care spectrum emphasized in the review process--the identification of people who need medical care, the diagnostic and treatment process, patient follow-up, and outcome assessment. [5] Some examples of each were identified and included in the study.

Within programs which review the process of care, variations in types of review usually were not as great as variations in the organizational auspices and structures through which review is conducted. Therefore, the study includes examples of programs conducted by statewide foundations or medical societies, government bodies such as Medicaid agencies, hospitals or other facilities, prepaid health plans, and solo offices. As an alternative to an institutional or programmatic approach, one might concentrate on the quality of all care for an individual or population regardless of the setting in which care is provided. However, very few systems have taken this approach; and for that reason it is not emphasized in this report.

The state of development of the review program was influential in the selection process. Programs usually were excluded unless they had sufficient operating experience to provide some information over a period of time.

Finally, so that available resources would be used most efficiently, programs were selected on the basis of their ability to provide information about the priority areas and their geographic proximity to investigators conducting relevant research.

Review programs for detailed analysis were selected in stages. Initial suggestions from the steering committee and others and review of existing material resulted in the identification of about fifty programs which were categorized according to the organizational groupings mentioned above. Information was obtained to reflect the following program characteristics: the types of review conducted (pre-admission or admission certification, concurrent or retrospective review, profile analysis, medical care evaluations, outcome assessments); type of corrective actions taken (continuing education, incentives, sanctions, other); patient coverage (Medicare, Medicaid, other than federally reimbursed); age of review system; geographic location and degree of urbanization; extent of consumer involvement; and presence or absence of cost data.

Illustrative programs were selected from each category on the basis of this preliminary information. They were described in more detail and later visited by field team members. These programs are listed in Appendix B.

DATA COLLECTION

So that quality assurance programs could be compared, an attempt was made to obtain similar information about each program, including a description of the formal characteristics of the program, an evaluation of actual or expected impact, and information about unique characteristics which might influence program effectiveness. Because substantiating documentation was often lacking, this information reflects a mixture of documented and undocumented data provided by program administrators and a subjective assessment by the study staff and steering committee. An outline of descriptors was developed (see Appendix C) to organize the information and indicate whether it reflects data provided by program staff or a judgment by persons involved in the Institute of Medicine study.

Information provided by program staff was divided into five categories: origins and description of review system; structure of the system; process of review; results; and long-range implications. Because of the difficulty of assessing the results of review, information was gathered about a wide range of items including methods to assess the attainment of goals, impressions and anecdotes about changes resulting from review activities, and changes in aggregate utilization and other statistics based on systematically gathered data. The final category, long-range implications, was intended to elicit opinions from the staff about the program's flexibility and potential for change necessitated by increased scientific knowledge, new developments in medical practice, or social and economic factors. Questions were also asked about any underlying problems (either general or specific to the setting) which should be considered in developing policy and research recommendations.

Assessment by the Institute of Medicine staff and steering committee included the current status and accomplishments to date of each program reviewed, unique characteristics which may influence the program's effectiveness, and unresolved administrative, methodological, or policy issues. The notation of unresolved issues was not intended for evaluative purposes. Instead, the objective was to determine whether common problems existed across systems and, if so, to incorporate them in study recommendations. Required follow-up activities were also noted, as well as unanticipated factors which may have influenced staff ability to obtain the required information.

Before the site visit the outline of descriptors was completed as fully as possible based on information from the program administrators, other studies, and telephone conversations. The site visit was then devoted primarily to observing the manner in which the system actually functions, as distinguished from the formal written description, and reviewing the motivations for initiating the program, reasons for selecting the particular approach to review, incentives built into the program to facilitate behavior change, perceptions of participants about success to date, impressions of underlying problems, areas requiring further development, and any available data suggesting impact.

The outline of descriptors was not applied as a formal questionnaire or survey instrument, but rather, constituted a general guide to the kinds of information required, which varied, depending on the program. For some programs, specific

information items were not relevant and were omitted; in other cases desired information could not be obtained.

Most program administrators were extremely cooperative and willing to provide extensive descriptive material. However, some information did not arrive early enough to be reviewed before the site visit. The visit was then conducted on the basis of information from other sources. A few program administrators were reluctant to provide written information in advance, so the material reflects what was learned during a relatively short period of time on site, supplemented by whatever material was provided later. Occasionally, program officials were unwilling to provide specifically requested information, especially about costs and evidence of impact.

The Institute of Medicine usually was represented during the site visits by three or four people, including a member of the steering committee or a consultant or both, as well as full-time study staff. Whenever possible, a physician was included. Representatives from the program under review usually included policymaking and administrative officials, as well as people involved in the day-to-day review and data gathering activities. Most visits were conducted in one day, although the length of time on site ranged from four hours to two days.

PRIORITY AREAS

Seven topics were designated priority areas because of their importance in determining the effectiveness of quality assurance programs and the absence of reviews to integrate and analyze pertinent information and delineate gaps in knowledge. The areas, which are interrelated, are outcome-oriented approaches to quality assurance; quality assurance for ambulatory care; quality assurance for long-term care; assessment of costs and cost effectiveness; medical care evaluation studies; methods for changing behavior patterns of health care providers; and patient and consumer involvement in quality assurance programs. Because medical care evaluation studies and cost effectiveness issues are integral parts of the review of operational programs, the findings and recommendations in these areas are included in Chapters 3 and 4. The five remaining priority areas are summarized in Chapter 5; future priority area reports will be published as supplements to this volume.

In exploring each area the basic approach was to review existing literature and current research in an attempt to delineate what is currently known, the adequacy of that information for generating policy recommendations, and specific areas in which further research and development are needed. The relationship of current research to operational quality assurance programs was noted.

Institute of Medicine staff was responsible for initial drafts of background papers, which were reviewed by steering committee members and consultants and formed the basis for recommendations.

LIMITATIONS

The adequacy of the priority papers rests primarily on the care with which the literature was analyzed and the soundness of judgment on which the conclusions are based. The papers are essentially literature reviews rather than policy statements, and generally provide a guide for future activities rather than immediate decisions. The implications of the assessment of quality assurance systems may be felt more immediately, however. Thus, the limitations should be clearly specified.

The non-systematic nature of selecting quality assurance programs for review limits the generalizability of the information reported. The programs visited do not constitute a representative national sample and the conclusions do not reflect the status of quality assurance systems across the country. One hears reports of perfunctory implementation of the PSRO program. Such programs were not visited, however, because the purpose of the study was to learn about review mechanisms that might be instituted elsewhere. Similarly, some institutions are reported to have serious deficiencies in the quality of care, which are readily apparent and do not require a quality review system for their detection. These facilities also were excluded from the study.

The steering committee believed that by concentrating on what have been regarded as some of the "better" quality assurance programs, it would be able to ascertain the effects of such programs under ideal circumstances. If they were found to be generally effective, one might assume that similar success could be attained elsewhere by using existing programs as models. On the other hand, if serious questions were raised, one might assume that more severe reservations might be warranted elsewhere.

The inadequacy of documentation and limited time on site must be viewed as limitations of the data. Whenever programs are identified by name, the material has been reviewed by program officials to ensure the accuracy of factual information. The interpretation and recommendations are the responsibility of the steering committee. A conscious attempt has been made to provide a balanced presentation, which can constitute a framework for conducting a more detailed and definitive assessment of health care quality assurance programs in the future.

FOOTNOTES

Chapter 2

1
U.S. Congress, Senate, Health Maintenance Organization Act of 1973, Pub. L. 93-222, 93d Cong., 1st sess., 1973, S.14.

2
U.S. Department of Health, Education, and Welfare, amended contract with Institute of Medicine, National Academy of Sciences, for Evaluative Study of Health Care Quality Assurance Programs, Contract No. 282-75-0437 PM, 23 July 1975, p.3.

3
U.S. Congress, House of Representatives, Social Security Amendments of 1972, Pub. L. 92-603, 92d Cong., 2d sess., 1972, H.R.1.

4
Institute of Medicine, An Assessment of the Reliability of Abstracted Hospital Utilization Data: Final Report (Washington, D.C.: National Academy of Sciences, Institute of Medicine, 1976).

5
The distinction between process and outcomes-oriented reviews refers to Donabedian's conceptualization of approaches to quality assessment. He defines three approaches as follows: 1) structural--"the evaluation of the settings and instrumentalities available and used for the provision of care"...including the available resources and manner in which they are organized; 2) process-oriented--"the evaluation of the activities of physicians and other health professionals in the management of patients"--usually in relationship to implicit or explicit professional standards; and 3) outcome-oriented--"the evaluation of end results in terms of health and satisfaction." American Public Health Association, A Guide to Medical Care Administration, 2 vols. (New York): American Public Health Association, 1969), vol. 2: Medical Care Appraisal-Quality and Utilization, by Avedis Donabedian, pp. 2-3.

Chapter 3

QUALITY ASSURANCE PROGRAMS

The quality assurance programs reviewed in detail are described in this chapter. Because there are many similarities among programs, much of the discussion is general. Specific programs are discussed separately only if unique characteristics deserve more detailed consideration. A tabular comparison of programs on most characteristics discussed below is included as Chart 1.

GOALS AND ORIENTATIONS

The explicit goals of most programs relate to the necessity of ensuring high quality medical care at reasonable cost. Some statements of objectives also incorporate the effective and efficient utilization of services. One group referred to efficient statewide distribution of services (Colorado); another, to the continuity of care (Indian Health Service). In general, goals are not defined in specific terms. It is possible, however, to infer more detailed objectives and priorities by examining the orientation of the program's review process and the way in which it functions.

The emphasis given to reviewing the cost rather than quality of care is difficult to determine conclusively, because the two are intertwined. In the case of hospital and PSRO programs, the amount of time and money devoted to concurrent review activities, which deal primarily with utilization patterns, could imply a primary emphasis on cost. But eliminating exposure to the risk of unnecessary medical intervention and potential iatrogenic illness through control of utilization has implications for quality. Although most program administrators place more emphasis on concurrent review than on medical care evaluation and the quality of medical practice, many express the desire to concentrate on quality in the future. A precise separation of the effect of quality assurance programs on cost from their impact on quality of care may be impossible. It may be more appropriate to refer to cost components and non-cost components of quality review. A subjective determination of the relative importance of those two components for any given program can be made by

CHART 1. CHARACTERISTICS OF QUALITY ASSURANCE PROGRAMS VISITED

	Bethesda Lutheran Hospital St. Paul, Minn.	Mt. Sinai Hospital New York City	Overlook Hospital Summit, New Jersey
DATE QUALITY ASSURANCE ACTIVITIES INITIATED	Audit 1967 Utilization Review 1971	Initial program 1973 Expanded program 1975	Early 1960s
GEOGRAPHIC & PATIENT COVERAGE	All hospitalized patients	All hospitalized patients	All hospitalized patients
TYPES OF REVIEW	Admission certification, continued stay review, MCEs, patient care monitor (profiles)	Pre-admission screening (non-emergency), admission certification, continued stay review, MCEs	Limited concurrent review, MCEs (special studies)
HOSPITAL DELEGATION STATUS	Delegated	Delegated	Not applicable (no local PSRO)
CORRECTIVE ACTION EMPHASIS	Primarily educational; full review and restricted privileges possible	Peer pressure and education	Peer pressure and education
SOURCE OF COST DATA	PSRO reports; hospital	Hospital budget	Hospital budget
AVAILABLE IMPACT DATA	Reported quality improvements; length of stay data	Recommended quality improvements; length of stay data	Reported quality improvements; length of stay data
FACTORS INFLUENCING EFFECTIVENESS	Strong leadership and administrative changes; need for improvement; support of board of directors	Demand for beds despite excess in the area	Strong leadership; shortage of beds in area
SPECIAL FEATURES	Patient care monitor; experience with MCEs; Increased responsibility of nurse coordinator	Pre-admission approval of treatment; integrated discharge planning	Selective concurrent review; experience with MCEs

[a] Current or prior EMCRO support. [b] Conditional PSRO. [c] Research-oriented.
[d] This program was not visited; description based on Brook and Williams, "Evaluation of the New Mexico Peer Review System 1971-1973" Medical Care, forthcoming.

	Colorado Foundation for Medical Care Denver [a,b]	Foundation for Health Care Evaluation Minneapolis [b]	Medical Care Foundation of Sacramento Sacramento [a,b]
DATE QUALITY ASSURANCE ACTIVITIES INITIATED	Foundation created 1970 Ambulatory review 1972 Hospital review 1973	Fee review 1969 Hospital review (PSRO) June 1974	Foundation created 1958 Hospital review
GEOGRAPHIC & PATIENT COVERAGE	Statewide Hospital--Medicare, Medicaid and commercial; ambulatory--commercial	7 counties All hospitalized patients	5 counties Hospital--Medicare, Medicaid, commercial; ambulatory--Medicaid and commercial
TYPES OF REVIEW	Hospital: admission certification, continued stay, profiles, MCEs; Ambulatory: claims	Admission certification; continued stay review; MCEs; patient care monitor (profiles)	Hospital: pre-admission certification and continued stay; Long-term care; Ambulatory: claims and profiles
HOSPITAL DELEGATION STATUS	Non-delegated at time of visit; now mixed	21 of 37 hospitals delegated	Non-delegated
CORRECTIVE ACTION EMPHASIS	Hospital: peer pressure and denials Ambulatory: fee reduction	Education and peer pressure	Hospital: denial of admission Ambulatory: denial of payment
SOURCE OF COST DATA	PSRO reports and special tabulations	PSRO reports available but not analyzed	PSRO reports available but not analyzed
AVAILABLE IMPACT DATA	Length of stay and bed days saved; cost avoidance	Anecdotal	Utilization data; quality (anecdotal); fee adjustments
FACTORS INFLUENCING EFFECTIVENESS	Strong leadership; centralized management of regionalized organizational structure	Consumer involvement; prior experience in claims adjudication and fee modifications	Strong leadership
SPECIAL FEATURES	Regionalized review using statewide standards	Potential review of hospitalized population	Pre-admission certification

CHART 1. CHARACTERISTICS OF QUALITY ASSURANCE PROGRAMS VISITED (continued)

	Multnomah Foundation for Medical Care Portland, Oregon [a,b]	National Capital Medical Foundation Washington, D.C. [b]	New Mexico Foundation for Medical Care Albuquerque, [a,d]
DATE QUALITY ASSURANCE ACTIVITIES INITIATED	Foundation created 1961 Hospital review 1972	Foundation created 1973 Hospital review Sept. 1975	1971
GEOGRAPHIC & PATIENT COVERAGE	County-wide Hospital: Medicare, Medicaid; commercial	Washington, D.C. Medicare, Medicaid	Statewide Medicaid
TYPES OF REVIEW	Hospital: admission certification, continued stay, MCEs, profiles; Long-term care; Amb: developmental	Admission certification, continued stay review, MCEs, profiles (preliminary)	Integrated claims review for ambulatory, hospital, long-term care, labs, X-ray, injections; Hospital: admission certification and continued stay review; LTC: level of care
HOSPITAL DELEGATION STATUS	5 fully delegated, 8 partially delegated and 1 non-delegated hospitals	3 fully delegated, 5 partially delegated and 5 non-delegated hospitals	Not applicable
CORRECTIVE ACTION EMPHASIS	Education and peer pressure	Education and peer pressure; denials of payments	Denial of payment and education
SOURCE OF COST DATA	PSRO reports and letter from foundation	PRSO reports available but not analyzed	Secondary source
AVAILABLE IMPACT DATA	Length of stay data; quality (anecdotal)	Not available (review only recently initiated)	Payment denials by type of claim and reason; quality changes for selected procedures
FACTORS INFLUENCING EFFECTIVENESS	Prior experience	Not yet determined	Cooperation between state and foundation; strong technical and computer support
SPECIAL FEATURES	Problem processing system and ambulatory data system (potential only)		Integrated, computerized review of comprehensive range of services

[a] Current or prior EMCRO support. [b] Conditional PSRO. [c] Research-oriented.
[d] This program was not visited; description based on Brook and Williams, "Evaluation of the New Mexico Peer Review System 1971-1973" Medical Care, forthcoming.

	San Joaquin Foundation for Medical Care Stockton, California	San Joaquin PSRO Stockton, California [b]	Utah Professional Organization Salt Lake City [a,b]
DATE QUALITY ASSURANCE ACTIVITIES INITIATED	Foundation created 1954 Manual review 1960 Patterns of Treatment 1970	Predecessor 1968 Hospital review 1974 Long-term care 1975	UPRO formed July 1971 Hospital review 1971 Ambulatory review 1972
GEOGRAPHIC & PATIENT COVERAGE	4 counties Commercial, including Medicare	5 counties Commercial and Medicare	Statewide Hospital: Medicare, Medicaid, commercial; Ambulatory: Medicaid
TYPES OF REVIEW	Ambulatory claims review and profile analysis	Hospital and long term care: admission certification, continued stay review, MCEs	Hospital: admission certification, continued stay review, MCEs, profiles; Amb: claims review and provider and patient profiles
HOSPITAL DELEGATION STATUS	Not applicable	9 partially delegated 4 non-delegated hospitals	Non-delegated
CORRECTIVE ACTION EMPHASIS	Denial of payment and total review	Primarily left to discretion of hospital; potential total review	Primarily educational; non-certification of ambulatory claims
SOURCE OF COST DATA	Foundation; secondary sources	PSRO reports available but not analyzed	PSRO reports and communication with foundation
AVAILABLE IMPACT DATA	Fee adjustments; changes in utilization (anecdotal); quality (anecdotal)	Length of stay data; quality (anecdotal)	Some length of stay data; quality (anecdotal); certification denial; secondary sources
FACTORS INFLUENCING EFFECTIVENESS	Strong leadership; lengthy experience; discontinuation of Patterns of Treatment	Earlier San Joaquin Foundation activities	Strong leadership; homogeneous setting; careful development phase
SPECIAL FEATURES	Patterns of Treatment program		Experimental approach to MCEs; PACE ambulatory review program; increased responsibility of nurse coordinator

CHART 1. CHARACTERISTICS OF QUALITY ASSURANCE PROGRAMS VISITED (continued)

	Texas Department of Public Welfare, Austin	Indian Health Service Health Information System, Tucson [a]	Columbia Medical Plan--Johns Hopkins Health Services Research Center Columbia, Md. [a,c]
DATA QUALITY ASSURANCE ACTIVITIES INITIATED	Elements started by 1971	Health Information System 1969; evaluation program 1974	Research project funded 1973
GEOGRAPHIC & PATIENT COVERAGE	Statewide Medicaid	Sells service unit of Indian Health Service Papago tribe	Columbia, Md. Health Plan enrollees
TYPES OF REVIEW	State monitor of utilization profiles (hospital and ambulatory); concurrent review of long-term care; fiscal intermediaries at risk and reponsible current hospital review	Ambulatory: concurrent and retrospective using automated information system	Patient perceptions of access and outcomes linked with record review
HOSPITAL DELEGATION STATUS	Not applicable	Not applicable	Not applicable
CORRECTIVE ACTION EMPHASIS	Denial of payment; education of provider and patient	Neglible	Feedback of review results to providers
SOURCE OF COST DATA	Not available	Program staff	Program staff
AVAILABLE IMPACT DATA	Quality (anecdotal); length of stay data; expenditure data	Quality (anecdotal)	Quality (anecdotal); research findings from application of problem status measure
FACTORS INFLUENCING EFFECTIVENESS	Strong leadership; governmental authority; integration of hospital and ambulatory data	Self-contained delivery system; consumers involved in policymaking and providing health services	Leadership and support of parent organization (Johns Hopkins Health Services Research & Development Center)
SPECIAL FEATURES	Comprehensive data system; recipient education program; medical assistance record book	Health information system transferrable to organization with defined population	Patient-reported problem status measure

[a] Current or prior EMCRO support. [b] Conditional PSRO. [c] Research-oriented.
[d] This program was not visited; description based on Brook and Williams, "Evaluation of the New Mexico Peer Review System 1971-1973" Medical Care, forthcoming.

	Kaiser-Permanente Medical Group Los Angeles [a,c]	Kaiser-Permanente Medical Group Oakland, California	UCLA-EMCRO Los Angeles [a,c]
DATE QUALITY ASSURANCE ACTIVITIES INITIATED	Research project funded 1973	1969	Research project funded 1973
GEOGRAPHIC & PATIENT COVERAGE	Sample of prepaid health plan enrollees with 6 diagnoses	Prepaid health plan enrollees	Patients with selected diagnoses or conditions
TYPES OF REVIEW	Experimenting with imput, process, outcome and access measures; emphasis on outcomes	CQAS Program--primarily retrospective review of problems in ambulatory and hospital care	Treatment algorithms (MAPs) suitable for MCEs and potentially for concurrent review
HOSPITAL DELEGATION STATUS	Not applicable	Delegation for MCEs	Not applicable
CORRECTIVE ACTION EMPHASIS	Not yet developed	Education and administrative changes	Feedback of review findings to providers
SOURCE OF COST DATA	Included in research design; not yet available	Personal communication	Personal communication
AVAILABLE IMPACT DATA	Not yet available	Quality improvements and administrative changes (anecdotal)	Preliminary results from applying MAPs
FACTORS INFLUENCING EFFECTIVENESS	Self-contained organizational structure and leverage of prepaid group health plan	Strong conceptual leadership; self-contained structure and leverage of prepaid group health plan	Strong conceptual leadership; previous research experience; academic environment
SPECIAL FEATURES	Attempt to develop proxy measures of outcome	CQAS program	Criteria mapping system (MAPs)

referring to Chart 2. On this basis, perhaps eight of the 18 programs visited are primarily interested in quality; and five, in cost. Five programs could not be categorized.

CHART 2. COST AND NON-COST PROGRAM CHARACTERISTICS

Characteristics	Cost Emphasis	Non-Cost Emphasis
Emphasis of concurrent review*	Certifying need for admission and continued stay only at specific points in time	Monitoring the content of care throughout the hospitalization
Interest and resources devoted to medical care evaluations*	Minimal	Considerable
Emphasis of ambulatory care review	Attention only to single visit and reasonableness of services as reflected by relative value scale	Attention to content and outcome of care provided over a period of time
Emphasis of corrective actions	Simple withdrawal of certification or denial of payment without information feedback	Mechanism to tell provider why his judgment was questioned and to design educational and other corrective programs to improve future quality of care
Examples of effectiveness provided by program administrators	Reduction in days of hospital care or ambulatory claims	Specific instances in which the quality of care has been improved

*These types of review are discussed below.

Most programs are concerned primarily with users of institutional or ambulatory health services, rather than people who do not use services; with few exceptions they do not question access to care or under-utilization of ser-

vices. Review processes focus on care provided in a particular facility or group of facilities or physicians' offices within a geographic or PSRO region. The patients whose care is reviewed usually are beneficiaries of Medicare or Medicaid programs or insured groups whose insurance companies have contracts for review. The potential benefits from review may not be available to the general public. Furthermore, available population-based data cannot be used to assess the effect of review on health status because of selective patient coverage.

Among the exceptions is the health care evaluation component of the Health Information System (HIS) developed by the Indian Health Service (IHS) in Tucson. HIS retrieves information on all care provided to tribal members, including care provided in homes and schools. Except for those who have never received health care from the IHS (about five percent of the population), follow-up care and under-utilization can be monitored. Thus, HIS covers almost all care provided to almost a total population.

The prepaid group health plans included in this study could monitor the quality of care provided to the total enrolled population, but primary emphasis is on users, rather than non-users. The experimental project conducted by the Johns Hopkins University Health Services Research Center and the Columbia, Maryland Health Plan, however, has surveyed enrollees who have not used its services to determine their health needs and reasons for not using the plan.

The Foundation for Health Care Evaluation (a PSRO located in the Minneapolis-St. Paul area) has the potential for reviewing the quality of hospital care given to a total population, since staff in participating hospitals are encouraged to review care rendered to all patients. Total review has been attained to date, but some hospitals have yet to be encompassed within the PSRO umbrella.

Some ambulatory claims review programs are developing the capacity to address under-utilization in a limited way. This is discussed in the section on ambulatory review.

SPONSORSHIP, MOTIVATION, AND LEADERSHIP

Except for prepaid health plans and the Indian Health Service, most programs are sponsored directly by medical societies or by foundations created under the leadership of a medical society. Responsibility for hospital-based programs offically resides with the boards of directors; however, medical staff leadership was instrumental in program development in each case. Universities and major medical centers seldom initiated review programs. In no instance did an organized consumer group provide the impetus to establish a quality assurance program.

Motivations for creation of programs were mixed. Most frequently mentioned reasons were an expressed need on the part of the medical profession to demonstrate public accountability and the desire to obviate further regulation by government agencies and third party carriers. Only one program was started because it was known that care was poor.

An inability to estimate precisely the margin by which care could be improved was strikingly apparent in all programs visited. Review programs may provide a lever for closely scrutinizing physicians who give less than optimal care. (Estimates of physicians with severe deficiencies are seldom more than five percent of the total physician population and never adequately documented with criteria.) But nowhere was a program official able to offer even a rough estimate of the extent to which medical care should be improved in its totality. This point is significant, since without a measure of the amount of deficient or inappropriate care, it becomes difficult to determine whether a program is achieving its objectives and whether the resultant improvement is sufficient to justify the expenditures required to maintain the program.

In almost every program it was possible to identify an individual who was instrumental in generating support for the creation of the review program and providing strong leadership from the development of the program into its operational phase. However, it is important to note that most programs also have a full-time professional staff to oversee day-to-day activities and maintain program continuity. In a few programs, the leadership role has passed from the initial person to a successor, thus demonstrating the viability of the program. Furthermore, the establishment of a successful program can stimulate the creation of similar programs throughout a geographic area. For example, the quality assurance program at Bethesda-Lutheran Hospital has been used as one of the prototypes in the creation of the PSRO of the Foundation for Health Care Evaluation. Some of the key individuals were the same in both programs. The experience of the hospital program was packaged into a review manual for use in other area hospitals. The Utah Professional Review Organization (UPRO) has evolved by expanding its activities as it acquired experience and capability. It grew from an experimental program in a few hospitals with selected categories of patients into a larger program which gradually accepted review responsibility for additional third party carriers. Now, UPRO covers almost all hospitals in the state.

LINKS WITH EXTERNAL GROUPS OR AGENCIES

By necessity, staffs of almost every program have developed working relationships with third party carriers, state Medicaid agencies, and Medicare fiscal intermediaries for which the program provides review. Non-physician health professionals, hospital, and occasionally consumer groups may have an official advisory responsibility. Beyond this, however, working relationships with other components of the health care delivery system are minimal. Links to planning and regulatory bodies are tenuous and perhaps antagonistic.

There is little consumer or public involvement at the policymaking level, with two exceptions. The Foundation for Health Care Evaluation includes consumers on its board of directors and also has a consumer liaison advisory committee. The foundation has arranged for expert testimony on behalf of patients who were sued by physicians for failure to pay claims which the foundation has disallowed. The National Capitol Medical Foundation also includes members of the public (currently three non-physicians) on its board of trustees. The Utah

Professional Review Organization has a consumer advisory committee which educates consumers about professional review activities, publicizes the program, encourages additional insured groups to use UPRO review, and considers such matters as confidentiality of information.

LONGEVITY

Most of the programs reviewed have been in existence for several years, since it was anticipated that the potential for impact was greater than in newer programs. The actual amount of operating experience is difficult to determine, however, since the transition from development to full operation probably occurred over a period of time. Some are still not fully operational.

Several programs have quite extensive experience. For example, the San Joaquin Foundation for Medical Care was created in 1953 and has been conducting manual review activities since 1960. The Multonomah Foundation for Medical Care was created in 1961; however, quality assurance activities did not get under way until a reorganization in 1970. The Foundation for Health Care Evaluation was incorporated in 1969 and gained considerable experience in claims review before its conversion to a PSRO. Most newer programs are located within prepaid health plans. For the most part, these are oriented toward research and are not yet incorporated into an ongoing review system.

In addition to relatively lengthy experience, most of these programs have also benefited from substantial grant and contract support. Some were initially funded by the federal government as Experimental Medical Care Review Organizations (EMCROs), a demonstration program to develop different methods for assessing the quality of medical care. [1] Others received special grants or state or local support. It was not possible to accumulate exact totals for the amount of developmental support, but in many cases it amounts to more than a million dollars. If the review mechanisms developed by these programs are readily transferrable, newer programs may require shorter developmental phases. Nevertheless, the sizable financial investment and operating experience of the programs reviewed here stand in contrast with the resources available to more recently initiated PSROs. Whether this leads to comparable differences in effectiveness is not known.

HOSPITAL REVIEW PROGRAMS

Hospital review programs, both those conducted independently of PSROs and those included within a PSRO, consist primarily of concurrent review and medical care evaluation studies. Retrospective profile analysis of patterns of care is a third review required by PSROs, but in most programs visited, this form of review is still being developed.

Concurrent Review

The initial step in concurrent review is admission certification, usually within 24 to 48 hours of admission, which assures that hospital admission

is medically necessary. Medical necessity is determined by referring to criteria developed for particular problems, diagnoses, or procedures or to more general criteria which specify the types of services which should be provided in a hosptital. PSRO guidelines were developed with the expectation that with more experience and analysis, it will be possible to identify specific patients, conditions, or physicians with either increased or decreased likelihood of inappropriate admissions. The latter might be automatically certified, while the former may require re-admission certification. Most programs visited had not reached this point, however.

When an admission is certified, a length of stay is assigned based on the patient's condition and the date when hospitalization should no longer be required or when review of the necessity for continued stay would be appropriate. Reimbursement is approved for the initial stay. The assignment is usually based on either the 50th percentile of lengths of stay for similar patients (which may be obtained from regional data provided by discharge abstract services) or on more general level of care criteria.

Continued stay review is the final step in concurrent review. At the expiration of the initially assigned length of stay, records are reviewed to determine whether continued stay is necessary and, sometimes, to monitor selected aspects of the quality of care. Justification for an extended stay may be determined by referring to any of three types of criteria: indications for discharge, specified services which require hospital care, or the provision or planned provision of critical diagnostic or therapeutic services consonant with a particular diagnosis or condition. If continued stay is certified, another length of stay is assigned and the process is repeated. The information obtained during the review process is used to assist in discharge planning.

Typically, both admission certification and continued stay review are performed by a review coordinator, usually a nurse, who has authority for approval only. When questions arise, the case is referred to a physician advisor who has authority to make adverse decisions. In the case of PSRO review, either the attending physician or patient may appeal a decision to the state level and, ultimately, to the national level.

Although the general pattern is described above, variations are apparent in the timing, depth, and frequency of review. The Medical Care Foundation of Sacramento conducts pre-admission certification of elective hospital admissions, and in other programs that option is available. Mt. Sinai Hospital in New York City requires pre-admission screening of elective admissions using explicit criteria to ensure that hospitalization is necessary, that as many procedures as possible are performed outside the hospital, and that an appropriate treatment plan has been developed. The pre-admission form includes socio-demographic information which is forwarded to the social services department, so that discharge planning can begin prior to admission when appropriate. The Utah Professional Review Organization does not conduct pre-admission certification and is not convinced of its value. However, the state Medicaid agency requires prior approval for certain restorative or elective procedures, which may reduce the volume of questionable admissions for UPRO review. The Colorado

Foundation for Medical Care included pre-admission certification for elective admissions during a developmental phase of its hospital review program, but it is no longer required, although two or three hospitals continue to use it. Pre-admission certification was discontinued because of the reported inability of most hospital organizational structures to accommodate the prior approval process and requisite paperwork.

The comprehensiveness of admission certification varies. Bethesda-Lutheran Hospital uses an adaptation of the Commission on Professional and Hospital Activities' Concurrent Review Screening procedure, which assigns admissions to the following categories: diagnosis alone justifies admission, and certification is automatic; diagnosis plus a scheduled surgery or hospital procedure justifies admission and, after confirming the scheduling of the surgery or procedure, certification is automatic; or, diagnosis for which symptoms and problems are compared to predetermined criteria reflecting the level of care required. This procedure has also been adopted by the Foundation for Health Care Evaluation.

In other programs, all admissions are reviewed, but with varying degrees of stringency. At the time of the Colorado site visit, for example, there were no explicit criteria for judging the necessity of admissions. The nurse coordinator relied on her judgment, and questionable cases were referred to the physician reviewer. Greater emphasis was then placed on reviewing the medical record to ascertain whether the admission diagnosis was validated. In May of 1976, however, explicit screening guidelines were implemented in all major Colorado acute care facilities.

There are similar variations in continued stay review. The Utah review program is one of the more intensive and concentrates on facilitating the provision of services throughout the entire hospital stay, rather than intermittently assessing the need for admission and continued stay. Sets of explicit guidelines have been developed for quality care, admission indications, and length of stay; however, they are not routinely applied to individual cases, but are more likely to be used for profiles or quality assessment studies. For routine review, nurse coordinators usually rely on personal judgment, supplemented by guidelines for level of care and indications for denial of admission.

The review program at Mt. Sinai Hospital includes admission certification and continued stay review, based on the 50th percentile of length of stay data from the New York State Hospital Utilization Review (NYSHUR) program. The utilization review coordinators are expected to alert the medical staff when inappropriate quality is suspected and also are responsible for coordinating their activities with other hospital departments. For example, they meet bi-weekly with the social services department and weekly with the home care staff, admissions office, and medical care evaluation committee. Their approach to utilization review is interdisciplinary and appears to be firmly established throughout the hospital.

At Overlook Hospital there is no admission certification or assignment of length of stay. Instead, two utilization review coordinators review the care provided

to all medical and surgical patients, as well as those in the 80-bed extended care unit, once per week, primarily to determine whether the level of care is appropriate. For about 75 percent of the patients, the coordinator's assessment is based on a review of a Kardex file maintained in the nursing station, which lists diagnosis and physician's orders. For the rest of the patients a more detailed review of the medical record might be made.

In no program visited was there extensive routine use of explicit review criteria, with the possible exception of the recent changes in Colorado.

The extent to which review coordinators and physician advisors are trained and supervised also varies. Within the foundations and PSROs, most nurse coordinators are hired, trained, and paid by the foundation or PSRO. Exceptions may be made for small outlying hospitals where the patient load may not justify a full-time coordinator. In these hospitals the foundation may contract for a percentage of the time of a regular hospital nurse.

As an example, the Colorado Foundation provides a three-week training program for nurse coordinators, which includes both conceptual and applied content. A foundation supervisor oversees the work of the hospital coordinators and, in the case of rural hospitals, makes a bi-monthly visit and simultaneously replicates the work of the hospital's nurse coordinator. Foundation officials are concerned that after a period of time, coordinators may identify more with the hospital to which they are assigned than with the foundation. They are considering rotating coordinators among hospitals, but there is currently no consistent rotation policy. The Sacramento Foundation has already adopted a policy of rotating nurse coordinators every eight to 12 months. As hospitals receive delegated status under PSROs, nurse coordinators most likely will become hospital employees, which may increase mixed loyalties.

Arrangements for physician advisors are even more varied. At the Sacramento Foundation, physician advisors are appointed by the foundation's board of directors and paid by the foundation. A review manual or set of guidelines is provided, although it is not always used in the review process. Some PSROs which do not officially delegate responsibility for review to hospitals still permit the hospital to select and reimburse the physician advisors. The PSRO usually retains formal authority to appoint the advisor, but the hospital's nomination is seldom overridden. Nevertheless, the physician advisors are specifically identified and officially involved in many functions, usually including membership on advisory committees, where they exchange experiences with colleagues from other hospitals within the PSRO area. If the hospital has delegated status, the physician advisor would be more closely identified with the hospital. The San Joaquin PSRO combines standardized policies for the nurse coordinator with more flexible procedures for the physician advisor. Nine of the 13 hospitals have delegated responsibility for appointing physician advisors and conducting MCEs. Those hospitals have lists of physicians on whom the nurse coordinator may call when questions arise. In non-delegated hospitals the nurse coordinator can call any of about 150 physicians, depending on specialty. (The San Joaquin PSRO has about 340 physician members.) Physicians receive a one-page summary of review procedures when they are asked to volunteer for review functions; volunteers may receive additional assistance

from the nurse coordinator. In responding to questions about appropriateness of admission or continued stay, the physician advisor apparently relies primarily on personal professional judgment except for a few procedures, such as ileal by-pass, for which explicit criteria have been developed.

Medical Care Evaluation Studies (MCEs)

Under PSRO, medical care evaluation studies are a "form of health care review in which an in-depth assessment is made of the quality and administration of health care services" to assure that services are "appropriate to the patient's needs and are of appropriate quality, and...health care organization and administration support the timely provision of quality care." [2] MCEs may be performed within a single hospital, within a department of a hospital, or within a group of hospitals. Results of MCEs are intended to lead to improvement, either through administrative changes or continuing medical education. This detailed, frequently retrospective assessment of the care given to groups of patients stands in contrast to concurrent review of individual patients.

The potential subject matter of an MCE is broad and could include a "review of the patient care process, patient outcomes, the use of a given procedure, or the operating characteristics of an institution." [3] An MCE should not be equated with clinical research, however, and is confined to diagnoses and therapies for which there are well established criteria for appropriate practice. An example of an MCE objective would be to assure that outcomes of patients with pneumococcal pneumonia are acceptable.

PSRO requirements for MCEs are intentionally general so that traditional medical audit activities can be included, as well as programs such as the JCAH's Performance Evaluation Procedure for Auditing and Improving Patient Care (PEP) and the California Medical Association's Patient Care Audit (PCA), which are usually more specific. For example, the PEP system requires the specification of criteria with 100 or zero percent compliance standards; the PCA format includes a "threshold of action," usually a specified percentage of aberrant cases which indicates that remedial action should be initiated. A comparison of PSRO, PEP, and PCA requirements is included in Appendix D.

The intent of the national PSRO guidelines is to link the three review components into an integrated review system. Ideally, concurrent review and MCEs should reinforce each other. Similarly, profile analysis could identify areas for increased or decreased attention for concurrent review and MCEs, and monitor their effectiveness.

Most PSRO administrators concentrated their initial efforts on the concurrent review process and are just now beginning to develop and implement policies for MCEs, whereas hospital programs pre-dating PSROs place more value on MCEs than on concurrent review. At the Sacramento and San Joaquin PSROs, in particular, hospitals are permitted to continue with whatever medical audit activities they had traditionally done, pending development of the final PSRO requirements. Among the programs visited, delegation to hospitals of responsibility for MCEs appears to be more likely than for concurrent review.

The Multnomah Foundation has already delegated MCE responsibilities seperately from concurrent review. At the time of the site visit the Colorado Foundation conducted a non-delegated review system. By the end of September 1976, however, 84 of 93 hospitals have received delegated status for MCEs. Five Colorado hospitals have delegated responsibility for concurrent review. In one hospital visited, the non-delegated concurrent review activities and resulting documentation were conducted independently from the hospital's utilization review committee. No information was obtained on the medical audit process, but it apparently was not integrated with concurrent review. Within the Colorado Foundation responsibilities for concurrent review, MCEs, and profile analysis are departmentalized, which may encourage fragmentation, although more recent information from the foundation indicates an effort to integrate review components. Review programs are developed at the central office and implemented on a regional basis.

Some programs have conducted MCEs, either areawide or within individual hospitals. The Foundation for Health Care Evaluation has conducted at least two areawide audits. These were preliminary efforts to test methods for criteria development, data gathering, and analysis, and did not include the total process of education and re-assessment. Areawide audits are planned by the National Capital Medical Foundation. More extensive experience has been accumulated in Utah. In all places visited common problems were encountered, including the incompatibility between JCAH and PSRO requirements; the difficulty of selecting audit topics which result in the identification of significant problems so that improvement can be made; the difficulty of developing criteria relevant for all patients but which do not become too general; and the difficulty of achieving change, once deficiencies have been identified. Some innovative attempts to deal with these problems were also explored.

The difficulty of identifying "real" problems for medical audit was mentioned above. Common methods for selecting topics are to concentrate on the ten most frequently occurring diagnoses within a hospital or to cover all diagnoses which account for a certain percentage of admissions. These approaches automatically exclude cases with non-specific diagnoses and ignore certain procedures which may affect all patients, regardless of diagnosis.

The Multnomah Foundation staff expressed concern with the usefulness of traditional medical audit. They are beginning to monitor MCEs and are developing a mechanism to review hospital-initiated MCEs at the protocol design and completion stages. As a way of identifying potential MCE topics which should lead to improvements in patient care, the possibility of instituting a "problem processing" system is being explored. As planned, the system would permit anyone connected with a hospital or quality assurance program to note perceived deficiencies in the patient care process which might be worthy of audit. A standard form would be distributed throughout the hospital for recording such information, which would be forwarded to the review coordinator or foundation staff for analysis. Over time, problems would be accumulated. If patterns emerged, they would then become the subject of an MCE.

Bethesda-Lutheran Hospital staff has had extensive experience with medical audit, beginning in 1968, and has encountered similar problems. Initially,

efforts were made to develop criteria for specific diagnoses and to conduct audits for all diagnoses which accounted for two percent or more of total hospital admissions. About 20 months were required to complete the total review cycle; nevertheless, many patients were never reviewed because they were not included among the diagnoses which constituted two percent or more of the total admissions. To overcome these problems, the patient care monitor (PCM) was developed. The PCM is a data retrieval mechanism which routinely gathers basic information on all patients, including history and physical, lab tests and procedures, transfusion practices, and complications. The data are analyzed quarterly within and across diagnoses. Identified problems are assigned on a priority by the quality assurance staff and may become the topic of an MCE. Use of the PCM has greatly facilitated the identification of significant problems for audit.

Bethesda-Lutheran's PCM is not unlike the PSRO requirements for profile analysis, except that the PCM appears to include more information. The experience at Bethesda-Lutheran suggests that as profile analyses are more routinely performed, the difficulties in selecting MCE topics may be partially alleviated.

The Comprehensive Quality Assurance System (CQAS) of Kaiser Permanente in Northern California, Denver, and Cleveland constitutes a pragmatic approach to medical care evaluation that is not grounded in a systematic coverage of all diagnoses or any kind of baseline information. [4] Instead, CQAS concentrates on specific problems found to exist--either by an informal review of a small number of medical records or professional opinion. The CQAS philosophy suggests that any number of probable patient care problems can be readily identified and that it is a better use of resources to concentrate on them, rather than to waste time attempting to analyze the total spectrum of care. CQAS is described in more detail below as an ambulatory care review system. For purposes of this section, however, it may be regarded as an alternative approach to medical care evaluation.

Another recurring problem is the amount of time required to generate criteria for MCEs and the difficulty of specifying criteria which are appropriate for the wide range of variations which may occur within a single diagnostic or problem category. An approach called "criteria mapping," or MAPS, has been developed, which incorporates branching techniques and attempts to replicate the clinical decision-making process in a manner which would permit assessing the quality or appropriateness of care provided to an individual patient at a particular point in time. [5] It builds on earlier work using protocols or algorithms to train physician extenders. [6]

In using the MAPS approach, criteria are developed by physicians to reflect medical logic and cover the entire spectrum of care, ranging from an initial ambulatory contact to potential hospitalization. Criteria are grouped according to patient care objectives, and the results or findings at each step lead to subsequent decisions or actions. The criteria are put into a map or branching format and applied by non-physicians in conducting retrospective audits of the medical record. Only relevant criteria are applied to any individual case. The data are computerized, and findings permit the determination of individual case scores based on compliance with applicable criteria and the degree of

compliance of all applicable cases with specific criteria. Existing maps have been tested for reliability and transferability. Training manuals and abstracting guidelines are available. The investigators believe that their technique is probably most appropriate for complex decision-making problems or the treatment of very complicated diagnoses. For simpler conditions, where patient characteristics have little influence on treatment, mapping may not be worthwhile.

The other major problem identified with MCEs is the difficulty of altering provider behavior to correct identified deficiencies. The Utah Professional Review Organization has had extensive experience with traditional medical audit, has summarized the deficiencies, and is testing new approaches. Minimal behavior change resulted from about 20 traditional medical audits conducted during an 18-month period, beginning in December of 1972. The extensive process-oriented data gathered could be categorized as follows: criteria with which there was high compliance, criteria which the physicians believed were of questionable validity, and the very few criteria which actually influence outcome. The last category was further complicated by the difficulty of attempting to change behavior retrospectively. More specifically, by the time that the MCE data were gathered, analyzed, and incorporated into an educational activity, the patient had long since been discharged from the hospital--usually with a positive outcome--and the need for changed behavior was not immediately apparent.

To overcome these deficiencies in traditional audit, UPRO is experimenting with new approaches. One emphasis is to reduce the amount of process data gathered and concentrate on a few procedures which obviously influence outcome and would be harder to ignore, such as treatment of patients with cataracts, the extent of fetal monitoring in induced obstetrical deliveries, use of whole blood instead of packed cells, or failure to work-up patients with anemia. Special studies are being conducted to assess the achievement of a few, critical "management objectives," which are statements of the objectives of the treatment process for a particular diagnosis or problem by the time of discharge. Objectives have been written for 14 diagnoses. As an example, management objectives for a patient with appendicitis are: ambulatory, afebrile (temperature below 99 degrees), and able to maintain nutrition orally. Finally, UPRO staff hopes to conduct some concurrent MCEs which would permit intervention during treatment if necessary to improve care.

LONG-TERM CARE REVIEW

Of the programs visited, only the Multnomah and Sacramento foundations and the San Joaquin PSRO review the quality of long-term care. The emphasis in these programs is similar to the review of acute care; sometimes the same staff review both. A study of long-term care in Colorado, that also attempted to develop assessment instruments, has been conducted under the sponsorship of the Colorado Foundation. Although the foundation was not reviewing long-term care at the time of the site visit, it will begin a demonstration project in October 1976. The project includes the development of improved documentation for patient transfers among facilities, an exploration of the need for alternative lower levels of care providing supportive social services,

and the testing of criteria based on functional level and problems rather than on diagnoses alone.

The limited activities elsewhere may partially stem from the fact that PSRO draft guidelines for long-term care review have only recently been discussed by the National Professional Standards Review Council and not yet issued to local PSROs. PSRO review for both acute and long-term care emphasizes the medical necessity and appropriateness of admission and continued stay and requires medical care evaluation studies. According to the draft long-term care guidelines, however, there also are important differences.

Pre-admission certification will be required for long-term care, either by the hospital review staff (when a patient is discharged from a hospital to a long-term care setting) or by independent agencies such as geriatric assessment centers or community mental health centers (if the patient does not enter from an acute care hospital). In addition to the usual elements of concurrent review, the long-term care requirements include a review of the health services provided to each patient and the extent to which they meet the patient's needs or are "provided in a manner consistent with local standards of care." [7] Concurrent quality assessment will be performed on site, based primarily on the medical record. At least one yearly bedside review of the patient is also required. Delegation of long-term care review responsibility is expected to be less frequent than in acute settings. A multidisciplinary group of providers must be involved in all aspects of long-term care review.

Because most long-term care review activities were still being developed, they were not examined in detail during the site visits. They are the subject of a separate paper, however, which is summarized in Chapter 5.

AMBULATORY CARE REVIEW

Ambulatory care review programs can be categorized into either ongoing claims review systems or different approaches which generally evolved, or are evolving from research activities or special projects. Both categories are discussed below and additional issues relating to quality assurance for ambulatory care are summarized in Chapter 5.

Claims Review Programs

Ambulatory quality assurance programs based on claims review are conducted for or in conjunction with third party carriers. Occasionally, the review organization is the insurance carrier. After a claim has been submitted for payment, review may include such activities as ascertaining that the patient was eligible for coverage, that the services provided were among those included in the insurance benefit package, that any deductibles or coinsurance requirements were met, that the claimed fee on the relative value scale was commensurate with services rendered, and that the services were not clearly

inappropriate for the diagnosis or condition. The quality assurance programs visited vary in the extent to which they conduct these functions, although only the latter function is directly related to the quality of care.

For example, the San Joaquin and Sacramento foundations perform all above functions for all services provided to beneficiaries of certain insurance carriers. The Colorado system for Medicaid claims (discontinued in October 1975) consisted of a manual review of only claims which had been rejected from a computerized screen operated by the fiscal intermediary and based on criteria developed by the foundation. The manual review included an assessment by non-physicians of the content of the visit to determine the appropriateness of the relative value scale coding and a comparison of content and frequency of visits with previously defined criteria to evaluate the appropriateness of care. Questionable cases were referred to physician reviewers for analysis. Until recently, the Utah Physicians Ambulatory Care Evaluation (PACE) program was not involved in the payment process and concentrated its review of Medicaid claims exclusively on questions of medical appropriateness.

Most claims review programs concentrate on over-utilization (excessive number of visits for a single diagnosis; prescribed drugs or injections not indicated by diagnosis; or multiple visits to multiple providers). However, the profile analysis components of the PACE and San Joaquin Patterns of Treatment programs also permit the detection of under-utilization by considering delays in establishing a diagnosis, or the absence of diagnostic and therapeutic procedures indicated by the reported diagnosis.

The extent to which review by explicit criteria is computerized also varies. The Colorado review for commercial carriers, as well as the Sacramento and current San Joaquin programs, are manual operations. As noted above, the discontinued Colorado Medicaid review program was computerized at the fiscal intermediary level, although the foundation's subsequent involvement was manual. The New Mexico Medicaid review system is one of the more comprehensive computer reviews and includes hospital and nursing home stays, surgical services, office visits, emergency room visits, outpatient visits, laboratory tests, injections, X-rays, prescriptions, and "other." It was not visited during this study, but has been extensively described and evaluated elsewhere. [8]

The Patterns of Treatment (formerly Model Treatment) program, developed by the San Joaquin Foundation for Medical Care, is a computerized review. It was used to review ambulatory care received by 47,000 Medi-Cal recipients. Although it is no longer used in California, it is being tested in two other sites. Review criteria were developed by the data committee of the United Foundations for Medical Care in consultation with several speciality colleges.

Claims subjected to the Patterns of Treatment program are initially processed through an administrative review, which checks for patient eligibility and such errors as incorrect procedure or provider number. Claims which pass this review are subjected to medical review against the patient's claims history to check on duplications in drugs or other services. Claims are then submitted to the "broad screen" which eliminates from further consideration and pays claims for initial visits involving minimal sums of money, or remands for

manual review those claims related to rare disorders for which criteria have not been developed. Claims which do not pass the broad screen enter the Patterns of Treatment program, which specifies recommended amounts and types of procedures and prescriptions for 56 diagnostic groupings. Claims which pass this portion of review are paid. Those which do not are reviewed by a physician, along with a patient profile and any other information requested from the attending physician.

The Utah Physician Ambulatory Care Evaluation (PACE) program was initiated to test further the extent to which claims information can be used for quality assessment, provided there is a high volume of claims and the system can generate both physician and patient profiles. Originally, PACE had the capacity to provide additional information on an on-line basis, using a cathode ray terminal, but this feature is no longer operational.

PACE has been linked to the Utah Medicaid Management Information System (MMIS). The state Medicaid office provides UPRO with a computer tape containing claims information from physicians, other health professionals whose services are covered by Medicaid, and pharmacies. The tape is processed through the PACE screen; exceptions are remanded for physician review. Screening guidelines were developed by specialty panels and consist of combinations of diagnoses, therapies, or investigations which are either critical to, or inconsistent with, ideal care. Criteria have also been developed to link events over a specified time period. In addition to reviewing exceptions, reviewers periodically examine profiles. Ready access to this additional information has been credited with stimulating the interest of reviewing physicians in the review process. It has also led to the generation of additional review criteria, as questions for a particular case are found to have more general applicability.

Other Ambulatory Review Programs

Within the ambulatory review programs which are not based on claims information, some are not fully developed and, for that reason, are discussed only briefly. Others are operational and may be regarded as alternatives to claims review.

The Southern California Region of the Kaiser-Permanente Medical Care Program is conducting a research project to develop and implement a quality assurance program which can compare the Kaiser medical centers and also provide overall estimates of quality. Measures of input, process, outcome, and access to care are being developed for six diagnoses or conditions in both ambulatory and inpatient treatment settings. The primary focus of the study is on health outcomes. An attempt will be made to isolate correlates of outcomes to determine whether short-term proxy outcome measures can be developed. Data sources vary depending on the diagnosis, and include both the medical record and physical examination. A questionnaire has been used to elicit patient characteristics, perceptions of outcome, and satisfaction. The study design includes a calculation of cost and time requirements for routine use of these techniques. Findings are not yet available.

The Multnomah Foundation is developing the Multi-Use Medical Care Data System (MUMCDS) which should make available to physicians a computer record of each patient's personal characteristics, insurance coverage, and past medical history, as well as information about each encounter in a format that would replace much of the conventional medical record. MUMCDS will include criteria to assess the process of care; assessments will be provided to the physician in an educational context to improve the quality of care.

An informed consent form has been developed on which a patient may give written permission to include information from his medical record in MUMCDS. The form stresses benefits to be derived from MUMCDS by simplifying record keeping, avoiding duplication, and making more physician time available for patient care.

Data sources include a patient data form, completed once unless there are changes, and a patient encounter form which covers all aspects of the visit including presenting complaints, findings, conditions treated, selected treatment procedures, drugs prescribed, diagnostic procedures ordered, counseling, follow-up plan, and length and place of visit.

A long developmental period is expected. Nevertheless, MUMCDS is intended eventually to be used in many different practice settings, including small fee-for-service offices. With that exception it resembles the Health Information System of the Indian Health Service in Tucson, which assesses the quality of ambulatory care provided to the Papago Indian tribe.

The Health Information System (HIS) retrieves information on all ambulatory care provided to tribal members, regardless of site, including care rendered in schools and homes by public health nurses and tribal health workers, as well as care provided in the four clinics and 50-bed hospital. Remote computer terminals are available for entering and retrieving information.

The executive health staff of the tribal council is officially responsible for selecting problems for assessment. The decision is based on prevalence, potential severity, and the existence of effective treatment. Two "maps" are constructed for each problem. Staging maps break each health problem into stages of increasing severity to define areas for intervention and anticipate outcome. Process maps define the general steps in the clinical management of the problem and usually include screening, diagnostic work-up, preventive and remedial therapy, and follow-up. Finally, criteria, standards, and indicators are developed to be used in the automated quality assessment.

The assessment is based on information from encounter forms and lab slips and consists of the following steps: location within the data base of patients for a particular audit; categorization of patients by priority status (a function of risk and prognosis) based on their histories and the staging maps; identification of encounters for the priority patients (for example, if the audit concentrated on screening, follow-up visits would be ignored); identification and separate storage of audit information; and application of the indicators to the stored information to determine effectiveness of care.

The system produces three reports: population-based reports to be used by system managers; provider-based reports for use by health workers in self-assessment; and provider-based reports to be used by supervisors. It should be noted that this is a closed health care system, where providers have recognized responsibility for the care of a well-defined and relatively stable population.

Another population-based review program is the Comprehensive Quality Assurance System (CQAS) developed by the Kaiser-Permanente Medical Care Program of Northern California. [9] CQAS is designed to identify and examine instances of less than optimal care to bring about an improvement in quality. There is no concern with documenting overall levels of care and, for that reason, systematic sampling techniques are not used. Instead, the selection of topics and records is deliberate and designed to yield the greatest possible number of instances of poor performance.

In the CQAS system, records are selected for review by a process called micro-sampling, in which small numbers of records are analyzed at infrequent intervals emphasizing the times and areas where performance is likely to be poor. If a CQAS committee felt that sampling among records or patients seen at the end of a day would yield more instances of inadequate care, for example, then records would be drawn from that group. Records are reviewed by a physician, who identifies and records problems based on personal judgment. Records are then reviewed independently by an additional reviewer and other problems in care are added. Unanimous agreement is required to assure that the problems represent significant deficits in care. The problem list then goes to a committee. Committee actions include standard setting, recommendations for education, imposition of sanctions, changes in or development of new systems, or purchasing of equipment. Standards are set if the problem is thought to occur often and if it could have a serious impact. Compliance with standards is determined according to the usual audit cycle of measurement, action, and re-measurement.

This technique has been applied to both hospital and ambulatory care and to the full range of providers, and appears to be flexible. It is largely dependent on the medical record, and in its early stages, on physician involvement. Improvement can be documented for the specific types of cases audited, if one assumes that comparable samples of patients are included in both measurement sessions. However, overall performance cannot be assessed.

The system's developers note two problems in its implementation. Some CQAS committees have had difficulty establishing measurable standards to resolve identified problems, and technical assistance is sometimes required. In addition, the initial assumption that an untrained person could retrieve selected medical records and abstract required information has been questioned. CQAS officials now believe that familiarity with medical terminology and medical audit are essential.

The EMCRO project at the Columbia Maryland Medical Plan has developed an outcome oriented "patient reported problem status measure" (PSM), which bases an assessment of care on the patient's perception of his health problems in terms of symptoms. [10] At this point the PSM is primarily a subject of research, but it could be used for routine quality review.

In one application of the PSM, patients' assessments of health problems were obtained by questionnaires completed one month after treatment for either sore throat, upper respiratory infection, or urinary tract infection. The patient rated himself on a scale from "none" to "extreme" for the following items: frequency of symptoms, intensity of symptoms, activity limitations, and extent of anxiety. The patients' assessments were compared with outcome standards developed by the medical staff to reflect the maximum symptomatology expected for each item. Medical records were reviewed to assist in identifying reasons for not meeting outcome standards, giving particular attention to errors in the delivery of care and patient characteristics or illnesses. The record review included all patients with sub-standard outcomes and a 30 percent sample of patients with acceptable outcomes, and employed explicit process criteria, as well as implicit judgments of the total process of care. After completing the process assessment, the reviewer learned the patient-reported outcome and noted any further actions which, if taken, would have improved the quality of care.

The detected deficiencies in care for the two groups of patients were significantly different. Of those in the "acceptable" group, 56 percent had a possible error in diagnosis and three percent had a definite error in diagnosis; the comparable numbers for the "sub-standard" group were 29 percent and 57 percent, respectively. Specific actions which could have improved the quality of care were identified for 22 percent of the total sample of patients; of those, 71 percent had sub-standard outcomes. Actions to improve quality were suggested for 30 percent of the cases defined as sub-standard by the process review and for 95 percent of the cases defined as sub-standard by outcome assessment. At least in this application, then, an outcome approach to assessing the quality of ambulatory care was more efficient than a process review. Furthermore, involvement of patients in assessing quality contributes information which is not available from the medical record (especially if poor outcome stems from the absence of a follow-up visit) and lessens demand on physician time, since physicians can then concentrate their attention on cases with less than optimal outcome. Physicians who initially provided the care reportedly were receptive to the review findings, but current experience is insufficient to determine whether the quality of care improves, once this information is made available to them. [11]

METHODS FOR CHANGING BEHAVIOR

Quality assurance programs are generally based on the assumption that when inappropriate care is detected, specific actions can be taken to correct the deficiency and ultimately improve the quality of care. However, administrators of almost all programs visited noted the extreme difficulty of changing provider behavior after deficiencies are identified. In a few instances, infractions were so severe as to warrant a report to the state board of medical examiners; board action was not discernible, however.

Most programs rely on educational means for encouraging improvement, but the frequency and structure of such activities vary. Bethesda-Lutheran Hospital regularly reports the results of medical audits or conducts appropriate

educational sessions at weekly medical staff meetings, attended by about 25 percent of the staff. The findings of MCEs at Overlook Hospital are considered by the appppropriate department of the medical staff and eventually are reported to the board of trustees to determine whether further action is warranted. Results of review by the San Joaquin Foundation may occasionally lead to education activities sponsored by the medical society or, in extreme cases, referral to state authorities for appropriate action.

Several approaches have been tried in Utah ranging from formal education programs and specially designed hospital rounds to a series of increasingly more severe letters that discuss inappropriate care uncovered by the PACE review. If physicians continue to provide inappropriate care despite earlier notices from the PACE program, they are informed that their claims will no longer be certified for payment. The decision to impose payment sanctions is relatively recent. [12]

Most program administrators reported that physicians who consistently differ from review guidelines may be counseled by their peers--in the case of a hospital, this would generally be the department chairman. Similarly, most programs include provisions for putting a physician on total review, in which every claim or hospitalization by that physician would be reviewed. At Bethesda-Lutheran Hospital, documentation of inappropriate care is recorded in the hospital's file on the responsible physician. However, documentation of compliance is also recorded in the physician's file if the deficiency has been corrected upon re-audit.

The Sacramento Foundation does not rely on an educational approach and is quite explicit in applying sanctions. It attempts to obtain compliance with review guidelines for ambulatory care by denying reimbursement. In cases where care appears to be inappropriate, the foundation may arrange to have another physician examine the patient. The attending physician must inform the patient that there will be a consultation.

A few programs provide for patient involvement. In Utah, a brochure was developed to explain the purpose of UPRO and the review program. The brochure was intended to be given to patients at the time of admission, but apparently some hospital administrators were reluctant to distribute it. At Multnomah, a letter of denial of continued stay is sent first to the patient, although the attending physician is notified that the letter is being sent and presumably may discuss it with the patient in advance. Similarly, the San Joaquin Foundation routinely notifies the patient of the disposition of each claim. On occasion, patients have appealed the foundation's review decision. However, the extent to which this makes the patient more aware of the need for appropriate utilization is not known.

The Texas Department of Public Welfare mails Medicaid recipients a monthly packet which includes the Medicaid card, a statement of all services for which the state has been charged to be verified by the recipient, and any special notices such as the availability of free health examinations for people under 21 years of age. The department recently instituted a program whereby monthly patient profiles will identify patients who appear to be using services

inappropriately. For those people, the monthly letter will not include the Medicaid card. Instead, the recipient will be requested to attend an educational session to discuss his health care. The Medicaid card will be provided during the session, adding an incentive to attend. The impact of the recipient education program on subsequent utilization of services will be assessed.

In addition, the Texas Medicaid program provides each recipient with a medical assistance record book in which all services are supposed to be recorded by all providers. To date, about 50 percent of physicians regularly complete it. The record permits each provider to review the care being rendered by all others and has been especially useful in detecting drug incompatibilities.

One change resulting from medical audits at Bethesda-Lutheran Hospital was the initiation of a pre-surgical unit, which reduces the number of hospital days needed to prepare a patient for surgery. Patient satisfaction with the unit was ascertained during outpatient follow-up. A pilot program to explore patient expectations and responsibilities for follow-up care is planned. The extent to which it improves patient outcome will be assessed.

METHODS FOR SELF-ASSESSMENT

Specific inquiries were made in each program visited to determine whether a formal mechanism for self-assessment existed. The Overlook Hospital review program is viewed as a management tool which includes self-assessment. Plans for evaluation through medical audit have been included in the development of new patient care programs, such as cardiac catheterization and outpatient abortions. For those two procedures, audits have been expanded and now constitute a routine monitoring mechanism. Usually, however, programs do not have formal assessment methods, although an implicit, continuing process of analysis and program development obviously has guided the evolution of such programs as the Utah Professional Review Organization and Bethesda-Lutheran Hospital's review. Some programs have already submitted to evaluation by outside groups, and relevant studies are cited in the next chapter. In addition, the monitoring of hospital reviews by PSRO staffs may be viewed as a form of self-assessment.

The Bethesda-Lutheran staff conducted a special project to determine whether their review process had adversely affected patient outcome, since approximately 65 percent of their patients are discharged before the 50th percentile of CPHA regional norms for length of stay. A sample of re-admitted patients was studied to determine whether the reasons for re-admission could be related to the prior discharge. They concluded that no re-admissions were attributable to early discharge stimulated by the review process.

Staffs of review programs were asked how the effectiveness of their programs should be assessed. Staff of the Foundation for Health Care Evaluation felt that in time their program should have an impact on the health status of the population reviewed. In Colorado, program officials felt that evaluation should be based on the extent to which they succeeded in instituting a process

for review. The Multnomah staff suggested that their review activities should be judged on reliability and validity. The executive director of the National Capital Medical Foundation suggested that one measure of effectiveness might be an increased availability of nursing home beds as a result of the ability of concurrent review to document the need for long-term care. In other areas, staff were ambivalent and felt that they should not be expected to evaluate the effectiveness of their review programs.

Despite the willingness of some staff to discuss measures of effectiveness, none had established measurable objectives for improving the quality of health care. Some had delineated activities and time tables for implementing review. Others might specify the number of hospitals or patients that should be covered by review by a certain time, or the number of MCEs which must be done per year. But the desired accomplishments with respect to health status were not specified.

SUMMARY

Most quality assurance programs reviewed have benefited from considerable financial support and relatively lengthy experience. They are generally viewed as some of the "better" quality assurance programs and are not a representative national sample. Many were pioneers in the field of quality assurance and serve as models which have been adapted elsewhere. Thus, their contributions are real. However, they have also encountered some difficulties which may be equally instructive. In drawing conclusions from the experiences of these programs, one runs the risk of prematurely passing judgment about a very complex problem and programs that may not have had sufficient time to prove themselves. Nevertheless, the information should be useful in considering the need for mid-course re-directions which may be ultimately beneficial.

Most statements of program goals refer to the need to ensure high quality medical care at reasonable costs, but do not include measurable objectives or methods for improving the quality of care. Indeed, the margin by which quality might be improved is not known. No program official was able to offer even a rough estimate of the extent of deficient or inappropriate care. Without such a measure, it becomes difficult to determine whether a program is achieving its objectives and whether the resultant improvement is sufficient to justify program expenditures.

Most programs are oriented toward users of institutional or ambulatory health services, rather than non-users, and with a few exceptions, do not address questions of access to care and under-utilization of services.

Most hospital review programs place primary emphasis on concurrent review activities and medical care evaluations, as required by PSROs, but the two activities are seldom integrated. There is considerable variation among programs in the timing, depth, and frequency of review. Similarly, the extent to which review coordinators and physician advisors are trained and supervised varies from program to program. Common problems have been identified in conducting medical care evaluations: the incompatibility between JCAH

and PSRO requirements; the difficulty of selecting audit topics which result in the identification of significant problems so that improvements can be made; the difficulty of developing criteria relevant to all patients without becoming too general; and the difficulty of achieving change, once deficiencies have been identified. Innovative efforts which address these problems are underway.

Some ambulatory care quality assurance programs are evolving as alternatives to claims review. They have the potential of permitting greater emphasis on quality by viewing the provision of medical care over time (rather than individual encounters) and assessing access and health outcomes. However, they require further refinement and evaluation before being widely implemented.

Most programs rely on educational methods for encouraging improvements in performance. Although there are some internal appraisals of the effects of review, no program had established a formal mechanism for self-assessment. Some have submitted to independent evaluations by external groups, however.

STEERING COMMITTEE RECOMMENDATIONS

1. Within quality assurance programs, the review components should be better integrated. Further development of profile analysis may help to identify quality deficits and permit better targeting of both concurrent review and MCEs, but a conscious effort is needed to link the three types of review. The policy of delegating responsibility to hospitals for conducting MCEs independently of concurrent review should be reconsidered, since it may encourage fragmentation. Within hospitals, PSRO review activities should be better integrated with prior utilization review and other quality assurance activities.

2. There should be fewer, better designed, and better evaluated MCEs, and experimentation should be encouraged. The JCAH and PSRO requirements should be compatible in content, as well as in their numerical requirements. Hospitals should be permitted to count re-audits of completed audits in fulfilling numerical requirements.

3. Establishment of quality criteria would be facilitated by increased knowledge of the efficacy of medical procedures derived from clinical research. The Department of Health, Education, and Welfare should further specify the responsibilities of its component agencies in this area and increase available funds.

4. Quality assurance programs should further specify their objectives for improving health status and establish internal self-assessment units for program evaluation. The Department of Health, Education, and Welfare should provide technical assistance for such activities. Appropriate linkage with health services research centers should be encouraged.

5. The components of quality currently addressed by quality assurance programs should be expanded. Access to care and potential under-utilization should be assessed. This requires attention to the availability of health care providers and facilities, appropriate links between levels of care, and policies (such as on-call arrangements) to assure that services are easily accessible to patients who need care. Better working relationships and exchange of information should be encouraged between quality assurance programs and health planning agencies. Benefit packages and reimbursement policies should be examined to determine their impact on the quality of care, particularly with respect to coverage of long-term care (both institutional and non-institutional).

6. A priority for research is the systematic accumulation of data to describe current patterns of care, determine the reasons for variation, and identify deficiencies. This information would provide a better estimate of the margin by which quality and utilization might be improved, which in turn would help to determine the magnitude of the required quality assurance effort.

FOOTNOTES

Chapter 3

1
U.S. Department of Health, Education, and Welfare, National Center for Health Services Research and Development, Experimental Medical Care Review Organization (EMCRO) Programs, Arthur D. Little, Inc., DHEW Pub. No. (HSM) 13-3017 (1973).

2
Michael Goran et al., "The PSRO Hospital Review System," Medical Care Supplement 13 (April 1975): 15.

3
Ibid., p. 17.

4
Leonard Rubin, Comprehensive Quality Assurance System: The Kaiser-Permanente Approach (Alexandria, Va.: American Group Practice Association, 1975).

5
Charles Lewis, EMCRO Annual Report (Los Angeles: UCLA Center for the Health Sciences, 1975). See also Sheldon Greenfield et al., "Peer Review by Criteria Mapping: Criteria for Diabetes Mellitus," Annals of Internal Medicine 83 (December 1975): 761-70.

6
Sheldon Greenfield et al., "Protocol Management of Dysuria, Urinary Frequency, and Vaginal Discharge," Annals of Internal Medicine 81 (October 1974): 452-57; Greenfield et al., "Management of Low Back Pain by a Protocol and a Physician Extender," Western Journal of Medicine 123 (1975); and Anthony Komaroff et al., "Protocols for Physician Assistants: Management of Diabetes and Hypertension," New England Journal of Medicine 290 (7 February 1974): 307-12.

7
Department of Health, Education, and Welfare, Washington, D. C., Minutes of Meeting of the National Professional Standards Review Council, 12 July 1976.

8
Robert Brook and Kathleen Williams, "Evaluation of the New Mexico Peer Review System 1971-73," Medical Care, forthcoming.

9
Rubin, Comprehensive Quality Assurance System.

10
Alvin Mushlin et al., "The Use of Patient-Reported Problem Status in Evaluating Ambulatory Care," presented at the National Meeting of the American Federation for Clinical Research, Atlantic City, N. J., 3 May 1975.

11
Alvin Muchlin, Francis Appel, and Daniel Barr, "Quality Assurance in Ambulatory Care: A Strategy Based on Outcome Assessment," 1976. (Mimeographed.)

12
James Cannon, PACE project manager, personal letter, 28 June 1976.

Chapter 4

EFFECTIVENESS OF QUALITY ASSURANCE PROGRAMS

A wide range of material was gathered to show the initial effects of quality assurance programs, including impressions and anecdotes, as well as more systematically gathered evaluative data. Because documentation is frequently inadequate, a definitive assessment of effectiveness is not possible at this time. Nevertheless, the information is sufficient to permit a preliminary assessment of current programs and to suggest areas in which additional research and evaluation are required.

General problems in evaluating program effectiveness and limitations of current measures are discussed before presenting information about the effectiveness of the programs visited. All issues are discussed in more detail in the forthcoming priority paper on "Cost and Cost Effectiveness of Health Care Quality Assurance Programs."

GENERAL PROBLEMS IN EVALUATION

Few quality assurance programs were instituted with explicit objectives and plans for program evaluation. Inferences were made by the study staff about the relative emphasis given to cost and non-cost components of quality review. The translation of general program goals into policies and procedures for routine operations was examined to shed further light on specific program objectives and orientations. Nevertheless, the absence of clearly defined objectives complicates the assessment of program effectiveness.

Furthermore, in most quality assurance programs, and particularly in an undertaking as complex as the national PSRO program, there are many different, sometimes conflicting, objectives. The declaration of purpose in the PSRO legislation refers to the "effective, efficient, and economical delivery of health care services of proper quality...." [1] In fulfilling this purpose, many specific objectives and required activities are determined by the Bureau of Quality Assurance. Members of local PSROs may place additional or greater emphasis on the preservation of local autonomy and may concentrate their efforts initially on specific tasks required to establish an independent program and begin routine review activities. The demands of program implementation may overshadow the broader goal of improving the quality of health care, so that an appropriate evaluative measure for the short-term might be the extent to which

tasks associated with program implementation and operation are completed. However, most programs reviewed in this study have passed the implementation stage. Furthermore, the study addresses broader, long-term issues of quality assurance. Measures of effectiveness, therefore, must also be viewed from a broader perspective.

Throughout this report, the primary objective of quality assurance is assumed to be maintaining or improving the quality of health care. Program effectiveness is regarded as the extent to which this objective is achieved and should be measured by improvements in health status or patient satisfaction (non-cost components of quality) and the conservation of resources (cost components of quality). Determination of cost effectiveness involves the relationship between the cost of operating the review program and effectiveness as measured by improvements in health status and satisfaction and reduction in the cost of health care. If the quality assurance program is an addition to a health care delivery system, the cost of quality assurance is the difference between the cost of the delivery system with and without quality assurance activities.

Even if objectives are well specified, differences among programs limit comparisons of their effectiveness. Differences in the type of medical care reviewed and approaches to review make it difficult to compare review costs or effectiveness. Assessments of the relative effects of different types of review mechanisms might be attempted by comparing programs according to the magnitude of changes within them and assuming all other influences could be held constant. However, adequate baseline data are not available to permit before-and-after measurements.

Since is is not known when the effects of a review system should become apparent, it is difficult to determine when measurements should be made. One may argue that the anticipation of quality assessment and the heightened awareness of health care providers to increasing public scrutiny may change performance patterns even in the absence of a formal review system. Nelson has noted that the act of establishing process criteria for psychosis resulted in increased compliance with criteria from 64 to 88 percent (based on 50 hospital stays) before the assessment was formally initiated. [2]

On the other hand, it may be unrealistic to expect immediate changes. If a program is expanding its base of support from physicians and hospitals at the same time that it becomes operational, program administrators may be reluctant to impose stringent criteria until all providers have been brought within the system. Once change is documented, it is important to determine whether it is permanent. Although an initial impact resulted from the imposition of the Approval by Individual Diagnosis (AID) program of recertification for continued hospital stay in New Jersey, Bailey and Riedel have shown that the effect was short-lived. [3] After physicians became more familiar with the program, they apparently returned to their prior utilization practices.

Even if an appropriate evaluative design can be developed, the identification of variables to indicate effectiveness and specification of reliable measures present additional difficulties.

MEASUREMENT PROBLEMS

The effect of review on quality of care independent from utilization and cost is the most difficult to assess. Health status of a population is an obvious referent for assessing the outcome of health care. It is typically measured by mortality and morbidity statistics. However, a substantial lag time can be expected before changes in health status are reflected in statistics. Casual interpretation is complex because of the multiple factors influencing health and the limited effect of medical care. Another end result index is patient satisfaction, but consistent measures are not currently in use, and there are limited plans for the collection of such data.

Some programs review intermediate or more proximate outcomes, which may include the incidence of preventable complications or the performance of critical therapeutic procedures as outcomes of the diagnostic decision-making process. Such assessments are often included in medical care evaluation studies. Unfortunately, there have been few attempts to accumulate information on both successful and unsuccessful MCEs, assign values to the data, and aggregate them in a manner which would permit an overall assessment of effectiveness. Methods for doing so are not well developed. The number of MCEs performed under PSROs will be reported by the PSRO information system, but this has limited utility for evaluation.

Improved methods are needed to identify and aggregate the effects on health status which result from health care. It may not be necessary to express those improvements in dollars or comparable units of resource expenditures. But better summary measures must be devised in order to permit assessment of improvements which stem from quality assurance programs, continuing medical education, and other activities designed to elevate the health status of the population.

Because of the close link between quality and utilization of services, the relative ease of measurement, and the associated emphasis on cost control, impact is often measured in terms of utilization, as expressed in costs. Customary measures and their limitations are discussed below.

Admissions and admission denials. Data on admission rates and admission denials are not uniformly collected and are easy to misinterpret. The population base for calculating rates may be difficult to determine. A denied elective admission may become a necessary or emergency admission. Alternatively, the absence of admission denials does not mean that the system is not effectively deterring admissions, since physicians may not attempt to admit cases they suspect will be denied.

Denied requests for continued stay. A denied request for continued hospital stay is also difficult to interpret, since an inappropriate denial may result in a subsequent need for additional, possibly more intensive, care. Also, the possibility of denial may result in patients being discharged earlier than would otherwise be the case, so the opportunity for denial is eliminated.

Reductions in length of stay. Average length of stay before a quality assurance program is initiated helps define the maximum savings that concurrent review can achieve. One may assume that the longer the average length of stay, the greater the probability of finding unnecessary days of stay, but this may not be true. Referral centers may have more difficult cases which require longer stays, and other social and environmental conditions may affect medical decisions. At the other extreme, however, one can not expect to achieve major savings if length of stay is already low.

To the extent that admissions are denied or deterred by the review process, cases admitted are likely to be more serious and may require longer stays. In some hospitals, therefore, an effective review program may leave unchanged or even increase length of stay. Finally, average length of stay data reflect a combination of case, provider, and service mix for any given facility, and for a combination of facilities whenever an areawide average is used. Therefore, data should be adjusted for age, sex, and diagnosis; and the potential influences of provider and service mix should be considered when interpreting the data. Available data are seldom adjusted, however.

Bed days saved. Estimates of bed days saved per 1,000 population are sometimes used as a means of incorporating the deterrent effect of both denied admissions and extended stay requests. These estimates reflect the number of bed days which would have been used in the absence of the review programs, based on one of two techniques. One requires an extrapolation of demand for bed days before establishment of the review program, based on several years and on relatively large, stable populations to minimize year-to-year variations. This method is complicated by the difficulty of defining service areas and the potential for changes in available facilities. The extrapolation should be accompanied by an analysis of the reasons for trends observed, which may not be feasible after the fact. This technique requires further refinement before being widely applied.

The second method is a comparison of an area with a review program and another area with no review program or a different approach to review. This technique assumes that by design or by the accident of a "natural" control, the two populations are under similar influences except for the review programs, and that for analytic purposes there will be no interaction between the two populations. It has not been used often, but may receive more attention if there continue to be some areas without PSROs. More adequate trend data are needed, however.

Cost of alternate care. If bed days are saved, patients who initially were considered for acute hospital care may need care in a different setting. There will be costs for this other treatment. Therefore, the total value of bed days saved does not equal the value of per diem times number of days saved, but should be adjusted downward to reflect the estimated cost of alternative care.

Riedel et al. analyzed hospitalization data for federal employees in Washington, D. C. who were insured by Group Health Association (a prepaid health plan) or high option Blue Cross-Blue Shield. They found that GHA enrollees used 40 percent fewer bed days than the population served by fee-for-service physicians; however, the total cost of care for the two populations was about the same.

Additional costs for GHA ambulatory care offset hospital cost savings. [4] A similar conclusion was reached by Perkoff et al. who studied an experimental prepaid group practice at Washington University. Savings resulting from a 23 percent reduction in hospital days did not compensate for the increased primary care and specialty ambulatory care costs. [5] To fully explain these findings, a more detailed analysis is needed of the units of service used, cost per unit, and influence of the benefit package. Nevertheless, if areawide hospitalization criteria were based on these prepaid group practices, the net reduction in hospital bed days would not result in an equivalent reduction in health care expenditures.

Variable expenses. The use of average cost per day of hospitalization as the value of a bed day saved implies that all expenses vary, so that the reduction in total costs will be proportionate to the reduction of bed days. However, all costs do not vary. Some costs are fixed--at least for the short-run. Cost-plus methods for reimbursement provide few incentives for hospital administrators to manage aggressively all the costs that might vary with occupancy rates. Moreover, days saved are likely to be days of less intensive care and, therefore, less expensive care. Thus, full per diem evaluation of bed days saved overstates true hospital savings.

The proportion of hospital costs which vary according to occupancy is not known and needs further study. The Cost of Living Council based Phase IV hospital regulations on the assumption that 40 percent of average costs were variable, but noted that with a declining volume of admissions, the percent of variable costs might be less. [6] The relationship between utilization review activities and variable costs has not been examined in detail. Nevertheless, the percent of variable costs is unlikely to be constant over a wide range of occupancy rates. The ability to control variable costs may further depend on the period of time over which the reduction in occupancy rates occurs, the level of occupancy rates before length of stay is reduced, and the influence of the area planning and rate regulating authorities in controlling availability and utilization of hospital resources.

If the concepts of variable costs and costs of alternate care are incorporated into the estimate of the value of bed days saved, the result may help to identify the amount of savings needed to achieve the threshold of cost effectiveness.

Communitywide effects. Estimates of cost containment based on areawide statistics introduce an additional factor for consideration. Area savings are not necessarily the sum of savings of individual institutions, but are affected by the relative variability of hospital expenses in different facilities, the amount of revenues exceeding costs (as a measure of economic pressure to find economies in operations), and the ability of each facility in an area to attract additional physicians. Hospitals with higher investments, advanced technology, and greater prestige may try to attract additional physicians and patients as shorter lengths of stay threaten to reduce their revenues, instead of closing wards and sections. Closing wards might further increase their per diem rates, reduce their competetive status, and create other problems. Since high technology hospitals are usually facilities with higher

per diem rates, a shift of patient population from lower to higher cost facilities could offset savings derived from a reduction in bed days used.

Ambulatory impact measures. Effects of ambulatory quality assurance programs are usually determined by the numbers and types of services rendered as stated on claims forms. Forms are examined for appropriateness of care rendered and the appropriateness of the charge, usually based on the designated unit of a relative value scale (RVS). Determination of the appropriateness of care requires medical or peer judgment. The appropriateness of charges, however, is an administrative decision that is made by claims review programs which do not include an assessment of quality. In assessing the effectiveness of ambulatory review activities, the reasons for which judgments are made should be identified, since they require different personnel with differing levels of training and associated costs. As with hospital-based programs, the difficulty of assessing the deterrent effect of review and the importance of the influence of patient, provider, and service mix and the cost of alternate care should be noted.

Cost savings and shifting of costs. A denial of hospital certification or the denial or reduction of ambulatory claims may result in a shifting of costs, rather than savings. Although a retrospective review of care already provided may save money for the fiscal intermediary, often the patient, the community, or another intermediary will pay the provider instead.

Attention to unmet health needs. The ability to meet previously unmet needs for health care is a valid measure of the effectiveness of quality assurance programs, even though costs and utilization of services would increase. However, most existing quality assurance programs do not address unmet health needs.

Measures of program effectiveness and their limitations obviously influence the resulting judgments. The PSRO Program Evaluation Plan is noteworthy because it is one of the first attempts to design a systematic assessment of the impact of a federal program before nationwide implementation, and its introductory sections reflect an appreciation of the associated complexities. [7] Nevertheless, the method selected for assessing cost savings from hospital review makes no explicit allowance for cost of alternate care, makes inadequate allowance for fixed and variable costs in estimates of "savings," and makes no allowance for the change in cost of care that would result from a shift between lower and higher cost facilities. Accordingly, savings which may result from PSRO review will be overstated.

EFFECTS OF REVIEW ON QUALITY

The difficulty of separating improvements in quality of care from effects on utilization and cost and making an overall assessment of the effectiveness of review activities was noted above. However, the kinds of quality improve-

ment said to derive from medical care evaluation studies can be described anecdotally. [8] Whether the improvements are causally associated with the imposition of a review program or other factors is a matter for conjecture. To a limited degree, the costs of conducting MCEs are also known.

The quality assurance program at Bethesda-Lutheran Hospital emphasizes medical audit. Audit activities were intensified simultaneously with a reorganization of the hospital administrative and committee structure and the institution of a problem-oriented medical record. Examples of changes related to medical audit, which are thought to have improved the quality of care, follow:

- purchase of new equipment including central fetal monitor and portable cardiac monitors in outpatient department;
- creation of specific patient care units, such as a presurgical floor, post-myocardial infarction and cardiac floor, and a proposed post-surgical critical care floor;
- establishment of a "Surgaday" program in which surgical patients are admitted and discharged on the same day;
- education programs including a general staff conference and tour of the occupational therapy department, which resulted in increased use of rehabilitative services;
- increased compliance with medical audit criteria upon re-audit;
- improved documentation in the medical record;
- detection of previously undetected cases of hypertension as a result of an audit conducted by the nursing staff;
- institution of patient education programs; and
- hiring of registered nurses to meet new demands resulting from the increased number of patients requiring intensive nursing care and for telephone follow-up of "Surgaday" patients.

Similar information has been presented to indicate impact of the CQAS program as implemented in the Northern California region of Kaiser Permanente:

- institution of new systems to transfer information on drug allergies and prescriptions from the hospital to the ambulatory record, to provide information on current drug use for each patient visit, and to provide clinical information to the anesthesiologist before surgery;
- contracting with a new vendor for improved arm bands for patient identification;
- earlier hospital discharge after establishing policies to ensure that patients do not remain hospitalized for suture removal;

- specific improvements in administration of immune globulin to post-partum patients, use of blood fractions, hypertension detection, preoperative electrocardiograms, pediatric neonatal appraisal;

- purchase of equipment, such as more baby scales;

- reduced waiting time for radiological contrast studies; and

- improvements in problems associated with "no show" outpatient appointments.

Overlook Hospital has had extensive experience with medical audits, which are thought to have achieved the following:

- more appropriate use of packed cells, rather than whole blood;

- decrease in inappropriate postoperative length of stay;

- decrease in inappropriate retrograde pyelography performed on young patients;

- increased use of rehabilitation facilities for stroke patients; and

- 98-100 percent compliance with surgical criteria for hysterectomies, caesarian sections, and cholecystectomies upon initial audit, which was maintained upon re-audit.

A review of patients at Overlook Hospital with hip fractures showed that over 30 percent of the patients had decubitus ulcers. As a result, a hospital-wide monitoring system and a pressure sore prevention and treatment protocol were developed. The decubitus ulcer program is directed by a rehabilitation nurse who was hired as a result of an audit in 1973 of patients with strokes.

Medical audits at Mt. Sinai Hospital in New York City led to a series of department conferences and reported improvements in medical record documentation. An audit of patients with impacted teeth led to recommendations that all dental patients receive a physical exam, that radiographic findings be documented, and that all morbidity be described in progress notes and the discharge summary. As a result of an audit of patients with myocardial infarction, staff initiated a log to record requests for admission to the coronary care unit and the disposition of such cases, and an intermediate care area was created. A study of appendectomies led to the recommendation that a surgical resident be available 24 hours daily for emergency room consultation and that the incidence of normal appendices removed surgically should not exceed 10 to 15 percent.

The San Joaquin Foundation reports that the frequency of certain procedures, such as cholecystectomies and tonsillectomies, has been reduced by placing particular physicians on total review. Computer printouts from the discontinued Medi-Cal review indicate that the dollar amounts of claims were reduced and the number of pap smears and appropriate immunizations increased.

An independent evaluation of the Patterns of Treatment program confirms a reduction in unnecessary injections. [9]

Intervention by nurse coordinators at the San Joaquin PSRO led to quality improvements for specific patients. A review of an EKG report which arrived after a patient had been discharged led to the patient's re-hospitalization for treatment of myocardial infarction. Repeat hospital admissions of an 80-year old man were eliminated after arrangements were made for the visiting nurse to supervise his medications at home. A patient was transferred to a lower level of care after the nurse coordinator convinced a nursing home administrator to stock certain types of packing and dressings required for his care.

Although the Utah experience indicates a general disappointment with traditional audits, MCEs were instrumental in changing the medical school curriculum for physical diagnosis. Content of medical grand rounds was sometimes tailored to address identified deficiencies. More innovative MCEs involving the achievement of management objectives for hospitalized patients and potential intervention in the patient care process are being evaluated.

Limited information on the cost of conducting MCEs in individual hospitals is available. The differences in cost have not been thoroughly analyzed and may be affected by the number of studies performed, the subject matter examined, associated personnel costs, and the efficiency and quality of their work. The cost of MCEs per admission at Bethesda-Lutheran is about $5 for all patients; the comparable cost at Overlook is about $4. Most recent information on MCEs reported to the Bureau of Quality Assurance shows a cost of $.86 for the Colorado PSRO and $1.83 for the Utah PSRO. These costs are incomplete, however, since the MCE components of PSRO review are still being developed and most costs are being borne by the hospitals and are not included in the PSRO cost data. The cost of the Kaiser CQAS system is about $.25 per member per year for both ambulatory and hospital care. The operating cost of the Indian Health Services' Health Information System on which quality assessment activities are based is about $12 per person per year.

The changes summarized above have no doubt improved the technical quality of the process of care and should result in improved health outcomes, even though it is difficult to quantify the outcome benefits achieved--particularly for such activities as detecting previously unknown cases of hypertension, assuming treatment is successful. Greater uncertainty arises, however, in attempting to determine whether the improvements are sufficient to justify the resources expended. The total magnitude of activities (successful and unsuccessful) is not known. It is not possible to conclude that the improvements resulted solely from the presence of quality assurance programs, since many other factors were operating simultaneously. Furthermore, one might argue that many of the changes should be the routine responsibility of a competent hospital or health professional and should not depend on the imposition of a special quality review program. With such inadequate information, it is impossible to base an assessment of value or effectiveness on anything

other than personal opinion. Bits of additional information may be gleaned from other sources, however.

Fleisher et al. have recently reported the results of their "Mandate Project" [10] in which the bi-cycle concept of medical audit [11] was voluntarily implemented in ten hospitals between 1970 and 1973. The Mandate Project was based on the assumption that its success would depend on the extent to which participating hospitals officially endorsed it. The first phase consisted of a bi-cycle workshop attended by representatives from each hospital (a member of the board of trustees, an administrator, a representative from medical records, and three physicians, preferably including the director of medical education or someone with responsibility for administering the project). To continue in the study, each hospital had to provide a letter, signed by the chairman of its board, administrator, and chief or president of the medical staff, indicating an understanding of the project and an institutional commitment to implement it. The second phase, auditing two or three diseases or conditions, was completed by eight of the ten hospitals. The third phase required that actions to correct identified deficiences be planned and carried out and that a re-audit be conducted one year later to determine the level of improvement. Five hospitals completed the third phase.

Differences among hospitals in audit topics, criteria, and improvement programs hamper precise comparisons of degrees of change. Nevertheless, least improvement was apparent in the hospitals which did not conduct the corrective action efforts. Factors related to improvements included the presence of a nucleus of committed physicians, involvement of the medical staff in setting criteria and standards, active cooperation of medical records personnel, and support by the administration and board of trustees, as well as medical staff. The overall impact of the project is difficult to determine. No cost data were reported.

In 1973 the American Hospital Association initiated a demonstration in 16 hospitals of its Quality Assurance Program, which had been developed to meet JCAH and expected PSRO requirements for medical audit and utilization review. The specific purposes of the demonstration were: "1) to demonstrate and evaluate the Quality Assurance Program (QAP), 2) to develop educational materials to support the introduction and maintenance of the QAP, and 3) to encourage the adoption of quality assurance programs in community hospitals throughout the United States." [12]

During the one-year demonstration, an average of 14.9 sets of criteria for medical audits were developed in each of the 16 study hospitals, although this number may include some developed earlier and revised during 1974. Patterns of care were evaluated for an average of 64 percent of these criteria sets. Corrective actions were recommended for about 44 percent of the evaluated topics. Of the 13 hospitals which made recommendations for corrective actions, 54 percent recommended education programs; 69 percent recommended changes in organization policy or procedures; and 85 percent recommended direct intervention with individuals or groups. An average of 17 percent of the topics recommended for corrective action were re-assessed;

however, re-assessments were made in only six hospitals. Most of those hospitals reported "moderate improvements" in practice, but details were not provided. An example of improvement cited was a decreased incidence of normal appendices removed surgically. [13] Some cost information was gathered, but the cost of conducting medical audits was not provided.

The attrition rate between initiation of the study and completion of the full medical audit cycle is striking in both the Mandate Project and QAP demonstration. Participating hospitals could receive technical assistance from project staff in both studies, so an inability to comprehend audit requirements should not have been influential. The QAP demonstration may not have permitted sufficient time to complete the full cycle for all audits, but the Mandate Project covered a longer time span and should not have suffered from this problem.

The difficulties associated with QAP medical audits, as reported by participating demonstration hospitals, are similar to complaints voiced during the site visits for this study. Examples include difficulty in defining meaningful topics; difficulty in establishing concise and objective criteria; compromises in criteria development resulting in minimal rather than optimal standards; difficulty in achieving consensus across medical specialties; imprecise screening guidelines, producing too many records for review; inadequate documentation in medical records; excessive time devoted to abstracting process criteria--particularly if outcomes are acceptable; irrelevance of outcome screens, since negative outcomes are usually explained by pre-existing conditions; failure to attend audit meetings and inattention to committee reports; difficulty in transmitting corrective action needs among different departments; and failure to attend education programs, particularly by those most in need of improvement.

The major source of medical audits at present are the 2,500 hospitals using the JCAH-sponsored Performance Evaluation Procedure for Auditing and Improving Patient Care (PEP), summarized in Appendix D. To facilitate the implementation of medical audits, the JCAH publishes the Quality Review Bulletin. Each issue addresses a specific audit topic, showing an actual hospital audit of the topic, an analysis of the audit's strengths and weaknesses, and a minimum of two sets of alternate criteria used by other hospitals to audit the same topic. Although the Bulletin may serve a useful educational purpose, there is no equivalent mechanism to systematically accumulate sufficient information to permit assessment of the effectiveness of medical audits.

The JCAH intends to assess the "effectiveness and efficiency of retrospective review of the quality of care." [14] As currently planned, the report will be based on information gathered during regular JCAH hospital surveys and will concentrate on actions proposed to correct identified deficiencies in patient care and subsequent re-assessment. It should be available early in 1977. [15]

Some information about the California Medical Association's Patient Care Audit (PCA) is available. In April 1975, the 208 hospitals that had participated

in PCA workshops since their inception in 1971 were surveyed. The results indicate that 95 percent of the hospitals had implemented some PCA activities; 73 percent had completed audits of one or more topics; and 33 percent had completed a re-audit of one or more topics. Implementation was more likely if the PCA process was in effect in the hospital before the workshop, the hospital staff was committed to PCA and regarded it as viable, and it contributed to improved patient care. [16]

The "Audit Action Letter," published by the Patient Care Institute of Darien, Connecticut, emphasized innovative approaches to medical audits. Recent issues raised questions about traditional retrospective audits similar to those experssed by administrators of programs examined in this study.

Despite the potential future accumulation of evaluative data about MCEs, today there are no reliable data on the numbers, topics, and associated costs of currently performed MCEs; the identified deficiencies in patient care; the remedial actions proposed and taken; and the extent and duration of improvements in patient care. MCEs may have improved quality, but reliable, before-and-after assessments are not available. Any endorsement of the continued performance of MCEs must be based on the recognition that in isolated instances performance has improved; the assumption that the questioning and information exchange during conduct of audits may increase attention to quality issues, thereby informally leading to improvements; and the hope that future evaluations will provide more conclusive evidence.

EFFECTS OF REVIEW ON RESOURCE UTILIZATION AND COST

More information was available from the programs visited about the effects of concurrent hospital review and ambulatory review on utilization patterns and the costs of review. However, the information is still inadequate. Most programs have not specifically designed information systems to permit an evaluation of effectiveness. Reliability and specificity of data on hospital admissions may have improved as program staff gained an appreciation of the need for precision and an increased capability to achieve it, but this limits the utility of before and after comparisons. Political and environmental influences may have affected review in a manner which would not be routinely recorded. Effectiveness in satisfying unmet health needs is not assessed.

Cost data are particularly deficient. Resource constraints precluded the accumulation of cost information specifically for this study. Therefore, the data represent existing information that could be obtained with relatively little effort. Some data represent projections by the program, but the assumptions and methods by which they were derived are not clearly specified. Even "actual" data must be regarded as estimates, since the data sources are of recent origin, and uncorrected errors may persist. Estimates may not include depreciation and other indirect costs; fixed investments may have been paid for by other funding sources. Although the emphasis is on operating costs, some development costs may be included, since many systems are still

evolving. Variable costs and the cost of alternate care are not considered. In all cases, costs must be regarded as under-estimates, and benefits, as over-estimates. Despite these limitations, the data are probably the best currently available.

HOSPITAL REVIEW PROGRAMS

Information on the costs of hospital-based concurrent review programs from three hospitals and three PSROs was analyzed and related to measures of effectiveness. Cost information from the remaining programs was not analyzed because sufficient data were not available. In some cases, anticipated information was not received. Cost estimates are based on the incremental resources required to operate concurrent review programs, regardless of whether services are reimbursable or gratis. The same kinds of resources were examined for all programs to the extent that data were available. In addition to direct costs, incremental indirect direct costs were included. Variation among programs in the techniques or procedures used to perform review restricts the range of possible comparison. Nevertheless, the apparent purpose or intended outcomes of the programs reviewed are the same.

The estimated cost of concurrent review per hospital admission varies: for internal hospital systems during 1976, the average incremental cost is about $2.50 at Bethesda-Lutheran, $3.50 at Overlook, and $8.00 at Mt. Sinai in New York City. PSRO estimates for the last half of 1975 are $9.76 in Utah and $9.90 in Colorado. [17] Multnomah staff did not provide a per admission cost for concurrent review, but the cost of all review components, including gratis physician services, for the first quarter in 1976 was reported as $18.69 per admission. [18] Elsewhere the concurrent review portion of total costs is slightly over 50 percent.

A partial explanation for the lower cost of internal hospital programs may be that there are more patients per nurse coordinator, which implies that review is concentrated (perhaps unconsciously) on "problem" cases; economies associated with reviewing all patients rather than just those covered by federal reimbursement programs; and lower administrative or indirect costs. There is some information to suggest that the costs reported for internal review systems may increase as they are integrated into a local PSRO. Additional work is needed to adequately explain the reasons for variation in costs and to determine if equally effective but cheaper review mechanisms can be developed.

Against the background of cost information, examples of changes in hospital utilization patterns thought to result from concurrent review programs were considered.

Denied admissions to Bethesda-Lutheran Hospital resulted in an estimated annualized gross savings of about $71,000. The hospital's administrator estimates that variable expenses are about 40 percent of the total, which would yield an actual savings of about $28,000--somewhat more than the administrative cost of the entire concurrent review program. Information

on the cost of alternate care required by patients whose admissions were denied is not available. In any case, the net savings are substantially less than $28,000. The hospital's average length of stay declined between 1968 and 1972, but has remained about the same since, with a slight increase in 1974. Although admissions and some (0.4 percent) extended stay requests were denied in 1975, the stable average length of stay admissions implies that the impact was offset by the elimination of the "easier," shorter stay admissions and use of the "Surgaday" program, which further reduced the number of short-stay cases.

Overlook Hospital has reported a greater decline in average length of stay for Medicare patients between 1970 and 1975 than that reported by other hospitals in the immediate area of Union County, New Jersey. The decline occurred primarily between 1970 (14.9 days) and the second half of 1971 (11.9 days). In 1975 Overlook's average length of stay for Medicare patients was 11.6 days.

The Social Security Administration (SSA) has conducted a multivariate analysis of length of stay data for community hospitals for the years 1970, 1971, and 1974 (not for 1972 or 1973) which considers several factors such as hospital characteristics, typical mix of diagnoses and procedures, and characteristics of Medicare patients. The analysis for Overlook Hospital showed that the length of stay in 1970 and 1971 was not significantly different from that expected for the comparable class of hospitals in that area. [19] Therefore, the decline does not appear to be attributable to Overlook's concurrent review program. Since the program covers all patients, it is of interest that there was negligible change in the length of stay for non-Medicare patients between 1970 (7.4 days) and 1971 (7.5 days).

SSA reported that for 1974 the average length of stay for Medicare patients at Overlook was still within the expected range, since stays in other hospitals in that area have also declined. [20] These data suggest that there are countywide influences, such as shortage of available beds, that may be affecting length of stay. Indeed, even with reduced lengths of stay, Overlook's occupancy rate for medical and surgical beds in recent years has remained above 90 percent.

If Overlook's experience is considered independently of other hospitals in the area, the year 1970 becomes an appealing base for measuring effectiveness: gross savings of $2,000,000 would result through 1975 from the reduction of 3.3 days per stay for about 4,600 federal pay patients at an estimated per diem of $125. If variable expenses were 20 percent, savings would still equal $400,000 (not considering the cost of alternate care) or five times the estimated annual cost of concurrent review for all Overlook patients. However, if the second half of 1971 were used as the base year, such savings could not be claimed. The program's medical coordinator makes no such claims.

Mt. Sinai Hospital in New York City introduced a more intensive quality assurance program in 1975 and raised its associated annual budget from about $50,000 to $300,000. A seven percent reduction in average length of stay

(about one day per admission) during the 12-month period following initiation of the intensified program was reported. If variable expenses are estimated at 20 percent, this would yield savings of $1,500,000, so review is cost effective for Mt. Sinai. The program's effectiveness appears to result from more stringent requirements for patient treatment plans and more aggressive discharge planning.

The rate of change appears to be narrowing in 1976, and length of stay may be increasing slightly. Mt. Sinai staff is examining these statistics to see whether they may be influenced by changes in patient mix. Since the inception of the review program, patients admitted to Mt. Sinai tend to be more seriously ill and have longer expected stays.

Despite the change in length of stay, the occupancy rate at Mt. Sinai has not declined, even though it is located in an area which is overbedded. Since it is a relatively high-cost facility, a shift of patients from a low-cost facility to Mt. Sinai could mean a smaller amount of savings for the community than for Mt. Sinai alone, assuming the same patient outcome. For the community as a whole, therefore, the reduction in average length of stay at Mt. Sinai may have been associated with a higher community expenditure for acute hospital care, unless the lower occupancy elsewhere resulted in sufficiently lower total costs.

Adequate information for evaluating the impact of the Multnomah Foundation for Medical Care on hospital utilization is not available. [21] Conditional PSRO activities were instituted recently, however, so the absence of information should not necessarily be construed to imply a lack of impact. Given the cost of the Multnomah review, a reduction in average length of stay of 0.6 days, or a six percent reduction in a 9.4 average length of stay per admission (assuming per diem of $150 and variable expenses of 20 percent) would be required to break even, assuming no cost for alternate care.

Using trend analysis, staff at the Colorado Foundation for Medical Care has estimated a total cost avoidance during 1974 of $9.1 million, using full per diem rates to evaluate each bed day saved. This gross figure compares with an approximate review cost of $1.8 million. The Medicaid trend is based on data from two years; the Medicare trend, on three years. No rationale is provided for the trends observed.

The reasons for the claimed savings are unclear. Average length of stay for Colorado does not appear to have declined significantly. Admissions could have been deterred, but available data are insufficient to establish the extent to which this may have occurred. Except for increases in 1972 and 1973, Medicare admissions have been declining for some years. Data are not available for 1975 or 1976. Additional information on the source of the reduction in bed days of about nine percent in one year would help to justify the estimates and evaluate the savings.

The CFMC assumption that the total per diem will be saved for each bed day avoided is not valid. At most, only variable costs are saved. Firm estimates of fixed and variable costs for Colorado do not exist. If 20 percent of costs

were variable, the value of bed days saved (as estimated by CFMC) would about equal the amount of CFMC administrative costs. To the extent that savings are related to claimed reductions in admissions, the cost of alternate care becomes an important factor in an estimate of savings. After adjustment for alternate care, the cost comparisons would not be favorable. Over the longer term, if 40 percent of costs were variable, the cost of alternate care might still eliminate much of the savings. Without additional information, there is insufficient basis for concluding that the CFMC utilization review is cost effective.

The Utah Professional Review Organization stresses the quality improvement orientation of its hospital review activities. It has not provided data to evaluate changes in utilization or costs. Data are available from the Social Security Administration that describe the use of services by Utah Medicare beneficiaries, however. Using 1972 as the base year, if the total decline in average length of stay for Utah Medicare beneficiaries were exclusively due to the UPRO program, savings might be equal to cost, without adjustment for the cost of alternate care. [22] If a more recent year were used as a base, estimated savings would be less. Moreover, declines in average length of stay were reported for Utah before the 1972 advent of concurrent review in a few hospitals and for hospitals elsewhere in the country without a comparable concurrent review program. The Utah State Department of Health believes that its prior authorization program has helped to control utilization by Medicaid patients, but this opinion is not shared by UPRO staff.

Bonner has evaluated the UPRO concurrent review program with data provided by the Educators Mutual Insurance Association (EMIA). [23] Utilization and expenditure patterns for two groups of EMIA subscribers were compared before and after introduction of the review program. About 86 percent of admissions for subscribers in the Ogden area were to hospitals with the review program. About 94 percent of admissions for subscribers in the Provo area were to hospitals without the concurrent review program.

The analysis indicates no statistically significant evidence of positive impact from concurrent review on utilization as measured by average length of stay, admission rates, or days of care per eligible. Provo area subscribers had significantly higher admission rates in both time periods, but little change between periods, whereas Ogden area subscribers had rising admission rates. Expenditures in the Ogden area were significantly higher than in the Provo area for both ancillary and total charges after introduction of concurrent review. The possible influence of differences in population characteristics on the impact of review is not examined in detail, nor are individual hospital differences. Occupancy rates in two of the non-review hospitals increased considerably during the study period, and the occupancy rate in one review hospital declined greatly. Average length of stay in Utah is already low and further reductions may be difficult to achieve. Nevertheless, cost effectiveness of the Utah concurrent review program has not been demonstrated.

The National Capital Medical Foundation is still in the process of development and has not accumulated sufficient experience to show utilization or cost trends. Nevertheless, of the 32,813 hospital discharges reviewed

between the implementation of the program in the first hospital on September 29, 1975, and August 31, 1976, 355 admissions and continued stays were denied. Of these denials, 245 are attributable to a single hospital, which has participated in the program since December 15, 1975. Foundation officials also report that on any given day, 500 administrative stays can be expected in D. C. hospitals. These are stays in which the patient does not require acute care, but does require intermediate or skilled nursing care. Adequate alternative care is not available in the District of Columbia, so the patient remains hospitalized. Administrative stays comprise approximately one-third of the Title 19, 18, and 5 hospital census and cost about $36.5 million per year. If adequate long-term care is assumed to cost about one-fourth that amount, appropriate placement of those patients would yield about $27 million in gross annual savings. For the short-term, however, hospital administrators in the District of Columbia may lack incentives to pursue this option, since it would lower hospital revenues. The area is overbedded, and the average occupancy rate is about 75-78 percent.

In general, available information does not demonstrate convincingly the cost effectiveness of the concurrent review programs visited. Related literature is similarly pessimistic.

A 1969 study by the Social Security Administration examined the impact of Medicare requirements for certification on the 14th and 21st days of hospital stay, using 1966-67 data, and concluded that more patients were discharged on those days. [24] However, Slee and Cunningham reported in early 1971 that a similar discharge pattern existed for persons of age 65 and over before implementation of Medicare. [25] The effect of certification was reconsidered in 1975, based on certification at the 12th and 18th days. SSA found "no significant difference in the patterns. . . no evidence of minor or secondary peaking on the 12th or 18th day . . . In sum, even though mean length of hospital stay decreased between 1968 and 1971 under Medicare, there is no demonstrable evidence that the physician certification and re-certification regulations influence the distribution of short-stay hospital discharges in that period." [26]

In contrast with SSA's requirement that all diagnoses be re-certified at the same time interval, the Pre-Discharge Utilization Review program (PDUR) sponsored by Blue Cross of Western Pennsylvania specifies re-certification dates on the basis of diagnosis. (Most programs visited and the PSRO requirements also follow this pattern.) The impact of the PDUR program on average length of stay for Medicaid patients with 14 selected diagnoses has recently been evaluated. Both an initial study and a larger replication included experimental and control hospitals matched for geographical location, size, teaching status, and service mix. They produced similar findings. In the replication, no differences resulted in average length of stay which could be attributed to the review program with the exception of maternity cases. The statistical variance in average length of stay also was not reduced. When the data were combined for all diagnoses and crude rates were calculated, average length of stay did decline after the introduction of PDUR. However, the reduction was attributed to the decline in stays for deliveries, rather than for all diagnoses. [27]

These findings raise the possibility that more refined analyses might detect an impact from the review programs visited if data were adjusted for patient and diagnostic mix. Fetter and Riedel are currently analyzing the Colorado data with the Autogroup technique, which categorizes patients into homogeneous groups on the basis of characteristics affecting average length of stay, such as age, sex, diagnoses, and complications. [28] The results may shed light on the potential impact of the Colorado hospital review program and suggest refinements in the review process for other programs as well.

Similarly, it is possible that a more targeted approach to review, concentrating on diagnoses, patients, or providers associated with questionable patterns of care, would increase the effectiveness of quality assurance systems and perhaps be less expensive. Demonstrations of such approaches, using samples of cases rather than a total population, are underway in New Mexico and planned in Oklahoma. [29] These evaluations may lead to greater efficiency and effectiveness of review.

AMBULATORY REVIEW PROGRAMS

Cost data for ambulatory care review programs are even less adequate than those for hospital review. Although comparisons among programs are of questionable value, the data provide examples of the range of costs which might occur if these programs were replicated nationally. Furthermore, they provide a framework against which program effectiveness may be assessed.

The cost of manual review per physician claim ranges from about $1.50 for the San Joaquin Foundation to about $2.50 for the Colorado Foundation's commercial claims review and $4 for the Colorado Foundation's discontinued Medicaid claims review. The latter included only the more complicated cases referred by the intermediary's screen to the foundation for more intensive review and did not involve relative value scale (RVS) adjustment.

The cost of computer review is usually lower than for manual review if the volume of claims is sufficient to justify computer use. Computerized Medicaid claims review in New Mexico costs about $1 per physician claim. [30] The San Joaquin Patterns of Treatment program costs about $1.50 per claim, and the Utah PACE review costs about $1.75 per claim. [31] PACE review does not include RVS adjustment; San Joaquin does; in New Mexico the amount billed is compared with the 50th percentile of billings for a particular procedure by the individual physician and the entire physician community and paid at the lower rate.

Data processing expenses are not the major portion of cost. Economies are probably determined by many factors including the volume of claims, the quality of claims data, efficiencies of support personnel and the sorting routines, exception rates (the number of claims identified for more intensive, usually peer, review as a percentage of the total number of claims), and the frequency with which exceptions are reviewed (since special comparative tabulations must be compiled).

Exception rates range from a low of five percent for both Colorado ambulatory reviews to a high of 25 to 31 percent for the San Joaquin Patterns of Treatment. Variation in exception rates is difficult to interpret, however, without additional information on the extent to which this is an artifact of review criteria or is an accurate indicator of the amount of inappropriate care.

The Colorado Foundation for Medical Care reports that its claims review has an impact on cost and utilization of ambulatory care. Available information on its review for private carriers indicates a favorable benefit-to-cost ratio. For the first nine months of 1976, the total cost of private review was $101,950. The total dollar value of claims reduced was $196,499. Of this amount, $150,086 resulted from RVS adjustment, rather than peer review. Information is not available on the impact of Medicaid review, which has been discontinued.

The San Joaquin Foundation also claimed a substantial change in utilization of ambulatory care. The extent of the effect for all insurance carriers has not been fully documented, but one may assume that the benefits exceed the payments for review. Some data are available from other sources.

Buck's examination of the influence of the San Joaquin Foundation review on physician practice patterns includes some information on the costs of review and resultant savings in the costs of care. Between February 1968 and May 1971, adjustments to Medi-Cal billings totaled $1,401,522. Cost of review for that period is estimated to be $195,605 although this figure is known to under-estimate actual costs. Nevertheless, the savings were more than adequate to offset costs. Of the total adjustments to billings, $1,198,739 were made by claims examiners, rather than review physicians or the review committee. [32] Buck comments: "The savings listed under claims examiners are partially due to review based on criteria developed by the (foundation), but they often represent routine contract adjustments that would be realized under most claims processing approaches. The . . . savings as a result of physician review would probably not be achievable without some active participation by physicians." [33]

Holahan was unable to detect a significant difference between the impact of the San Joaquin review of Medi-Cal claims and the California Blue Shield review, which does not include a provision for formal peer review. [34] The two review mechanisms were not used simultaneously to monitor utilization in the same area, however, so a controlled comparison was not made.

Brook and Williams report that after a two-year effort, review activities of the New Mexico Foundation decreased injections "by an estimated 60 percent by modifying physician behavior through educational and direct sanction activities. Many adverse reactions due either to administration of the injections (e.g., abscesses, nerve damage, or hemorrhage from a vessel) or to specific side effects of the particular drug (death, disability) were most likely prevented." [35]

In addition to denials for injections, $43,000 appear to have been denied explicitly from physician claims for other medical reasons, and $133,000 for non-medical (administrative) reasons. An additional $19,000 in medical

denials and $84,000 in administrative denials are thought to have resulted from claims for physician services, but may have come from other providers. If these savings are added to the $107,000 from denied payments for injections and an estimated $160,000 from injections deterred, total savings would be $546,000. This compares favorably with an estimated cost of ambulatory physician claims review of about $340,000, which may include some developmental costs. [36] The authors note that injections received primary attention from the ambulatory review process during the first two years. However, they believe that "services rendered for many . . . ambulatory conditions are clearly candidates for more peer review (using) explicit process criteria . . . selected on the basis of their a priori relationship to health status." [37]

Limited information is available to describe the impact of the Utah PACE program for ambulatory care reivew. During the first quarter of 1975, 27 physicians with exceptional patterns of care received letters questioning their treatment methods. They accounted for 311 exceptions. Sixty-seven exceptions were noted for the same physicians during the first quarter of 1976. Information on improvements in specific exception rates is available, which expresses the change as the percent of deviant practice corrected. This method tends to overstate the extent of improvement. Nine physicians who received letters discussing inappropriate injection of antibiotics decreased their exception rates by 51 percent in 1976; inappropriate injection of ACTH (four physicians) decreased 25 percent; inappropriate injection of steriods (two physicians) decreased 19 percent; excessive urinalyses (two physicians) decreased 90 percent; and inappropriate injection of estrogen (four physicians) and vitamin B-12 (three physicians) and excessive visits (two physicians) were eliminated. Multiple comprehensive exam charges (one physician) increased by 11 percent. In each year, the majority of exceptions were accounted for by a few physicians. Between January and June 1, 1976, eight additional physicians received letters, and one physician was informed that further services which violate review guidelines will not be paid. [38]

The project manager expects that PACE will "produce savings by supplanting State utilization and quality review efforts in ambulatory care and by catalyzing an alteration of practice patterns regarding the utilization of injections, visits, certain common lab and x-ray procedures, and drugs. The capability of PACE to identify any provider whose practice consistently results in unnecessary expense to Medicaid has been demonstrated." [39] PACE has also helped to identify cases of abuse by patients. As of June 1976, "24 cases involving potentially serious patient abuse had been reported to the State." Of these, two or three involved criminal activity. For many of the cases, "the State is attempting to limit the patient to a single primary care provider of the patient's choosing." [40]

An examination of such a limited number of ambulatory quality assurance programs cannot be considered a conclusive study. However, where common data elements are available, the findings are surprisingly consistent. The dollar reductions in submitted claims are more than adequate to pay the costs of review. Thus, review has been demonstrated to be cost effective for the

fiscal intermediary, but not necessarily for society. Greater uncertainty exists when the effectiveness of the medical peer review component of such programs is examined separately from the administrative or non-medical review component.

SUMMARY

In this chapter the effectiveness of health care quality assurance programs was considered. The discussion of the difficulties of measuring impact and, in particular, the limitations of the data gathered during this study should not be overlooked. When cost data are available, they are usually underestimates. Claimed benefits are usually over-estimates. The information is not adequate to provide a definitive assessment of the effectiveness of quality assurance programs. However, it can illuminate current trends and raise questions for further research and evaluation.

The impact of review on the quality of medical care and health status is by far the most difficult to assess. Real improvements in quality were detected--for example, the identification of previously unknown cases of hypertension. But relating such an improvement to the total magnitude of quality assurance activities and determining whether the results justify the resource expenditures is extremely complex.

An assessment of the medical care evaluation or medical audit portions of hospital review programs is particularly difficult for this reason. Although accomplishments were noted, program officials expressed serious reservations about the value of traditional medical audit. Some are involved in innovative attempts to devise more meaningful MCEs. Despite the widespread performance of medical audits to meet the accreditation and reimbursement requirements, there are no methods for accumulating information on both successful and unsuccessful MCEs, assigning values to the data, and aggregating them in a manner which would permit an overall assessment of effectiveness. The Joint Commission on the Accreditation of Hospitals plans to issue a report on the efficiency and effectiveness of medical audits early in 1977. Similarly, the the Bureau of Quality Assurance has awarded at least one contract to explore these issues. Thus, better information should be forthcoming. At this time, however, the general effectiveness of medical care evaluation studies has not been shown.

Somewhat better information is available to describe the impact of the concurrent review portions of hospital review programs. Program costs vary widely. Of the programs visited, the costs of internal hospital systems are usually lower than those associated with PSROs--apparently because the hospitals assign more patients to a single nurse coordinator and their administrative and indirect costs are lower. In both hospitals and PSROs, the claims for savings are over-estimated, because they erroneously assume that the total per diem cost will be saved for each day denied and are not properly adjusted for variable costs and the cost of alternate care. Of the three hospitals visited, only one has a review program which is clearly cost effective, although all three have experienced changes in admission rates and lengths of stay. Of the PSROs, only one has claimed significant savings,

and data are not available to accurately explain this phenomenon. In general, evidence is not yet available to conclude that hospital concurrent review programs are effective.

The ambulatory claims review programs for which data are available have shown that dollar reductions in claims considerably exceed the cost of review. Although these programs may be cost effective for the fiscal intermediary, the burden of paying for denied claims may fall later upon the patient, other fiscal intermediaries, or society. When there are savings, they tend to come from routine adjustments that would be realized under most claims review systems, which are unrelated to considerations of either appropriateness or quality of care. The additional benefit which results from the peer review, qualitative component of the ambulatory review systems is not known.

If the current cost of review per discharge for Medicare and Medicaid were projected to all federal beneficiaries, current federal expenditures for hospital quality assurance activities would be about $200,000,000. If the anticipated level for fiscal year 1977 were projected to a national total, this would be $275,000,000. Although the amount includes some developmental costs, the budget could well become institutionalized at that level. Another $250,000,000 probably would be added to monitor the ambulatory care received by federal beneficiaries. This is based on the lower end of the cost spectrum observed for current patterns of review for Medicare and Medicaid patients. If the same data are used to estimate the cost of review for the total population, expenditures could reach $750,000,000 for ambulatory review and $500,000,000 for hospital review, or a total of $1,250,000,000. Although the sums are significant, the returns from those expenditures are by no means certain.

STEERING COMMITTEE RECOMMENDATIONS

1. Intensified efforts should be mounted immediately to evaluate systematically both federal and privately sponsored health care quality assurance systems, using careful evaluative designs and incorporating control areas whenever possible. The choice of review mechanisms for evaluation should not be left to chance, but should be explicitly planned in advance to consider a range of alternative approaches. A long-term prospective evaluation strategy is needed, since any major changes in provider and patient behavior may be expected to require a long time to emerge and become internalized.

2. Related research is needed to develop better evaluative measures. In particular, improved methods are needed to identify and aggregate the effects on health status which result from the provision of medical care. Summary measures are needed to assess improvements which stem from quality assurance programs, continuing education, and other activities designed to improve the quality of care and, ultimately, to elevate the health status of the population.

3. Criteria should be developed for categorizing successful and unsuccessful medical care evaluation studies and isolating factors associated with success,

so that more effective MCEs may evolve. This will require the resolution of an apparent dilemma. The success of MCEs has been said to rest on medical staff involvement in selecting topics, establishing criteria, and reviewing the results. Yet, without the involvement of an external monitor, such efforts are potentially self-serving. Experimentation with a mixture of internally and externally initiated MCEs may result in an optimal balance. A wide range of innovation and evaluation should be encouraged.

4. More refined techniques are needed to determine the impact of quality assurance programs on utilization and cost of medical care. Adjustments should be made for patient, provider, and facility mix; and community-based measures of effectiveness, including the costs of alternative care, should be used whenever possible. Additional research is needed to determine the conditions under which hospital costs vary according to occupancy rate in both short and long-term situations. The influence of cost-plus reimbursement policies deserve special attention. Adjustments for variable costs and the cost of alternative care should be included in estimates of cost savings resulting from utilization review.

5. The wide variation in the costs of both ambulatory and hospital quality assurance programs should be further explored to determine whether cheaper, but equally effective review mechanisms can be developed. With more extensive information to describe profiles or patterns of care, it may be possible to identify specific diseases, conditions, providers, or patients associated with inappropriate patterns of care. A targeted review could then focus on those cases, rather than on the total spectrum of care. This should result in more frequent identification of inappropriate cases and less frequent review of appropriate cases, which should increase the efficiency of review. However, cases which are excused from routine review should be monitored periodically to assure that more frequent review is not warranted. Evaluation of the effects of targeted review must be based on carefully coded diagnostic data with appropriate adjustment for factors influencing treatment requirements and lengths of stay.

6. Until more extensive knowledge of the efficacy of medical treatment accumulates, it may be desirable to devise separate methods for cost and quality control in the few areas where desired practice patterns are known. For the remaining spectrum of health care, the lack of unanimity regarding optimal treatment patterns may prevent the development of national standards. One would then expect considerable variation in local criteria and practice and little specific behavior change, which would be accepted on the assumption that greater involvement in and sensitivity to quality issues at the local level will raise the level of care for all conditions over time.

FOOTNOTES

Chapter 4

1 U.S. Congress, House of Representatives, Social Security Amendments of 1972, Pub. L. 92-603, 92d Cong, 2d sess., 1972, H.R.1.

2 Alan R. Nelson, "Quality Assessment and Utilization Review in a Functioning Peer Review System," 19 September 1975, p. 10. (Mimeographed.)

3 David Bailey and Donald Riedel, "Recertification and Length of Stay: The Impact of New Jersey's AID Program on Patterns of Hospital Care," Blue Cross Reports 6 (July 1968): 1-10.

4 Reported at the Department of Health, Education, and Welfare, National Center for Health Services Research, Seminar in December 1975; see also U.S. Department of Health, Education, and Welfare, Public Health Service, Federal Employees Health Benefits Program--Utilization Study, by Donald Riedel et al., January 1975. DHEW Pub. No. (HRA) 75-3125, Rockville, Maryland.

5 Gerald Perkoff, Lawrence Kahn, and Phillip Haas, "The Effects of an Experimental Prepaid Group Practice on Medical Care Utilization and Cost," Medical Care 14 (May 1976): 432-49.

6 Joseph Lipscomb, Ira Raskin, and Joseph Eichenholz, "The Use of Marginal Cost Estimates in Hospital Cost Containment Policy," Milbank Memorial Fund Quarterly, forthcoming.

7 U.S. Department of Health, Education, and Welfare, Office of the Assistant Secretary for Health, Office of Professional Standards Review, Program Evaluation Plan: Professional Standards Review Organizations, by Martin Baum et al., (22 September 1975), p 37.

8
The term medical care evaluation study (MCE) is used interchangeably with medical audit.

9
Charles Buck, "Peer Review: The Impact of a System Based on Billing Claims," (Sc.D. dissertation, The Johns Hopkins University, 1972), p. 92. See also Charles Buck and Kerr White, "Peer Review: Impact of a System Based on Billing Claims," New England Journal of Medicine 291 (24 October 1974): 877-83.

10
Daniel Fleischer et al., "The Mandate Project: Institutionalizing a System of Patient Care Quality Assurance," n.d. (Mimeographed.)

11
The bi-cycle concept is an approach to medical audit which includes a program of change to correct identified deficiencies and subsequent re-assessment to determine the amount of improvement. This approach is incorporated in the PSRO and JCAH MCE requirements. It is further described in: Clement Brown, Jr. and Henry Uhl, "Mandatory Continuing Education, Sense or Nonsense?", Journal of the American Medical Association 213 (7 September 1970): 1660-68.

12
Hospital Research and Educational Trust, American Hospital Association, "Final Report on the Quality Assurance Program Demonstration Project" to the W. K. Kellogg Foundation, Chicago, 1975, p. 11.

13
Ibid., pp. 34-42.

14
Department of Health, Education, and Welfare, Minutes of Meeting of the National Professional Standards Review Council, 3-4 May 1976, comments by John Porterfield.

15
John Porterfield, Joint Commission of Accreditation of Hospitals, Chicago, telephone conversation, 23 July 1976.

16
California Committee on Regional Medical Programs, "Summary Report on Evaluation of the Implementation of CMA/CHA Patient Care Audit in California Hospitals," April 1975. (Mimeographed.)

17
For consistency, cost figures for Utah and Colorado were taken from Bureau of Quality Assurance forms 121 and 151, and indirect costs were redistributed. Staff of the Colorado Foundation state that this figure over-estimates the per admission cost because the CFMC-PSRO information system does not capture data on patients who are admitted in one quarter and discharged in the next quarter. This discrepancy may exist elsewhere, as well.

18
David A. Stewart, Assistant Executive Director, Multnomah Foundation for Medical Care, personal letter, 26 April 1976. BQA figures comparable to those for Utah and Colorado could not be derived because of difficulty in capturing costs for delegated, non-delegated, and potentially delegated hospitals.

19
U.S. Department of Health, Education, and Welfare, Social Security Administration, Office of Research and Statistics, MADOC-4 (July-December 1970) and MADOC-5 (July-December 1971).

20
U.S. Department of Health, Education, and Welfare, Social Security Administration, Office of Research and Statistics, preliminary data from MEDPAR-1 (fiscal year 1974) not yet released.

21
Some utilization data from the Multnomah Foundation was received on September 28, 1976. However, it was not possible to analyze the information adequately and explain the inconsistencies in time to include the data in this report.

22
Idem, Current Utilization Tabulations of Length of Stay Based on 20% of Medicare Discharges, for six-month periods (tabulations used for internal SSA purposes).

23
Paul Bonner, "On-site Concurrent Hospital Utilization Review: An Evaluation of Impact on Utilization Patterns and Expenditures," (Sc.D. dissertation, Harvard School of Public Health, February 1976).

24
U.S. Department of Health, Education, and Welfare, Social Security Administration, Office of Research and Statistics, Use of Hospital Services Under Medicare: Length of Stay of Patients Discharged from Short-Stay Hospitals, July 1966-1967, by Aaron Krute, Health Insurance Statistics Report No. HI-10 (30 January 1969).

25
U.S. Department of Health, Education, and Welfare, Social Security Administration, Office of Research and Statistics, Utilization of Short-Stay Hospitals Under Medicare, 1968-1971, by George Chulis, DHEW Pubn. No. (SSA) 75-11702 (1975), citing Vergil Slee and Raymond Cunningham, "Discharge Patterns for Patients 65 and Older: Pre- and Post-Medicare," PAS Reporter 9 (25 January 1971).

26
Idem, p. 8.

27
M. Karlene Clendenning et al., "The Effect of a Target-Based Utilization Review Program on Length of Stay," Medical Care, forthcoming.

28
Donald Riedel, "Implementation, Evaluation, and Extension of Patient Care Monitoring Mechanism," Grant #240-75-0051, DHEW, PHS, Bureau of Quality Assurance, in progress.

29
"Oklahoma Utilization Review System Proposal," Office of Quality Standards, DHEW, to begin shortly. See also, Health Care Management Systems, Evaluation Report: New Mexico PSRO Revised Medicaid Ambulatory Care Review System, La Jolla, California, (August 1976).

30
The estimate of $1 per physician claim was derived from information reported in Robert Brook and Kathleen Williams, "Evaluation of the New Mexico Peer Review System 1971-1973," Medical Care, forthcoming.

31
Additional PACE cost information was received after the termination of this contract. It was not possible to analyze this material in time to include it in this report, but an attempt will be made to include it in the forthcoming paper on cost and cost effectiveness of health care quality assurance programs. To obtain the more recent information the reader is referred directly to the Utah Professional Review Organization.

32
Buck, "Peer Review," pp. 89-91.

33
Ibid., p. 92.

34
John Holahan, Physician Supply, Peer Review, and Use of Health Services in Medicaid (Washington, D.C.: Urban Institute (February 1976), pp. 63-64.

35
Brook and Williams, "New Mexico Peer Review," p. 102 of manuscript.

36
Ibid. The cost figures are taken directly or derived from the manuscript as follows: $43,000 (derived) in explicit denials of physician claims for medical reasons (p. 41); $133,000 (derived) for administrative denials (p. 63); $19,000 (derived) and $84,000 (derived) in claims from physicians or other providers (p. 63); $107,000 from injections denied (p. 71); $160,000 from injections deterred (p. 90); and $340,000 (derived) estimated cost of review (p. 103 and p. 211).

37
Ibid., p. 222.

38
James Q. Cannon, PACE Project Manager, personal letter, 28 June 1976.

39
Idem, personal letter, 2 April 1976.

40
Idem, personal letter, 28 June 1976.

Chapter 5

PRIORITY AREAS FOR QUALITY ASSURANCE

Several topics were defined as priority areas because of their crucial role in determining the effectiveness of quality assurance programs and the absence of reviews that integrate and analyze relevant literature. The conclusions and recommendations of the steering committee for five areas are presented in this chapter.

The areas overlap somewhat. In particular, outcome-oriented quality assurance programs are difficult to examine separately from the health care settings in which they are found. For that reason a separate paper was not prepared, and the discussions of quality assurance for ambulatory and long-term care include examples of outcome assessment. The conclusions and recommendations for outcome assessments are below, preceding the summaries of ambulatory and long-term care quality assessment. The chapter concludes with a summary of the implications of quality assessment for improving provider performance and a discussion of consumer involvement in quality assurance programs.

ASSESSMENT OF HEALTH OUTCOMES

The term "health outcome" usually refers to the end results of medical care measured by health status and patient satisfaction. [1] The assessment of health outcome as an indicator of the quality of care was advocated by Florence Nightengale in the mid-1800s, [2] and more recently by the U.S. Congress, which included in the Health Maintenance Organization Act of 1973 the requirement that each participating HMO provide "an ongoing quality assurance program for its health services which . . . stresses health outcomes."[3]

Outcome assessment is appealing, since the practice of medicine is based on the assumption that treatment benefits the patient. Furthermore, as concerns for the cost of care mount, health outcomes may increasingly be used to measure the return on the investment in medical care. Examples of the routine assessment of health outcome as an indicator of quality are somewhat limited, however.

Data on mortality and morbidity gathered by the U.S. Census Bureau and the National Center for Health Statistics show regional and national trends and are useful for disease surveillance. However, the time lag between the receipt of care and the reflection of changes in morbidity or mortality statistics may be substantial. In addition, the data are usually aggregated in a manner which makes it difficult to identify specific patient or provider groups associated with unusual trends who could benefit from a case-by-case quality assessment. Both factors limit the utility of national mortality and morbidity data for an ongoing quality assurance system as envisioned by this study.

Information on the incidence and outcome of some specific diseases (particularly malignancies and other catastrophic conditions such as end-stage renal disease) is captured on a case-by-case basis by disease registries, which may also include information on the treatment process. Registries are usually designed for epidemiologic research, however, rather than quality assurance activities, and are probably too expensive for routine use in quality assurance.

Despite the limitations of the more readily available mortality and morbidity data, in some cases they have been used successfully in quality assessments. Shapiro compared prematurity and perinatal mortality rates for women enrolled in the Health Insurance Plan of New York City (HIP) and women in the general population, using data on live births and fetal and infant deaths from the New York City Department of Health. [4] Kessner has applied the same data base more recently in his study of infant deaths in relation to the need for and receipt of health services by pregnant women in New York City. [5] Hospital discharge abstracts processed by the Commission on Professional and Hospital Activities' Professional Activity Study (PAS) have been used to compare surgical mortality rates in 1,224 hospitals included in the "Institutional Differences Study" conducted by the Stanford Center for Health Care Research. [6]

One problem, however, is the difficulty of controlling for the many factors which influence outcome, including the patient's general health, demographic characteristics, social and economic factors, and structural aspects of the health care setting. These factors are particularly important if one plans to use unacceptable outcomes to identify specific deficiencies in the process of care. Shapiro has written of the complexities of designing and analyzing end-result studies. [7] The importance of controlling for patient characteristics and surgical procedures in the Institutional Differences study is discussed by Moses and Mosteller. [8] Mushlin et al. studied outcomes for patients with upper respiratory infection, sore throat, and urinary tract infection and found that one reason for failure to achieve anticipated outcome was the presence of complicating factors related to the patient, including past history and comorbidity. [9] More recently, Romm et al. have reported that the most significant predictor of outcome status for patients with congestive heart failure is "the patient's initial status" and that "certain aspects of the process of care have little measurable impact." [10]

Shorter term, intermediate or proximate outcomes, each of which results from a previous step in the diagnostic and treatment process, can be derived from

Williamson's definition of health outcome: "... any characteristic of the patient, the health problem, the provider, or their interaction in the care process which results from medical care provided or required, measured at one point in time." [11] The JCAH requirements for medical audit, in particular, incorporate an assessment of proximate outcomes, generally defined as complications in hospitalized patients or performance of critical therapeutic procedures, which are regarded as outcomes of the diagnostic decision-making process. [12] If surgical procedures are considered outcomes of clinical decisions, Lembcke's studies of variations in appendectomy and hysterectomy rates would fall into this category. [13] Similarly, Starfield and Scheff assessed the proximate outcome of hemoglobin level in children in a hospital clinic. [14]

Proximate outcomes can be measured while the patient is receiving treatment or shortly thereafter and do not have the problems associated with longer range outcomes--the passage of time which makes it difficult to identify factors that cause particular outcomes and the time and expense necessary to locate patients and their medical records. Proximate outcomes usually do not project far enough into the future to permit direct assessment of the end-results of treatment as determined by health status and ability to function. Ideally, however, final outcome is correlated with proximate measures such as whether an appendix was perforated at the time of surgery, the APGAR score of an infant, lead level in children, and blood pressure.

Some research and demonstration projects have attempted to design and evaluate quality assurance programs which incorporate outcome assessments. Williamson's earlier work has evolved into "health accounting," which is designed to achieve and document improved patient health or reduced resource utilization. In implementing health accounting, a clinic priority team selects study topics based on prevalent health problems for which outcomes could be improved. The objective is to maximize the achievable benefit not achieved (ABNA). A study design team estimates impairment levels which should be expected in patients with the study conditions, depending on the extent of treatment and varying patient prognoses, and develops a plan for the study. A health accountant gathers and arrays data to compare estimated and actual outcome. The analysis includes an assessment of diagnostic outcome (considering both false negative and false positive diagnoses) and therapeutic outcome (measured on a six-point functional assessment scale). [15] Examples of health accounting have been described in the literature, [16] and a major demonstration is under way.

Kessner's "tracer" method is another which assesses quality by examining health outcomes. [17] As orginally conceived, the tracer method viewed the prevalence of specified diseases or conditions (detected by physical exam) within a defined community as an outcome of health care. Initially, it was assumed that the quality of care for tracers would be representative of the overall quality of care delivered by an individual provider or health care organization.

The health accounting and tracer methods are conceptually appealing, since they are based on an epidemiologic approach. However, recent attempts to apply them have led to questions about some basic assumptions. [18] The

demand on resources (particularly for more highly trained personnel than initially acticipated), the inadquacy of medical documentation, and limited generalizability of findings suggest that the techniques may be appropriate for special studies. However, additional refinements are needed before they could be instituted as routine quality monitoring systems--particularly in small, fee-for-service office practice.

The work cited above suggests that in the near future, it is unlikely that comprehensive outcome assessments will be included in formal quality assurance programs. This may change as a result of some ongoing and recently completed research. In one portion of the Institutional Differences Study, routinely gathered information on the PAS abstract formed the basis for sophisticated statistical estimates of the risk of death for each patient; the estimates were used to compute indirectly standardized mortality ratios for study hospitals. The authors believe that with refinements, their techniques could be used to develop a system for "computing valid and reliable measures of the quality of surgical care in hospitals . . . that would depend primarily on PAS-like data." [19] Detmer is attempting to correlate process and outcome measures for trauma patients in Wisconsin in hopes of developing proxy outcome measures. [20] Brook et al. recently published explicit, short-term outcome measures developed by expert panels for eight disease conditions. For each condition the report includes a discussion of factors not influenced by medical care that might adversely affect outcome and proposed methods of controlling these factors in analyzing outcome data. The measures have not been tested, however. [21]

It will be some time before the results of these efforts can be easily applied in a variety of health care settings. Nevertheless, it is possible to begin immediately to assess the quality of care on the basis of outcomes if simpler, but nevertheless meaningful, steps are taken.

STEERING COMMITTEE RECOMMENDATIONS

1. Existing techniques to monitor the progress of patients over time should be used in quality assessment programs. Most have been developed primarily for chronic diseases and have not been widely applied in quality assurance, but their potential is readily apparent. Several instruments have been developed to measure the patient's ability to function in daily life. [22] These may be viewed as outcome measures which do not have the limitations of mortality and morbidity statistics. Some have been evaluated to determine reliability, required resources, and associated costs. Similarly, increasing emphasis is being placed on describing the natural history of disease, specific stages of the disease process, and expected levels of functioning at each point along the spectrum. [23] Both bodies of information should be incorporated into ongoing quality assurance programs as a guide to plan for health care needs and to determine the extent to which each patient's functional ability is in accord with expectations.

2. In the same way that process measures of quality are required of PSROs, limited outcome information after discharge should also be gathered for

special studies. The cost of these studies should be carefully monitored to assure that the benefits outweigh the costs. Outcome information might identify patients and providers for more in-depth assessment. Variations in outcome using different treatment methods may identify areas for efficacy studies. The accumulated data should lead to a better understanding of the natural course of illness. Eventually, sufficient knowledge should be accumulated so that if patients of a particular provider have not progressed as expected, the provider's treatment methods could be questioned or the patient referred elsewhere for evaluation and consultation.

3. Assessment after discharge should be required for all patients and all facilities, not just federally reimbursed patients.

4. Individual practitioners should be encouraged to join with their patients to establish outcome objectives for patient care and examine reasons for failure to meet them.

5. The curricula of health professionals should include course content devoted explicitly to health care evaluation which can be applied throughout their careers.

6. Additional research is needed to establish the natural history of diseases and the efficacy of medical procedures and therapeutic regimens. For research findings to be useful in assessing the quality of care, determinations of efficacy should be made under average as well as ideal treatment situations at various points in time and should include a broad range of outcome measures.

7. Over the long term, medical practice should be re-oriented to emphasize health outcomes. Despite the sometimes questionable relevance of medical education to practice, one of the logical places to begin this re-orientation is in medical school. Medical education is currently oriented toward the technical content of unrelated episodes of illness, rather than toward health throughout a lifetime. Physicians should be educated to have an awareness of the natural course of disease, to view patients at any point in time as being in one particular phase of this natural course, and to plan for care and assess the results of care along this spectrum. They should realize that their responsibility does not end when the patient leaves the office or hospital, but that continued monitoring is necessary and that social, psychological, and environmental factors are as important to the patient's health as biomedical factors. The reward structure of medicine is similarly skewed. Physicians are not usually promoted to department chairmen, elected to offices in medical societies, or reimbursed on the basis of the functional status of their patients. Changes in the incentive structure to appropriately emphasize the health of patients may eventually improve the quality of care.

QUALITY ASSURANCE FOR AMBULATORY CARE

Ambulatory care may be defined as those health services provided to individuals not confined to bed. It is fundamentally different from acute

hospital care, and these differences must be considered in designing ambulatory quality assurance programs. The provision of ambulatory care is complex and diverse, permitting a wide range of discretion on the part of the health care provider. Many different functions are performed under this broad umbrella, each of which may require a different approach to quailty assessment.

Primary care and secondary and tertiary consultations are included within the ambulatory spectrum. Although the functions overlap, primary care, in particular, includes well-patient care; a broad range of ill-defined signs, symptoms, and conditions; care for acute, sometimes self-limiting episodes of illness; and continuing care, including that of patients with common chronic conditions. No existing assessment technique can accommodate this range of functions.

An adequate description of the manner in which ambulatory care is delivered is not available. The studies cited below provide information on patterns of care for the providers evaluated--usually group practices or a limited number of independent practitioners within a geographic area. Many of the studies are outdated. Among the more recent are Payne and Lyons' assessment of ambulatory care in Hawaii, [24] the American Association of Family Physicians-University of North Carolina study of general practitioners in the Fort Wayne area, [25] R. L. Riedel's evaluation of patterns of care in hospital outpatient clinics and private offices in the Greater Hartford and New Haven areas, [26] and the National Ambulatory Medical Care Survey. [27] Nevertheless, without a more comprehensive assessment of existing deficits in care, it is difficult to determine the amount of resources which can justifiably be allocated to quality assurance.

Furthermore, in the absence of convincing evidence of efficacy of treatment or a national reimbursement scheme, it is difficult to know what action is warranted when varying treatment patterns are identified. Patients may seek out physicians whose orientation toward medical intervention is similar to their own. Unless the patient or society suffers, it may be difficult to justify attempts to achieve conformity with whatever may be the usually accepted treatment of choice.

In addition to the physician and patient, other people, organizations, and facilities influence the quality of care and must be included in quality assurance efforts. Of particular importance are the small independent laboratories and radiology services for which quality and quality control are so problemmatic. Although techniques exist that could be used to monitor the quality of services provided by such organizations, they are seldom and non-systematically applied. Problems in the structure of the care setting may influence quality. These include supervision of aides performing such tasks as taking blood pressures, routine re-filling of prescriptions, and poor communication and recording skills which adversely affect both working relationships among office personnel and documentation in the medical record and other data sources. Access to and links among varying levels of care are yet another area for quality assessment.

Important data limitations include the inadequacy of current diagnostic and procedural terminology--particularly for classifying signs and symptoms, difficulties in linkage of information from multiple visits and episodes of illness, uncertainty about the range of information to be included and, in particular, the role of telephone calls and home visits and problems in capturing information from such encounters, difficulty of tracing patients among multiple providers, the cost of correcting data, and unresolved issues about data confidentiality. Considerable resources, primarily time and trained personnel, are necessary to conduct quality assessment in ambulatory settings. As data requirements become more demanding, the skills needed to retrieve data generally increase to a level that few small offices can support.

Despite these difficulties, a substantial body of literature describes activities related to quality assurance in ambulatory care. Existing review techniques seem to be determined by considerations of practicality, resource constraints, and leverage points within the delivery setting, rather than by the unique aspects of ambulatory care.

Many of the early assessments of ambulatory care were conducted in prepaid group practices or neighborhood health centers and concentrated on the process of care with some attention to outcome and structural factors. These studies include a series by Makover, Daily and Morehead within HIP clinics; [28] Shapiro's studies comparing the care received by HIP enrollees with care received by comparable populations in other settings; [29] a nationwide survey of clinical services provided in multi-specialty medical groups; [30] and more recent comparisons of the utilization and quality of services provided under alternative delivery arrangements. [31]

Many are one-time, special studies, but a few have been incorporated into routine quality assurance systems. The Health Insurance Plan of Greater New York, for example, has expanded its earlier efforts into a regular system which examines both process and structure. Charts for review are randomly selected from information provided on encounter forms and laboratory reports. The internal HIP structural evaluation reviews such factors as appointment waiting times and procedures for handling consumer grievances. It is supplemented by an external assessment conducted by the New York City Department of Health. [32]

Morehead's work at HIP has been expanded into a more comprehensive assessment of services provided by community health centers (formerly known as neighborhood health centers and funded originally by the Office of Economic Opportunity). Her methods have been used for comparisons among community health centers [33] and also to compare the centers with other health care providers. [34] Two series of assessment were conducted. The second assessments indicated that 73 percent of the centers showed no improvement in quality scores; ten percent declined; and five percent improved. For those centers in which the scores remained unchanged, the same items received low scores in both assessments. [35]

Some outcome oriented assessment programs have been developed (see the preceding section in this chapter and also Chapter 3). Gonnella, Louis, and McCord have developed the "staging" concept, which assumes that a patient's status at a particular point in time is a reflection of the quality of the care received earlier. [36] They have divided selected diseases into stages to reflect the progression or severity of the condition. The technique has been applied to hospital admissions to compare the quality of ambulatory care before admission for patient populations with different kinds of insurance coverage. It may also be used for a single group of patients to help identify deficiencies in prior care and to assess changes at various points in time. More recent applications have collected information at the ambulatory level, using both chart and encounter form data. Although most applications have been in organized health care programs, the investigators believe it could also be used in small offices. [37]

Most ambulatory care is delivered in small independent offices, in which there are very few quality assurance activities under way. Some special studies have been conducted. Peterson's study of general practice in North Carolina is noteworthy for employing direct observation of physicians at work. [38] Jungfer replicated Peterson's work in Australia, [39] and Clute conducted a similar study in Canada. [40] With these exceptions, direct observation has seldom been used to assess quality, even though it provides an opportunity to evaluate basic skills such as history taking and physical examination, which cannot be assessed from the medical record.

Kroeger's study of the office practice and related professional activities of internists in New York state showed variations in practice patterns, particularly in the use of laboratory procedures. [41] About two-thirds of the physicians kept sufficiently accurate records to be included in the study. The researchers concluded that it is possible for non-physicians to abstract office records which can be used later by physicians to assess the quality of care.

More recently, the American Society of Internal Medicine (ASIM) has developed criteria for assessing the quality of office practice and tested the feasibility of applying those criteria in evaluating the quality of care. [42] Internists from six geographical areas volunteered to participate in the study. The evaluation was based on special encounter forms completed by the physician. The findings show a high level of agreement among the geographic areas on the relative importance of the criteria, but a wide variation among regions in complying with criteria items. Response rates were very low. The ASIM suggests that these scores could have a role in the development of regional ranges of acceptable performance against which the practice of individual physicians could be measured, but the technique needs refinement.

With the exception of these studies, most ambulatory quality assessment of small, independent office practice is part of the claims review process for two reasons: the claim form must be submitted by the physicians to be reimbursed, so failure to complete it is unlikely; and the claims review process is perhaps the only point of leverage over solo practice physicians, with

the possible exception of the very few who may be referred to medical societies or licensing authorities for review of particularly egregious behavior.

Since claims review systems were reviewed in Chapters 3 and 4, they will not be considered here in detail, except to emphasize again the fact that they capture very limited data. Claims review systems can assess the quality of care by uncovering unnecessary injections and inappropropriate prescriptions. They may generate provider and patient profiles to detect over-utilization of services and excessive charges. They may be useful in monitoring speciality consultations, which are essentially episodic. Even in these instances, however, more refined sampling techniques are needed to improve the efficiency of review.

Claims review is not appropriate for monitoring the continuing and coordinating functions of primary care, unless methods are devised to enrich the data base and provide continuity over time.

All systems and approaches to quality assurance described above have been inadequately evaluated. In the future, it will be important to determine the extent to which they encourage permanent change in practice patterns.

STEERING COMMITTEE RECOMMENDATIONS

1. Ambulatory claims review should be more widely implemented in an experimental manner while more appropriate ambulatory quality assurance techniques are being developed. Despite the limitations of claims review, it will permit the detection of the most serious deficiencies. Government agencies and other purchasers of health care should be encouraged to require more stringent claims review by their fiscal intermediaries. Careful evaluation of these programs should be required.

2. Probability sampling techniques should be developed to focus on patients and providers who fall at the extremes of distributions of care patterns and to provide estimates of the broader spectrum of care provided to the total population.

3. Closer monitoring is required of pharmacy services, small clinical laboratories, and freestanding radiological units. Assessment techniques using preidentified specimens and X-rays should be more systematically applied to determine the accuracy of judgments within laboratories and radiology services.

4. Methods for supplementing information captured on the claim form should be developed. The Minimum Ambulatory Care Data Set [43] (see Appendix E) should be the basis on which such work proceeds. It is being tested and the steering committee believes it should be more widely implemented. In addition, the value of diagnostic, patient, and laboratory registries to facilitate problem identification and provide information over time should be explored.

5. Quality assurance procedures for primary ambulatory care should be different from those for secondary and tertiary care and should concentrate on the unique aspects of primary care. Many ambulatory quality assessment programs rely on a diagnostic-specific review of the medical record. Since most primary ambulatory care consists of signs and symptoms which cannot readily be assigned to diagnostic categories, other assessment mechanisms are needed. Some classification schemes which incorporate symptoms languages are already being developed [44] and could form the basis of an experimental quality assurance project. Another approach might focus on the basic skills or tasks which constitute primary ambulatory care, such as the elicitation of signs and symptoms and their history, performance of a physical exam, the synthesis of this information into recommendations for care, and determination of the appropriate point for referral. Techniques appropriate for reviewing acute, self-limiting conditions are probably inappropriate for monitoring continuing care of the chronically ill. Information to reflect the extent to which the practitioner coordinates care provided over a relatively long period of time is seldom found in the medical record, and other recording and assessment methods must be devised.

6. Additional research is needed to document current patterns of ambulatory care, giving special attention to unusual methods of treatment and the opposite extremes of under and over-utilization. The reasons for such variations and their influence on patient outcome should be determined and considered in developing standards for care.

7. Policy mandates with respect to quality assurance should impose comparable levels of stringency on all health care delivery arrangements, even though the manner in which requirements are met may vary. The greater ease of conducting quality assessment activities in larger, formally organized health care programs, such as Health Maintenance Organizations, should not lead to the imposition of more rigorous requirements on such organizations.

8. The ambulatory demonstration projects to be funded by the Bureau of Quality Assurance should assist in developing more effective methods for ambulatory quality assurance. The widest possible range of approaches should be supported, and recipients of awards should not be limited to PSROs.

9. A single approach to quality assurance will not accommodate the diversity of functions and personnel included within the ambulatory care sector. Further research is required before a range of proven alternative methods is available.

QUALITY ASSURANCE FOR LONG-TERM CARE

Long-term care in its broadest sense is both a treatment situation and a living situation. It encompasses those health care and other supportive services provided to individuals with chronic conditions or disabilities, as well as the environments in which they live. It is fundamentally different from acute hospital care, and these differences must be considered in designing quality assurance programs.

Many organizations provide long-term care, including chronic disease hospitals, extended care facilities, specialized rehabilitation facilities, group homes or domiciliary care facilities, home health agencies, day care centers, nursing homes, outpatient clinics, and physicians' offices. However, an accurate count of the number of providers and even the number of patients is not available because of the lack of uniform definitions and data reporting requirements. The average length of stay for a nursing home patient is about two years, [45] which emphasizes the importance of the social and environmental, as well as physiological, aspects of care.

Patients receiving long-term care can be divided into two major groups: those who require long-term care to achieve major rehabilitation goals (usually people recuperating from severe accidents and illnesses for whom care may either prevent further deterioration but bring little improvement, or produce significant improvement and render them more independent); and those for whom no substantial improvement in outcome can be expected, but who need care to be maintained at their present level of function for as long as possible before eventual deterioration and death.

People in the second category, in particular, may have little personal leverage to exert to ensure that they receive quality care. For the most part, they are old, [46] sick, [47] socially isolated, [48] poor, [49] highly medicated [50] and usually depressed. The long-term care environment may be their only environment for the duration of their stay, which is often the remainder of their lives. Deficiencies in medical or nursing care or in housekeeping or dietary services, which perhaps could be tolerated during a brief hospital stay, become intolerable and harmful when they are part of one's daily existence for years. Thus, structural factors, as well as the process and outcome of care, are particularly important in long-term care quality assurance.

In designing appropriate ways to assure quality for such patients, an understanding of the nature of chronic illness is vital. The etiology and pathogenesis of many chronic conditions remain obscure, and many patients, particularly the aged, may have several chronic conditions. Thus, it is often impossible to categorize patients by one aspect of a particular disease process and develop standards and criteria for judging the adequacy of their care. Furthermore, because of the long-term nature of the conditions and the frequent fluctuations in physical and mental conditions, treatment requirements vary. Patients may require differing levels of care within a relatively short time, ranging from intensive hospital care, skilled nursing services, custodial care, or home health services, to periodic office visits. Methods for assessing the quality of care rendered to such patients should include all sources of care and should consider the impact of care on the patient's expected and actual ability to function in daily life.

Several instruments have been developed to assist in classifying patients according to functional abilities. They could be used in any setting to assess appropriateness of placement, as well as the actual rather than expected progression of the patient throughout the course of illness. Some are relatively simple and deal essentially with socio-biological functioning. [51] They include such activities as feeding oneself, continence, transfer,

toileting, dressing, bathing, and walking. Others are broader and include special needs such as medication, diet, or safety supervision, as well as mental status and ability to cope with social situations. [52]

The Collaborative Patient Assessment Instrument (CPAI) was developed jointly by four university research groups and is a multipurpose data set which would permit a variety of assessments. [53] It contains information about patients' sociodemographic characteristics, functional status, impairment, medical status (including risk factor measurements such as smoking), and medically defined conditions. More recent applications have included items on services, medications, and tests received by patients.

Use of a 24-item minimum basic data set was recommended by the Conference on Long-Term Health Care Data. The set contains demographic data, information about the health and functional status of the patient, provider characteristics, and type of service rendered. [54] Some items can be implemented immediately; others need further refinement. The total data set will provide uniform information to assist in health planning and policy decisions, the management of individual facilities, the monitoring of patient care, and related research.

Some assessments of the reliability, validity, and costs of these instruments have been conducted. In general, the simpler instruments are more reliable and less expensive. The more comprehensive instruments, which include an assessment of mental status and social functioning, are less reliable and may require more highly trained personnel to administer them. Nonetheless, the instruments are available. They could be applied in a quality assurance context, but few have been used in that manner.

As an alternative to measuring functional status over time, some assessments have focused on specific occurrences as indicators of the overall quality of care within a facility. Examples include assessments of the prevalence of decubitus ulcers, the incidence of urinary tract infections in catheterized patients, or the use of particular drugs. [55] Although such investigations may be helpful in identifying facilities which need closer review, they do not constitute ongoing quality assurance systems as defined in this study.

A few special research projects have included comprehensive reviews of the quality of long-term care. A study of nursing homes in the Denver area identified deficiencies in medical record documentation, the value of diagnosis as a predictor of patient needs, and the present facility classification system. The need for a reimbursement system based on functional status and service needs was noted. [56] Batelle Institute is assessing the quality of long-term care by studying mental functional status, physical functional status, satisfaction, and morale. The relation between structure, process, and outcome measures of quality will be examined. [57] Williams is assessing the effectiveness of two kinds of patient evaluation and placement techniques: direct evaluation by a physician and public health nurse and evaluation on the basis of written reports. Changes in health and functional status of both institutionalized and non-institutionalized patients will be examined. The costs of alternative long-term care settings, including

home care, will be explored. [58]

Some quality assurance systems have been developed. The JCAH Long-Term Care Audit System [59] is similar to a system proposed by Ainsworth and Boyce, [60] but neither appears to be widely used. The Hospital Utilization Project (HUP) in Pittsburg sponsors an abstracting system for skilled nursing facilities which can be used for both utilization review and medical care evaluation studies. [61] The comprehensive Quality Evaluation System developed by researchers at Rush Presbyterian-St. Luke's Medical Center includes a survey of both facilities and patients. It is being tested for routine use by the Illinois Department of Health. [62] The EMCRO experience in nursing home review has been summarized by Arthur D. Little, Inc. [63]

PSRO guidelines for long-term care review have only recently been considered by the National Professional Standards Review Council and have not been implemented. They appear to specify a model similar to the PSRO hospital review of acute care, with a few exceptions. [64] A multidisciplinary group of providers is to be involved in all phases of long-term care review, which is a departure from the physician domination of acute care review. Preadmission certification is required. Additional requirements are an examination of the extent to which services provided meet the individual patient's needs and at least one bedside review of the patient each year. Whether these review requirements are adequate and appropriate to ensure quality for long-term care should be carefully evaluated.

The quality of non-institutional care for the chronically ill has not been extensively considered except in the context of more general quality assurance programs for ambulatory care. Katz has studied patients released from a chronic disease rehabilitation hospital to determine whether home-bound patients are more likely to maintain or increase physical, psychological, and social function with or without the supervision of a public health nurse. [65] HUP formerly sponsored an abstracting system for home health agencies which has been discontinued--reportedly because of the lack of comparable data. [66] More recently, the National League for Nursing is revising a statistical reporting manual for public health nurse, which is similar to a minimum data set. [67] Interest in assessing the quality of home health services is growing.

Except for the Medicare and Medicaid utilization review requirements, the primary continuing review of long-term care is the structural assessment which is part of the facility licensing and certification process and is assumed to influence the safety and quality of patient care. Examples of items for assessment include the presence of automatic sprinkler protection against fires, precautions so that doors to hazardous areas are not held open automatically, and specifications about the numbers, training, and supervision of personnel. These requirements are limited and evidence shows that they are not uniformly enforced.

A GAO study concluded that despite required ratios of staff to patients and inspection programs to enforce them, numerous nursing homes in the study sample violated these requirements. [68] Failure to meet the

required number of physician visits has been documented. [69] A DHEW report indicated failure to comply with fire safety regulations and concluded that only 6.1 percent of the long-term care facilities in a national sample met all requirements of the 1967 Life Safety Code. [70] Errors in prescribing and administering drugs have been documented. [71] There are shortages of therapy personnel and services. [72] Most nursing care is provided by unskilled, unlicensed, and low paid personnel. [73] The high turnover rate of staff is also a problem.

The importance of government financing in the provision of long-term care services is increasing. Medicaid supports over 50 percent of the nation's nursing home bill. [75] Reimbursement programs could provide a lever to improve both the adequacy of facilities and the quality of care. Part of the reason this has not been done, however, may be that strict enforcement of facility standards would mean the closing of some marginal facilities. There may be no other source of care for the residents of those facilities, and thus, inspectors are reluctant to close them.

Current reimbursement mechanisms contribute to inappropriate care. By requiring certain progressions of care (requiring a hospital stay in order to be eligible for lower levels) and designing the reimbursement to match the facility rather than the patient, reimbursement mechanisms destroy the continuity of care and lower the quality of life.

The difficulties in providing long-term care of high quality should not imply that all facilities fail. Indeed, many innovative centers serve as models which should be emulated. However, the current status of long-term care is described by documented examples of inferior quality, the failure to apply appropriate existing quality assessment techniques, the application of assessment techniques which may be inappropriate or inadequately enforced, reimbursement mechanisms which contribute to these problems, and the absence of funding to bring about improvement in the near future.

STEERING COMMITTEE RECOMMENDATIONS

1. Quality assurance programs for long-term care should be designed to address the unique needs of the chronically ill. The etiology of many chronic conditions remains obscure, and many individuals, particularly the aged, have several chronic conditions. An assessment of quality based on diagnostic-specific criteria is often inappropriate, and functional status is a more relevant measure. Furthermore, because of the long-term nature of the patient's condition and frequent fluctuations in physical and mental states, treatment requirements vary. Patients may require differing levels of care within a short time, ranging from intensive hospital care, skilled nursing services, custodial care, or home health services, to periodic office visits. Methods for assessing the quality of care rendered to such patients should include all sources of care and should consider the effect of care on the patient's expected and actual ability to function in daily life.

2. The responsibility for quality assurance in long-term care belongs at the community level. Anything less will be based on evaluation of care from the fragmented view of individual facilities or programs and will perpetuate the inefficient and costly services which currently exist. Steps should be taken to develop community-level organizations to include a broad range of providers, facilities, professional groups, consumers, and representatives from planning and certifying agencies. The community organization should consider such issues as access to care, appropriateness of placement, scope of available services, the structural characteristics of services, and the accumulation of uniform data to both plan for and assess long-term care services. Assessment of the technical components of care could be delegated to PSROs and other groups of health care providers.

3. Demonstrations to test the feasibility of a community approach in terms of both cost and effectiveness should be initiated. Evaluations should occur after prototype organizations have passed the developmental phase.

4. The uniform data elements and common language for reporting on long-term care services proposed by the Conference on Long-Term Health Care Data should be required nationally (see Appendix E). [76] Most items can be implemented immediately, but further work is required to define mental functioning, social functioning, certain aspects of physical functioning, and the events or reasons for use of services other than diagnoses. These data will not only facilitate the development of long-term care quality assurance, but will assist in patient care, program planning and evaluation, and policymaking.

5. The data set should be required in all records and reporting systems of programs serving long-term care patients under Titles 18, 19, and 20 of the Social Security Act. Patient assessment based on these data should be required at successive intervals.

6. State and federal reimbursement policies for long-term care should be reformed. State and federal regulations for reimbursement and accounting should be made compatible and redesigned to enhance their influence on the quality of care. The levels of reimbursement should not be so inadequate as to lead to poor quality. Topics for experimental reimbursement projects might include capitation, which would permit the individual to move from one level of care to another without being penalized. Another option is to establish the reimbursement rate for a specific facility on the basis of its usual mix of patients and then permit patients to be moved from one level to another depending on their conditions.

7. The certification and licensure process for long-term care providers should be reconsidered. The Department of Health, Education, and Welfare study, scheduled to begin in April of 1977, should go beyond a review of existing structural standards to address more fundamental issues of quality and analyze the financial and other ramifications of forced compliance with standards.

8. Support of existing programs to train personnel to work in long-term care should be continued and expanded. Program content should focus on the unique characteristics of long-term care, the multiplity of skills required to meet patient needs, the necessity of a team approach, and an appreciation of the contributions of all health professionals in providing high quality care.

9. The long-term care quality assurance demonstrations to be funded by the Bureau of Quality Assurance should include a variety of alternative approaches to review and should not be limited to PSROs. More basic research is also required.

10. Existing standards to protect the residents of long-term care facilities should be enforced while improved mechanisms for assessing the quality of long-term care are evolving.

QUALITY ASSURANCE AND IMPLICATIONS FOR PROVIDER PERFORMANCE

Health care quality assurance programs are generally based on two assumptions: first, that quality can be defined and measured; and second, that when inappropriate care is detected, specific actions can be taken to correct the deficiency and ultimately improve the quality of care. The experiences of operating quality assurance programs lead one to question these assumptions, however.

Correcting inadequacies in the patient care process is one of the major difficulties encountered by review programs, particularly when deficiencies relate to the clinical decision-making process, rather than simply a decision to admit or discharge a patient from the hospital.

In part, the difficulty may reflect inadequate information about the reason for deficiencies. There are some data from medical audits to suggest that many deficits in patient care do not stem from lack of knowledge and, thus, cannot be remedied by traditional education techniques. [77] Some studies have revealed inadequate basic clinical skills. [78] Additional information shows failure to conform with explicit criteria for treating patients with particular diagnoses. [79] In general, however, current patterns of practice are not well enough documented to permit the design of immediately relevant corrective measures.

The situation is further complicated by the professional tradition of medicine, which emphasizes "self-government for the profession as a whole and autonomy for each practitioner within the limits laid down by the profession." [80] The traditional reluctance to pass judgment on one's peers has been partially superceded by recent demands for professional accountability. Nevertheless, the effectiveness of attempts at change is primarily governed by the visibility of support within the professional community and the amount of peer pressure which is brought to bear to achieve conformity.

These difficulties notwithstanding, several approaches have been (or could be) used in an attempt to change provider performance and improve the quality of care.

Programs of continuing medical education (CME) are proliferating as CME is increasingly being required as a condition of membership in state medical associations and specialty societies, as a legislative requirement for relicensure, and in order for hospitals to receive JCAH accreditation. The educational supplement to the Journal of the American Medical Association

lists 4,862 approved CME programs. A rough estimate of total annual national expenditures for CME approximates $1,850,000,000. [81]

In some instances physicians have improved their medical practice after attending CME programs. For example, the Back-to-Medical School program at Mills Hospital in San Mateo, California has positively influenced the performance of staff physicians from hospitals in that area. [82] The program consists of two one-hour sessions per week devoted to basic clinical skills, recent clinical advances, and appropriate indications for medical procedures. The performance of specific procedures was assessed one year before and after relevant educational sessions, and definite improvements were shown.

The effect of an intensive course in cardiac auscultation, which consisted of 12 to 20 hours of presentations over a two to three-day period, has also been assessed. [83] Although the ability to recognize accurately normal and abnormal heart sounds improved immediately after the course for most participants, measurements taken six months later were not significantly different from those taken prior to the course.

In most cases, the effect of CME has not been assessed. A review of the educational supplement suggests that most courses are oriented toward specific diseases or conditions and presented in a manner which resembles the medical school curriculum. The relevance of undergraduate medical training to continuing education of a mature professional has been questioned. [84] The courses rarely relate to basic skills in the daily practice of medicine, such as history taking or physical examinations, effectiveness of treatment, or quality assessment. Furthermore, there is some evidence of a lack of significant correlation between the number of courses attended and the quality of physician performance. [85] In general, the effectiveness of traditional continuing medical education in improving the quality of patient care has not been convincingly demonstrated.

Some alternative educational approaches attempt to provide greater relevance for the practitioner's daily activities by addressing identified performance deficits (based on either group or individual data) or by attempting to simulate the routine practice of medicine.

Williamson's [86] and Brown's [87] early efforts, which link medical staff education programs with performance deficits and require a subsequent re-audit to determine the level of improvement, were described in Chapter 3. These concepts have been incorporated in medical audit requirements by PSROs, the JCAH, and the California Medical Association. But achieving long lasting improvements remains difficult. Sivertson et al. in Wisconsin have designed individual physician profiles, which provide the basis for professional consultation and the development of an educational program to meet each physician's needs. [88] Hamaty's program in West Virginia was also tailored to the practice of individual physicians. [89] Anecdotal improvements have been noted in both situations, but systematic evaluations are lacking.

Educational techniques which simulate the patient care process are useful because of their flexibility and interactive nature. Both computerized and paper-and-pencil simulations are being developed, [90] but their implementation in quality assurance programs is currently limited.

As an alternative to formal education programs, much medical learning occurs informally as a by-product of routine practice. Conversations in hospital dining rooms, discussions of problem cases with colleagues, and consultations may all help to upgrade a physician's performance. Some medical care delivery settings capitalize on the potential of informal learning by developing organizational features which foster these informal processes.

Some studies indicate that organized arrangements whereby physicians practice in groups facilitate the exhange of professional information, guide the flow of patients among professionals, provide access to a wider range of resources, and result in more appropriate patient care. [91] Interpretation of results is complicated by the fact that many group practices are also reimbursed on a capitation basis, so the influence of organization on performance is difficult to separate from the influence of reimbursement. Nevertheless, there are differences among prepaid plans, [92] and among non-prepaid practices, [93] which apparently stem from organizational characteristics.

Hospital characteristics have also been related to variations in the use of resources and quality of care, but the findings are more contradictory. Size is sometimes associated with improved care [94] and sometimes, with poorer care. [95] Intervening variables apparently are key. Structured medical staffs with salaried full-time department chiefs are associated with improved care. [96] Coordination is also an important attribute leading to increased efficiency and quality of care. [97] A study currently under way hypothesizes that working relationships at the ward level will be more influential than overall hospital characteristics. [98]

Technology may be used as a tool for improving the quality of care. The Harvard Community Health Plan in collaboration with the Laboratory of Computer Science of Massachusetts General Hospital has developed a Computer-Stored Ambulatory Record (COSTAR), which is an information and communication system replacing the traditional paper medical record. Standards of care are being developed for several diagnoses or conditions to assist in patient monitoring. Deviations from standards are identified at the time they occur, so that feedback of information to the physician can be both relevant and timely. One protocol identifies patients with positive throat cultures for beta hemolytic streptococci for whom appropriate antibiotic therapy is not recorded within four days of treatment. Seven months after program initiation, only three patients did not begin appropriate therapy within ten days after treatment. A similar program for patients with newly discovered hypertension is being evaluated. [99] The system also has a follow-up capacity for either individuals or groups of patients. When the Food and Drug Administration removed a sequential birth control pill from the market, the names of women receiving this medication were retrieved by computer. Each women was contacted by her physician to arrange for alternative medication. [100]

At a more rudimentary level, technology may refer to the basic instruments, equipment, and support services in the office or hospital. Some inadequacies in patient care are caused by the absence of such items, and the purchase of equipment or administrative changes may be more effective than education programs in leading to improvements.

The influence of rewards and incentives has not been systematically explored in relation to quality assurance, although certainly they are influential in the practice of medicine. The current reward structure does not recognize the provision of high quality patient care. One of the few explicitly identified rewards for practicing physicians is the Physician Recognition Award (PRA), which is given by the AMA for participating in continuing education activities for a qualifying period of three years. [101] In the absence of evidence that CME influences practice, however, it is difficult to assume that receiving the PRA is an indication of high quality care.

Additional incentives for improving performance may be provided by the voluntary self-assessment programs being developed by specialty societies and boards to assist in recertification. The American College of Physicians' Medical Knowledge Self-Assessment Examination can be purchased by physicians who receive a syllabus, practice questions, and CME courses. After taking the self-assessment exam they receive test scores and additional summaries, bibliographies, and reprints for further preparation before the recertification exam. The names of physicians who pass the recertification exam will be noted by the American Board of Internal Medicine in the Directory of Medical Specialties. The recertification process for the American Board of Family Practice will include a review of office records in disease categories selected by the physician, in addition to a cognitive exam. [102]

Incentive payments have been used by the British National Health Service to encourage continuing education, as well as specific types of services such as home visits, pap smears, and family planning. [103] Comparable examples in this country are difficult to identify.

It has been hypothesized that some prepaid group health plans have been able to reduce their use of hospitals by permitting physicians to share in savings which result from lower hospital utilization rates. [104] In order for the effectiveness of such incentives to be convincingly documented, however, the impact of the physician bonus would have to be isolated from all other factors which might be associated with reduced hospitalization in prepaid health plans. This has not been done.

The most extreme method of behavior change is the imposition of sanctions, but even here, many options are available. Some hospital medical staffs and medical groups have developed internal policies which specify accepted practices and sanctions for deviations, including limitation of practice privileges, mandatory consultation, and eventual suspension from staff. The threat of their imposition may encourage adherence to standards, but little is known about the effectiveness of such policies.

Denial of reimbursement is a form of sanction. A decrease in unnecessary injections in both New Mexico and the San Joquin area was observed after

payments were denied (see Chapter 4). It has been suggested, however, that physicians may copmpensate by increasing the use of procedures which they know are reimbursable, [105] so total change in inappropriate behavior may be minimal.

Imposition of more drastic sanctions such as restriction of privileges or revocation of licenses occurs less frequently--in part, perhaps, because they are so drastic. Less severe, intermediate sanctions might be applied more readily, and thereby provide more effective leverage for improving inappropriate practice.

Despite the variety of potential mechanisms for encouraging improved provider performance, existing experience is somewhat discouraging. Some successes are seen, but the factors associated with them have not been isolated in a manner which would permit more general application. More typically, provider performance did not change or the change was not long lasting.

STEERING COMMITTEE RECOMMENDATIONS

1. Quality assurance programs should not mandate any particular method to improve provider performance, including continuing medical education. Evidence of effectiveness is inadequate.

2. Research is needed to categorize deficiencies in the quality of care, determine the reasons for deficiency, and design appropriate corrective actions. All methods for improvement should be carefully evaluated to determine the extent to which they result in lasting behavior change.

3. Hypotheses about optimal learning conditions in other fields should be further explored in medical settings. The impact of working arrangements which make performance more visible and facilitate the sharing of information should be evaluated, since it is hypothesized that such arrangements also improve the quality of care. The potential for informal learning in actual medical practice should be examined. For example, medical consultation may provide an opprotunity for the consultant to enrich his appreciation for social-psychological aspects of medical practice and the referring physician to upgrade his technical skills. The point at which consultation is sought then becomes important.

4. Additional research is needed on the relative effects of alternative methods for providing the physician with assessment results indicating need for improvement. These might include simple unstructured feedback of information, a more targeted response concentrating on particular areas, or the provision of incentives for review and change. The reasons for failure to change should be explored.

5. Research on the diffusion of medical information might identify potential points of intervention to hasten the process of information exchange.

6. The effect of sanctions which are less drastic than permanent loss of licensure should be tested where clearly inappropriate care is identified and

behavior does not change. Experimentation with intermediate sanctions should include temporary curtailment of privileges, licensing with restrictions on specified areas of practice, mandatory supervision of medical practice for one year, remedial education, or curtailment of privileges for certain procedures (perhaps surgical) which are seldom performed. Related demonstrations should test the effectiveness of equipping PSROs with a wider range of sanctions, including more direct links with licensing bodies or perhaps authorization to remove a license with due cause.

7. State legislative bodies should waive or amend existing statutes, if necessary, to permit the experimentation suggested above.

8. The feasibility and effectiveness of publicizing instances of persistently poor quality by individual practitioners in public media should be explored.

QUALITY ASSURANCE AND THE HEALTH CARE CONSUMER

Consumers of health care traditionally have not been involved in either formally assessing the quality of care or reviewing the results of such assessments in a manner which might encourage them to take actions beneficial to their own health or influence the behavior of the health care professional. Some might argue that this role is inappropriate, since consumers, or patients, are inadequately prepared both intellectually and emotionally to make such assessments or to act rationally upon the information. As one might expect, at least one study [106] indicates that patients are currently poor judges of the technical adequacy of their medical care. However, there is also some evidence to the contrary. In any case, this is only one dimension of quality. The consumer's attitudes and expectations about health care, the provider's technical and supportive services, and the manner in which the two interrelate all influence quality as measured by health outcome.

Consumers already informally assess the medical care they receive and take actions accordingly, either personally or collectively. As the accuracy of their perceptions about health care increases, their use of the health care system should become more appropriate. The challenge, then, is to find ways of involving the consumer in the health care process, educating him to accept more responsibility for his own health and use resources more appropriately, while simultaneously drawing upon his experiences to make qualitative assessments of the delivery of care and suggest potential alteration where warranted. The manner in which this can be accomplished is not clear, but initial beginnings can be made.

Several levels of consumer involvement can be envisaged. Increasing federal support of health care programs implies a responsibility to assure the appropriateness and quality of services purchased. Health care consumers and lay policymakers, as well as health professionals, should be in a position to express opinions and to have a voice in assessing the return on their investments. Similar decisions about the use of resources are made in state planning agencies, group health plans, and hospital boards of directors, with a subsequent need to evaluate the results. At the individual level, the need

for involvement and understanding is perhaps even more compelling, since the individual's health status is influenced by his behavior. Some would argue that changes in one's environment and way of life, rather than necessarily receiving more and bettter health care, are key factors in improving health. [107]

A growing body of literature and experience is emerging which deals with consumer involvement and behavior. In Green's discussion of factors influencing health behavior, he describes predisposing factors as those psychological and social forces, such as attitudes and knowledge, that induce people to act or not to act in specific ways. [108] Attitudes toward health care (especially satisfaction) and health information or education have been related to health behavior and outcome. They suggest that some specific changes in the provision of care may improve the results.

Studies of patient satisfaction without reference to particular health care encounters are not particularly helpful for quality assessment, except to note the demographic and utilization characteristics of patients who are more or less satisfied with health care in general. [109] Studies of patient satisfaction with respect to particular practice arrangements yield more specific findings. Patients can adapt to, and be satisfied with, changes in the manner in which care is provided--in particular, to increased use of paramedical workers. [110] Satisfaction with prepaid group practice increases as patients gain experience in using the services, acquire more information about the plan, and become generally more familiar with its provisions. [111] But as overall satisfaction increases and patients become more involved with a particular health care provider, criticism of specific aspects of health care delivery may increase. [112] Perceived access to care is an important component of satisfaction. [113] Satisfaction is also related to a person's general attitude. [114]

A few studies go beyond the relationship of satisfaction to patient characteristics and structural factors and address the process and outcome of care, as perceived by the patient. Attempts to relate satisfaction to communication between patient and physician, which measured communication in terms of information items exchanged, have produced equivocal results. [115] Other investigators have found that the content of communication, rather than necessarily the amount, influences satisfaction. Problems in communication include the tendency of physicians to seize the initiative and use unexplained medical terminology, and their emphasis on alleviating the problem, rather than explaining its cause. The key to satisfaction may be meeting patients' expectations. Satisfaction decreases when anticipated behavior (for example, giving injections) does not occur and when the physician is expected to be friendly and concerned and is not. When communication addresses the patient's anxieties, concerns, and expectations, satisfaction increases. [116] Failure to provide information on child care and to meet the patient's educational needs has resulted in decreased satisfaction. [117]

Patient compliance is related to satisfaction, but the relationship is not clear-cut. [118] Compliance decreases when the physician is regarded as unfriendly and not understanding and when a complicated therapeutic regimen is prescribed. Compliance is also less for those whose expectations are not

met. Compliance has been shown to increase when the patient's condition is prolonged or increases in severity, even though initial failure to comply may have produced the worsened condition. [119]

Satisfaction with the process of care apparently is related to the extent to which patient expectations are met and this, in turn, influences compliance, but the relationships need further exploration. If patient expectations are unrealistic or would lead to inappropriate care, communication between the patient and physician should make this apparent. With patient education, more realistic expectations should result without decreasing either satisfaction or compliance.

A few studies have compared patients' assessments of the results of medical treatment with physicians' estimates of expected outcome. [120] Patients have been questioned on several measures, including amount of sickness and dysfunction, the quality of life following gall bladder surgery, satisfaction with postoperative length of stay, and more general measures of outcome. Each study has revealed some compatibility between physician and patient assessments. When patients report a less desirable status than expected, it frequently stems from social or psychological limitations, which may not have been considered in the physician assessment. In one study, patient assessment was used as an initial screen to detect cases for which a more detailed review by physicians was warranted. The validity of patients' judgments was shown to a limited extent when a chart review showed that in some cases for which the patients' assessments were less than optimal, there were correctable errors in the process of care. [121]

The above work suggests that the patient perspective adds an important dimension to quality which may influence compliance and outcome and assist in assessing quality of care, even though that perspective may not be adequately represented in existing quality assurance programs. The effectiveness of patient involvement may be enhanced by adequate health education.

Educating individuals to alter ingrained behavior patterns in a manner which might improve their health status is equally difficult as convincing physicians to change the manner in which they practice medicine. The inhibiting and facilitating factors in both cases are not adequately understood. Despite many examples in which no change occurred, however, there are some successful health education programs which might be examined and replicated.

Health education of the general public has been attempted through the media. A survey of viewers of the television program "Feeling Good" showed some impact on behavior, but conclusive findings await the results of a controlled evaluation in four cities. [122] The Stanford Heart Disease Prevention Program covers three years and uses a variety of media to reach the target population in two communities and a control community. [123] Preliminary findings show the greatest changes for the group which received intensive group instructions as well as a media campaign. Although improvements appeared in parts of the physical examination, reports of smoking and eating habits, and diet knowledge, no significant changes occurred in weight, sugar

intake, serum cholesterol, or leisure activity--factors which may be more deeply linked to one's lifestyle.

A study of an inner-city population has shown that personal contact is more effective than media programs. [124] A health education program incorporated into an elementary school science curriculum had a significant impact and led to speculation that children might educate their parents for more healthy lifestyles. [125] Mothers have been trained successfully to recognize indications of possible strep infection and to take throat cultures from their children. [126] But other programs to educate parents to care for their children have been less successful. [127]

Similarly mixed findings result from educational programs for patients with particular diseases or conditions. A multidisciplinary, individualized program for patients with congestive heart disease syndrome and their families resulted in increased patient knowledge and compliance, improved social interactions, and reductions in hospital admissions and length of stay. [128] A self-care program for patients with asthma led to a significant reduction in emergency room visits for symptomatic relief and was estimated to have a cost-to-benefit ratio of at least one-to-five. [129] However, less positive findings resulted from a program for elderly males with bronchitis [130] and another intended to increase compliance with an antibiotic regimen. [131]

Despite the potential for attitudinal factors and knowledge to influence individual behavior and health status, many questions remain unanswered. At the societal level, however, greater precedent exists for such involvement.

The Comprehensive Health Planning Act, the Health Maintenance Organization Act of 1973, the National Health Planning and Resources Development Act of 1974, and the National Health Education and Promotion Act of 1975, all include provisions for consumer involvement. Consumer's reactions to their health care is an expressed concern of the FY 1977-81 Forward Plan for Health, issued by the Department of Health, Education, and Welfare. Even the legislation for Professional Standards Review Organizations includes a limited reference to consumers--in states with three or more PSROs, which are therefore required to have a statewide Professional Standards Review Council, four persons on that council must be representatives of the public. A few states have increased non-professional representation on state licensing boards; locally the inclusion of consumers on hospital boards of trustees is increasing.

The effect of consumer representation is very difficult to evaluate--in part because of methodological problems and in part because it is value-laden. The complexities of the issues and a few evaluative attempts have been described in the literature, however. [132] The rationale behind public representation usually assumes that social services should be provided in a manner which is responsive to the needs and desires of the users. Thus, representatives of users should be included in policymaking bodies. As resource constraints increase, it is important that users appreciate the trade-offs involved in considering competing demands and allocating resources. In regulatory or quality control agencies, the users have an additional interest in assuring that their health and safety are being protected. Ultimately, a

recommendation to include the public in such decisions must rest on the judgment that it is desirable. So it is with health care quality assurance programs.

The steering committee is of the opinion that consumer involvement in quality assurance should be encouraged and expanded. If the public (both as individual patients and representatives in policymaking bodies) can gain a better understanding of the determinants of health, the limitations of health care, the resources required to provide it, and the necessity to work in partnership with professionals to create a system of health care, this should result in improvements in the quality and appropriateness of health services and a healthier public. Although the objective is clear, the methods for achieving it are not. Therefore, the recommendations emphasize the need for additional research, demonstration, and evaluation.

STEERING COMMITTEE RECOMMENDATIONS

1. Increased consumer involvement in quality assurance should begin with representation of the public on the National Professional Standards Review Council. This may require a legislative amendment.

2. Additional research is needed to identify dimensions of health care that are important from the consumer's perspective, which can be incorporated into valid and reliable instruments for assessing patient expectations and satisfaction. Once the measures are adequate, the feasibility of implementing them in formal quality assurance programs can be better tested.

3. Experimental projects involving consumers in formal quality assurance programs should be funded. Consumer or patient boards to hear patient complaints, evaluate their validity and causes, and link into quality assurance programs might be instituted. The use of patient questionnaires in assessing the quality of care should be tested. An assessment should be conducted of the effect of explicitly noting patient expectations in the medical record, providing education to modify unrealistic expectations, and using that information to guide and monitor the provision of patient care. A more direct involvement of consumers with providers in assessing the quality of care should be evaluated, since both groups might learn from one another and heighten their appreciation of the complexities of quality assessment, particularly as it relates to the expenditure of resources.

4. The provision of patient education is an important consideration in assessing the quality of care in instances where education is known to be beneficial. To the extent that process-oriented criteria are used to monitor care, efforts to include educational components (such as dietary instruction for diabetics) should be encouraged. If changes in the process of care or delivery settings are contemplated, the acceptance of such changes will be increased if information is provided to the patients in advance.

5. Additional research is needed to identify factors associated with effective health education. Attention should be given to the effect of alternative media, differing levels of patient and family involvement, the duration of behavior change and whether reinforcement is needed, the potential contribution of motivational research, and patient factors which may influence effectiveness, such as emotional state, demographic characteristics, and health status. Different approaches may be required for different patient conditions, ranging from preventive care, to care for acute illness and chronic conditions.

6. Because the treatment process by definition involves a health care provider, additional research is needed to explore the psycho-social perspective of the provider and, in particular, to identify factors associated with provider satisfaction or stress. The influence of patients' mannerisms and conduct on physician behavior should be further explored. Greater understanding of these factors may improve the patient-provider relationship and health outcomes.

7. Changes in the content of the medical curriculum and inclusion of material about the relationship between patient and provider should be evaluated. Alternative models of the patient-physician relationship should be tested to determine whether certain models are more or less appropriate for particular patients or conditions.

8. Existing legislative requirements which might further health education should be exploited. For example, informed consent reyuirements might provide a unique chance to educate the patient about his condition, rather than simply obtaining an unthinking agreement to treatment.

9. The consumer's role in governance and policymaking needs careful documentation and analysis so that more responsible, comfortable, and effective relationships may evolve.

FOOTNOTES

Chapter 5

1 American Public Health Association, A Guide to Medical Care Administration, (New York: The American Public Health Association, 1969), vol. 2: Medical Care Appraisal--Quality and Utilization, by Avedis Donabedian, pp. 2-3.

2 Florence Nightingale, Notes on Matters Affecting the Health, Efficiency, and Hospital Administration of the British Army (London: Her Majesty's Stationer, 1858).

3 U.S. Congress, Senate, Health Maintenance Organization Act of 1973, Pub. L. 93-222, 93d Cong., 2d sess., 1973, S. 14.

4 Sam Shapiro, Louis Weiner, and Paul Densen, "Comparison of Prematurity and Perinatal Mortality in a General Population and in The Population of a Prepaid Group Practice, Medical Care Plan," American Journal of Public Health 48 (February 1958): 170-85.

5 Institute of Medicine, Panel on Health Services Research, Contrasts in Health Status, (Washington, D.C.: National Academy of Sciences, 1973) vol. 1: Infant Death: An Analysis by Maternal Risk and Health Care.

6 "Study of Institutional Differences in Postoperative Mortality," a report to the National Academy of Sciences under Subcontract MS 46-72-12, Stanford University, (December 1974).

7 Sam Shapiro, "End Result Measurements of Quality of Medical Care, Milbank Memorial Fund Quarterly 45 (April 1967): 7-30.

8
Lincoln Moses and Frederick Mosteller, "Institutional Differences in Postoperative Death Rates, Commentary on Some Findings of the National Halothane Study," Journal of the American Medical Association 203 (February 1968): 492-94.

9
Alvin Mushlin et al., "The Use of Patient-Reported Problem Status in Evaluating Ambulatory Care," paper presented at the National Meeting of the American Federation for Clinical Research, Atlantic City, N.J., 3 May 1975. (Mimeographed.)

10
Frederic J. Romm et al., "Correlates of Outcomes in Patients with Congestive Heart Failure," Medical Care, forthcoming.

11
John W. Williamson, "The Major Concepts of Quality Assurance," p. 11, Sect. I, Chpt. 2 of "Medical Care Outcomes: Assessment and Improvement," manuscript; see also, John W. Williamson, "Evaluating Quality of Patient Care, " Journal of the American Medical Association 218 (25 October 1971): 564-69.

12
Charles Jacobs and Tom Christoffel, The PEP Primer--The Rationale for Outcome Audit (Chicago: Joint Commission on Accreditation of Hospitals, 1974), p. 5.

13
Paul A. Lembcke, "Measuring the Quality of Medical Care Through Vital Statistics Based on Hospital Service Areas: 1. Comparative Study of Appendectomy Rates," American Journal of Public Health 42 (March 1952): 276-86; Idem, "Medical Auditing by Scientific Methods," Journal of the American Medical Association 162 (13 October 1956): 646-55.

14
Barbara Starfield and David Sheff, "Effectiveness of Pediatric Care: The Relationship Between Process and Outcome," Pediatrics 49 (April 1972): 547.

15
Williamson, "Medical Care Outcomes"; see also Martin Berdit and John Williamson, "Function Limitation Scale for Measuring Health Outcomes," in Health Status Indexes, ed. Robert L. Berg (Chicago: Hospital Research and Educational Trust, 1973), pp. 59-69.

16
John Williamson et al., "Health Accounting: An Outcome-Based System of Quality Assurance: Illustrative Application to Hypertension," Bulletin of the New York Academy of Medicine 2d ser., 51 (June 1975): 727-38.

17
Institute of Medicine, Panel on Health Services Research, Contrasts in Health Status, vol 2: A Strategy for Evaluating Health Services (Washington, D.C.: National Academy of Sciences, 1973).

18
David Kessner, Assessing Ambulatory Care: The Use of an Enriched Encounter Form, Department of Health, Education, and Welfare, Office of Assistant Secretary for Planning and Evaluation, Washington, D.C., (1975), p. 11; Steven Schroeder and Molla Donaldson, "The Feasibility of an Outcome Approach to Quality Assurance--A Report from One HMO," Medical Care 14 (January 1976): 49-56.

19
Stanford Center for Health Care Research, "The Hospital as a Factor in the Quality of Surgical Care," (Stanford, Calif.: Stanford University, September 1975), p. 32. (Mimeographed.)

20
Donald E. Detmer et al., "An Evaluation of Major Trauma Care for Hospital Inpatients: Pre-EMS Program Experience in Wisconsin," (April 30, 1976). (Mimeographed.)

21
Robert Brook et al., Quality of Medical Care Assessment Using Outcome Measures: An Overview of the Method (Santa Monica, Calif.: The Rand Corporation, 1976). Prepared for the Health Resources Administration, Department of Health, Education, and Welfare, Contract No. HRA 230-75-0012.

22
Sidney Katz and C. Amechi Akpom, "Measure of Primary Socio-Biologic Functions," International Journal of Health Services 6 (Summer 1976): 495; Susanne Donaldson, Conlin Wagner, and Glen Gresham, "A Unified ADL Evaluation Form," Archives of Physical Medicine and Rehabilitation 54 (April 1973): 175; F. Mahoney and D. Barthel, "Functional Evaluation: The Barthel Index," Maryland State Medical Journal 14 (1965): 61; Herbert Schoening and Iver Iverson, "Numerical Scoring of Self-Care Status: A Study of the Kenny Self-Care Evaluation," Archieves of Physical Medicine and Rehabilitation 49 (April 1968): 221; Margaret Linn, "A Rapid Disability Rating Scale," Journal of the American Geriatric Society 15 (February 1967): 211.

23
Patrick McKee et al., "The Natural History of Congestive Heart Failure: The Framingham Study," New England Journal of Medicine 285 (December 1971): 1441; New York Heart Association, Diseases of the Heart and Blood Vessels, 6th ed. (Boston: Little, Brown, 1964); Joseph Gonella, Daniel Louis, and John McCord, "The Staging Concept--An Approach to the Assessment of Outcome of Ambulatory Care," Medical Care 14 (January 1976): 13-21.

24
Beverly Payne and Thomas Lyons, Method of Evaluating and Improving Personal Medical Care Quality, vol. 1: Episode of Illness; vol. 2: Office Care; 2 vols. (Ann Arbor, Michigan: University of Michigan School of Medicine, 1972), 2.

25
Barbara S. Hulka and John C. Cassel, "The AAFP-UNC Study of the Organization, Utilization, and Assessment of Primary Medical Care," American Journal of Public Health 63 (June 1973): 494.

26
Ruth L. Riedel, "Connecticut Ambulatory Care Study," forthcoming.

27
U.S. Department of Health, Education, and Welfare, The National Ambulatory Medical Care Survey: 1973 Summary, United States, May 1973--April 1974, Vital and Health Statistics, Series 13: Data from the Hospital Discharge Survey, No. 21 (October 1975).

28
Henry B. Makover, "The Quality of Medical Care: Methodology of Survey of the Medical Groups Associated with the Health Insurance Plan of New York," American Journal of Public Health 41 (July 1951): 824-32; Edwin F. Daily and Mildred A. Morehead, "A Method of Evaluating and Improving the Quality of Medical Care," American Journal of Public Health 46 (July 1956): 848-54; and Morehead, "The Medical Audit as an Operational Tool," American Journal of Public Health 57 (September 1967): 1643-56.

29
Sam Shapiro et al., "Patterns of Medical Use by the Indigent Aged under Two Systems of Medical Care," American Journal of Public Health 57 (May 1967): 784-90; Shapiro, Weiner, and Densen, "Comparison of Prematurity and Perinatal Mortality."

30
Antonio Ciocco, G. Halsey Hunt, and Isidore Altman, "Statistics on Clinical Services to New Patients in Medical Groups," Public Health Reports 65 (27 January 1950): 99-115.

31
Payne and Lyons, Office Care Study; Riedel, "Connecticut Ambulatory Care"; Lester Breslow and Joseph Hochstim, "Sociocultural Aspects of Cervical Cytology in Alameda County, California," Public Health Reports 79 (February 1964): 107-12; Daniel Louis and John McCord, "Evaluation of California's Prepaid Health Plans (PHPs) (Santa Barbara: General Research Corporation, 1974). (Mimeographed.)

32
Donald Logsdon, Jeanne Magagna, and Alice Varela, "Quality Assurance Program of a Prepaid Group Practice Plan" (June 1975). (Mimeographed.)

33
Mildred Morehead, "Evaluating Quality of Medical Care in the Neighborhood Health Center Program of the Office of Economic Opportunity," Medical Care (March-April 1970): 118-31.

34
Mildred Morehead, Rose Donaldson, and Mary Seravalli, "Comparisons between OEO Neighborhood Health Centers and Other Health Care Providers of Ratings of the Quality of Health Care," American Journal of Public Health 61 (July 1971): 1294-1306.

35
John Hallman, Bureau of Community Health Services, Department of Health, Education, and Welfare, Washington, D.C., telephone conversation, May 1976.

36
Gonella, Louis, and McCord, "The Staging Concept."

37
John McCord, personal communication, May 1976.

38
Osler L. Peterson et al., "An Analytical Study of North Carolina General Practice, 1953-54," Journal of Medical Education part 2, 31 (December 1956): 1-165.

39
C.C. Jungfer and J.M. Last, "Clinical Performance in Australian General Practice," Medical Care 2 (1964): 71-83.

40
Kenneth Clute, The General Practitioner: A Study of Medical Education and Practice in Ontario and Nova Scotia (Toronto: University of Toronto Press, 1963), pp. 262-340.

41
Hilda H. Kroeger et al., "The Office Practice of Internists: The Feasibility of Evaluating Quality of Care," Journal of the American Medical Association 193 (2 August 1965): 371-76.

42
Robert Hare and Shlomo Barnoon, "Medical Care Appraisal and Quality Assurance in the Office Practice of Internal Medicine," (San Francisco: American Society of Internal Medicine, 1973). (Mimeographed.)

43
Jane H. Murnaghan, ed., "Ambulatory Medical Care Data--Report of the Conference on Ambulatory Medical Care Records," Medical Care 11 Supplement (March-April 1973): 1-205.

44
U.S. Department of Health, Education, and Welfare, National Center for Health Statistics, Health Resources Administration, National Ambulatory Medical Care Survey: Symptom Classification, Vital and Health Statistics, Series 2: Data Evaluation and Methods Research no. 63, (Washington, D.C.: U.S. Government Printing Office, May 1974); J. Reaner and R. Piernot, "A Revised Symptom Code List for Ambulatory Medical Record Data," paper prepared for Family Practice Program, University of Wisconsin, Madison, Wisconsin, 1972; Arnold Hurtado and Merwyn Greenlick, "A Disease Classification System for Analysis of Medical Care Utilization with a Note on Symptom Classification," Health Services Research 6 (Fall 1971): 235-50.

45
U.S. Congress, Senate, Subcommittee on Long-Term Care, Special Committee on Aging, Nursing Home Care in the United States: Failure in Public Policy, Introductory Rept., S. Rept. 1420, 93d Cong., 2d sess., 1974, p. 16.

46
Ibid.

47
Eric Pfeiffer, ed., Multidimensional Functional Assessment: The OARS Methodology (Durham, N.C.: Center for the Study of Aging and Human Development, 1975), p. 2; U.S. Department of Health, Education, and Welfare, Office of Nursing Home Affairs, Long-Term Care Facility Improvement Study--Introductory Report, DHEW Pub. No. (OS) 76-50021, (Washington, D.C: Government Printing Office, July 1975), pp. 30-31.

48
U.S. Congress, Senate, Nursing Home Care, p. 16.

49
George Maddox, "Families as Context and Resource in Chronic Illness," in Long-Term Care, ed. Sylvia Sherwood (Holliswood, N.Y.: Spectrum Publications, 1975), p. 322.

50
Jerry C. Hood, Max Lemberger, and Ronald Stewart, "Promoting Appropriate Therapy in a Long-Term Care Facility--Contributions of a Pharmacist," Journal of the American Pharmaceutical Association NS 15 (January 1975): 26-27; U.S. Congress, Senate, Subcommittee on Long-Term Care, Nursing Home Care, Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks, Committee Print, Supporting Paper 2, (Washington, D.C.: Government Printing Office, 1975), p. X.

51
Katz and Akpom, "Socio-Biologic Functions," p. 3; Mahoney and Barthel, "The Barthel Index," p. 61; and Schoening and Iverson, "Self-Care Evaluation," p. 221.

52
Linn, "Rating Scale," p. 211; Adeline Gauger et al., "Evaluation of Levels of Subsistence," Archives of Physical Medicine and Rehabilitation 45 (June 1964): 286; and Pfeiffer, OARS Methodology, p. 6.

53
Harvard Center for Community Health and Medical Care, Summary of Proceedings--Third Invitational Conference on Nursing Home Care (Boston, Mass: May 1974), p. 1.

54
Jane H. Murnagham, "Review of The (Long-Term Health Care Data) Conference Proceedings," Medical Care 14 Supplement (May 1976): 1-25.

55
Hugh Kabat, James Martila, and Jessee Stewart, "Drug Utilization Review in Skilled Nursing Facilities," Journal of the American Pharmaceutical Association NS 15 (January 1975): 34; Montgomery County Utilization Review Committee, "Frequency of Urinary Tract Infections in Patients with Indwelling Catheters" (May 1975). (Mimeographed.)

56
Kenneth Kahn et al., A Multi-Disciplinary Approach to Assessing the Quality of Life and Services in Long-Term Care Facilities (Denver, Colo: Colorado Foundation for Medical Care and Long-Term Care, November 1975), p. 3.

57
Kenneth McCaffree and Elizabeth Harkins, Interim Executive Summary of Evaluation of the Outcomes of Nursing Home Care, 30 April 1976 (Seattle: Battelle Human Affairs Research Center, 1976), pp. 1-9.

58
Franklin Williams et al., "Criteria and Guidelines for Evaluation of Aged or Chronically Ill Persons for Maintenance at Home or for Placement in an Appropriate Long-Term Care Institution," article submitted for publication.

59
Joint Commission on Accreditation of Hospitals, "New Evaluation Methodologies: Answers to Quality Assurance and Accountability in Long-Term Care," (1976). (Mimeographed.)

60
Thomas Ainsworth and Basil Boyce, Quality Assurance Program for Long-Term Care (Chicago: Ainsworth Associates, 1975).

61
Sharon Benedict, Medical Care Evaluation Studies for Utilization Review in Skilled Nursing Facilities (Pittsburgh, Pa.: Hospital Utilization Project, 1975). Prepared pursuant to Contract No. SSA 71-3166 with the Social Security Administration, Department of Health, Education, and Welfare.

62
Illinois Department of Public Health, Quality Evaluation System for Long-Term Care, Facility Survey and Surveyor's Guide, (Springfield, Ill., February 1975).

63
Arthur D. Little, Inc., Final Report on EMCRO: An Evaluation of Experimental Medical Care Review Organizations, 5 vols., February 1976. Submitted in partial compliance with Contract No. HSM-110-73-526 with the National Center for Health Services Research, Department of Health, Education, and Welfare.

64
National Professional Standards Review Council, Washington, D.C., Minutes of Meeting 12 June 1965, Tab IV, pp. 1-11.

65
Department of Health, Education, and Welfare, Effects of Continued Care: A Study of Chronic Illness in the Home, by Sidney Katz, et al., Department of Health, Education, and Welfare Pub. No. 73-3010 (Washington, D.C.: Government Printing Office, December 1972).

66
Benedict, Medical Care Evaluation Studies.

67
Nancy Tiger, Assistant Director, Department of Home Health and Community Health Services, National League for Nursing, New York City, telephone communication, August 1976.

68
U.S. Department of Health, Education, and Welfare, Problems in Providing Proper Care to Medicaid and Medicare Patients in Skilled Nursing Homes--Report to the Congress, by the Comptroller General of the United States (28 May 1971), pp. 10-11.

69
Nader Task Force on Nursing Homes, Nursing Homes for the Aged: The Agony of One Million Americans, (December 1970), p. 183; U.S. Department of Health, Education, and Welfare, Long-Term Care Facility Improvement Study, p. 46.

70
U.S. Department of Health, Education, and Welfare, Long-Term Care Facility Improvement Study, p. 13.

71
U.S. Congress, Senate, Drugs in Nursing Homes, p. 252.

72
U.S. Department of Health, Education, and Welfare, Long-Term Care Facility Improvement Study, pp. 48-49.

73
U.S. Congress, Senate, Nursing Home Care, p. 8.

74
Ibid., p. 24.

75
U.S. Congress, Senate Subcommittee on Long-Term Care, Nursing Home Care in the United States: Failure in Public Policy-What Can be Done in Nursing Homes: Positive Aspects in Long-Term Care, Committee Print, Supporting Paper 6, (Washington, D.C.: Government Printing Office, 1975), p. XII.

76
Murnaghan, "Review of Conference Proceedings," pp. 1-25.

77
Gerald Escovitz, "Continuing Education and Quality Care," The Hospital Medical Staff, March 1974, pp. 28-38; Hospital Research and Educational Trust, American Hospital Association, "Final Report on the Quality Assurance Program Demonstration Project" to the W. K. Kellogg Foundation, Chicago, 1975, p. 38.

78
Jacob Fine and Mildred Morehead, "Study of Peer Review of Inhospital Patient Care," New York State Journal of Medicine 71 (August 1971): 1963-73; Peterson et al., 1-165.

79
Payne and Lyons, Episode of Illness Study; Payne and Lyons, Office Care Study; Louis and McCord, "Evaluation of California's PHPs"; Hare and Barnoon, Medical Care Appraisal.

80
Mary Goss, "Patterns of Bureaucracy Among Hospital Staff Physicians," in The Hospital in Modern Society, ed. Eliot Freidson (New York: The Free Press, 1963), p. 171; see also Talcott Parsons, The Social System (Glencoe, Ill.: The Free Press, 1951), p. 454.

81
Lewis Miller, "The Current Investment in Continuing Medical Education." Background paper prepared for "The Relationship of Continuing Medical Education to the Quality of Medical Care, June 11-12, 1976," Boston University Program on Public Policy for Quality Health Care. (Mimeographed.)

82
Edward Rubenstein, "Continuing Medical Education at Stanford: The Back-to-School Program," Journal of Medical Education 48 (October 1973): 911-18.

83
Christine McQuire, et al., "Auscultatory Skill: Gain and Retention after Intensive Instruction," Journal of Medical Education 39 (February 1964): 120-31.

84
Jack Hall, "Foreword," in "Continuing Medical Education in Community Hospitals," eds. Stearns et al. New England Journal of Medicine 284 Supplement (May 1971): iv-vi.

85
Peterson et al., "North Carolina General Practice," p. 81; Clute, The General Practitioner pp. 262-340; and Charles Lewis and Ruth Hassenein, "Continuing Medical Education: An Epidemiologic Evaluation," New England Journal of Medicine 282 (January 1970): 254-59.

86
John Williamson, Marshall Alexander, and George Miller, "Continuing Education and Patient Care Research," Journal of the American Medical Association 201 (September 1970): 938-42; John Williamson et al., "Priorities in Patient-Care Research and Continuing Medical Education," Journal of the American Medical Association 204 (April 1968): 303-8.

87
Clement Brown, Jr., and Henry Uhl, "Mandatory Continuing Education: Sense or Nonsense?," Journal of the American Medical Association 213 (September 1970): 1660-68.

88
Sigurd Sivertson et al., "Individual Physician Profile: Continuing Education Related to Medical Practice," Journal of Medical Education 48 (November 1973): 1006-12.

89
Daniel Hamaty, "From West Virginia: The Doctor's Office Becomes His Classroom," Patient Care, May 1971, pp. 39-43.

90
Michael Goran, John Williamson, and Joseph Gonella, "The Validity of Patient Management Problems," Journal of Medical Education 48 (February 1973): 171-77; Richard Friedman, "A Computer Program for Simulating the Patient-Physician Encounter," Journal of Medical Education 48 (January 1973): 92-97.

91
Payne and Lyons, Episode of Illness; Shapiro et al., "Patterns of Use by the Indigent Aged," pp. 784-90; Breslow and Hochstim, "Cervical Cytology in Alameda County," pp. 107-12; Louis and McCord, "Evaluation of California's PHPs"; James Coleman, Herbert Menzel, and Elihu Katz, "Social Processes in Physician's Adoption of a New Drug," Journal of Chronic Diseases 9 (January 1959): 1-19; Coleman, Menzel, and Katz, "Dimensions of Being 'Modern' in

Medical Practice," Journal of Chronic Diseases 9 (January 1959): 20-40, Eliot Friedson and Bufford Rhea, "Physicians in Large Medical Groups," Journal of Chronic Diseases 17 (September 1964): 827-37; Paul Stolley et al., "The Relationship between Physician Characteristics and Prescribing Appropriateness," Medical Care 10 (January-February 1972): 17-28; Robert Brook and Kathleen Williams, "Quality of the Use of Injections: A Study of the Impact of the New Mexico Experimental Medical Care Review Organization," Annals of Internal Medicine, forthcoming; Leon Gordis, "Effectiveness of Comprehensive Care Programs in Preventing Rheumatic Fever," New England Journal of Medicine 289 (August 1973); Karen Davis, "A Decade of Policy Developments in Providing Health Care for Low Income Families," in Robert H. Haveman, ed., A Decade of Federal Anti-Poverty Policy: Achievements, Failures and Lessons, pp. 47-48 (in press); and L.S. Robertson et al., "Toward Changing the Medical Care System: Report of an Experiment," in Robert Haggerty, The Boundaries in Health Care, reprinted from Alpha Omega Honor Society, Pharos of Alpha Omega Alpha, 35 (1972): 106-11.

92
Makover, "Quality of Medical Care," pp. 824-32; Daily and Morehead, "Evaluating and Improving," pp. 848-54; Morehead, "The Medical Audit," pp. 1643-56; Social Security Administration, "Medicare Experience with Prepaid Group Practice Enrollees," Washington, D.C., Office of Research and Statistics, March 1971 (processed), as cited in Herbert Klarman, "Analysis of the HMO Proposal--Its Assumptions, Implications, and Prospects," Health Maintenance Organizations: A Reconfiguration of the Health Services System (Chicago, Ill.: Center for Health Administration Studies, University of Chicago, 1971), pp. 24-38.

93
Ciocco, Hunt, and Altman, "New Patients in Medical Groups, " pp. 99-115; Peterson et al., "North Carolina General Practice," pp. 1-165; Linda Demlo, "The Relationship of Physician Practice Patterns to Organizational and Personal Characteristics" (Ph.D. dissertation, Yale University, 1975).

94
Duncan Neuhauser, The Relationship Between Administrative Activities and Hospital Performance (Chicago, Ill.: Center for Health Administration Studies, Graduate School of Business, University of Chicago 1971), p. 8.

95
Basil Georgopoulos and Floyd Mann, The Community General Hospital (New York: MacMillan Co., 1962), p. 4.

96
Milton Roemer and Jay Friedman, Doctors in Hospitals (Baltimore: Johns Hopkins Press, 1971), p. 282.

97
Georgopoulos and Mann, Community General Hospital, p. 4; Beaufort Longest, "Relationship between Coordination, Efficiency, and Quality of Care in General Hospitals," Hospital Administration (Fall 1974): 65-86.

98
W. Richard Scott, "Hospital Structure and Post Operative Mortality and Morbidity: Preliminary Findings from a Survey of 17 Hospitals," Stanford Center for Health Care Research, Stanford University, December 1975. (Mimeographed.)

99
G. Octo Barnett, "Computer Stored Ambulatory Record: A Progress Report," Laboratory of Computer Science, Massachusetts General Hospital and Harvard Community Health Plan, Harvard Medical School, Boston, Massachusetts, undated, pp. 44-46.

100
Ibid., p. 29.

101
American Medical Association, "The Physician's Recognition Award," instruction booklet (1975).

102
Committee on Continuing Competence of the Coordinating Council on Medical Education, report on meeting held 23 June 1975, Philadelphia, Pa., dated 27 August 1975.

103
"Health Services in Britain," Central Office of Information, Reference Pamphlet 20, (London: Her Majesty's Stationer, 1973), pp. 18-19.

104
D. Scott Fleming, "Health Maintenance Organizations--A Prototype: California Kaiser-Permanente Program," Hospitals 45 (16 March 1971): 57.

105
John Holahan, Physician Supply, Peer Review and Use of Health Services in Medicaid (Washington, D.C.: Urban Institute, February 1976), pp. 63-64.

106
Ray Trussell, Mildred Morehead, and J. Ehrlich, The Quantity, Quality, and Costs of Medical and Hospital Care Secured by a Sample of Teamster Families in the New York Area (New York: Columbia University Press, 1962).

107
Hugh Leavell and E.G. Clark, "Levels of Application of Preventive Medicine" Chapt. 2 in Preventive Medicine for the Doctor in His Community, eds. Leavell and Clark, 3d ed. (New York: McGraw Hill Book Company, 1969); Victor Fuchs, Who Shall Live?: Health, Economics and Social Choice (New York: Basic Books, 1974).

108
Lawrence Green, "Toward Cost-Benefit Evaluations of Health Education: Some Concepts, Methods, and Examples," Health Education Monographs, 2 Supplement (1974): 34-60. This is a modification of Ronald Anderson's earlier conceptualization--see Ronald Anderson, A Behavioral Model of Families' Use of Health Services, Research Series, no. 25 (Chicago: University of Chicago Center for Health Administration Studies, 1968).

109
Barbara Hulka et al., "Satisfaction with Medical Care in a Low Income Population," Journal of Chronic Disease 24 (October 1971): 661-73; Hulka, et al., "Correlates of Satisfaction and Dissatisfaction with Medical Care: A Community Perspective," Medical Care 13 (August 1975): 648-58; John Ware et al., "Consumer Perceptions of Health Care Services: Implications for Academic Medicine," Journal of Medical Education 50 (September 1975): 839-48.

110
P.R. Kaim-Caudle and G.N. Marsh, "Patient-Satisfaction Survey in General Practice," British Medical Journal (February 1975): 262-64; Lawrence Linn, "Patient Acceptance of the Family Nurse Practitioner," Medical Care 14 (April 1976): 357-64.

111
Rashid Bashshur, Charles Metzner, and Carla Worden, "Consumer Satisfaction with Group Practice, The CHA Case," American Journal of Public Health 57 (November 1967): 1991-99.

112
Kaim-Caudle and Marsh, "Patient-Satisfaction Survey," pp. 262-64; Bashur, Metzner, and Worden, "Consumer Satisfaction," pp. 1991-99.

113
Richard Tessler and David Mechanic, "Consumer Satisfaction with Prepaid Group Practice: A Comparative Study." Journal of Health and Social Behavior 16 (March 1975): 95-113.

114
Ibid.; Milton J. Rosenberg, "Hedonism, Inauthenticity, and Other Goals Toward Expansion of a Consistency Theory," in Theories of Cognitive Consistency: A Sourcebook, eds. Robert Abelson et al. (Chicago: Rand McNally and Company, 1968), pp. 73-111.

115
Barbara Hulka et al., "Practice Characteristics and Quality of Primary Medical Care: The Doctor-Patient Relationship," Medical Care 13 (October 1975): 808-20; Hulka et al., "Doctor-Patient Communication and Outcomes Among Diabetic Patients," Journal of Community Health 1 (January 1975): 15-27.

116
Barbara Korsch, Ethel Gozzi, and Vida Francis, "Gaps in Doctor-Patient Communication: I. Doctor-Patient Interaction and Patient Satisfaction," Pediatrics 42 (November 1968): 855-77.

117
Jay Lebow, "Evaluation of an Outpatient Pediatric Practice Through the Use of Consumer Questionnaires," Medical Care 13 (March 1975): 251-55; Nancy Risser, "Development of an Instrument to Measure Patient Satisfaction with Nurses and Nursing Care in Primary Care Settings," Nursing Research 24 (January-February 1975): 45-52.

118
Vida Francis, Barbara Korsch, and Marie Morris, "Gaps in Doctor-Patient Communication: Patients' Response to Medical Advice," The New England Journal of Medicine 280 (March 1969): 535-40.

119
Lebow, "Evaluation of an Outpatient Pediatric Practice," pp. 251-55.

120
Marilyn Bergner et al., "The Sickness Impact Profile: Validation of a Health Status Measure," Medical Care 14 (January 1976): 57-67; Elizabeth Cay et al., "Patient's Assessment of the Result of Surgery for Peptic Ulcer," The Lancet 1 (January 1975): 29-31; John Mitchell et al., "Cholecystectomy Peer Review: Measurement of Four Variables," Medical Care 13 (May 1975): 409-16; and Mushlin et al., "Evaluating Ambulatory Care."

121
Mushlin et al., "Evaluating Ambulatory Care."

122
James Swinehart, "Children's Television Workshop--Feeling Good," in A Survey of Consumer Health Education Programs (Cambridge, Mass.: A.D. Little, Inc. 1976), pp. 38-42.

123
John Farquhar and Nathan Maccoby, "Stanford Heart Disease Prevention Program," in A Survey of Consumer Health Education Programs (Cambridge, Mass.: A.D. Little, Inc. 1976), pp. 97-103.

124
Erwin Montgomery, "Erie County Health Department," in A Survey of Consumer Health Education Programs (Cambridge, Mass.: A.D. Little, Inc. 1976), pp. 56-58.

125
Virginia Caramanica, Ellen Feiler, and Larry Olsen, "Evaluation of the Effects of Performance-Based Teacher Education on the Health Knowledge and Attitudes of Fifth Grade Students," The Journal of School Health 44 (October 1974): 449-55.

126
Harvey Katz and Robert Clanch, "Accuracy of a Home Throat Culture Program: A Study of Parent Participation in Health Care," Pediatrics 53 (May 1974): 961.

127
Michael Whitfield, "Group Health Education in General Practice," Journal of the Royal College of General Practitioners 24 (August 1974): 529-36.

128
Stanley Rosenberg, "Patient Education Leads to Better Care for Heart Patients," Health Services and Mental Health Administration Health Reports 86 (September 1971): 793-802.

129
Lawrence Green, Stanley Werlin and Helen Schauffler, "Research and Demonstration Issues in Self-Care: Measuring the Decline of Mediocentrism," paper presented at the Conference on Self-Care Programs, National Center for Health Services Research, Rockville, Maryland, 25-26 March 1976, pp. 14-15.

130
Whitfield, "Group Health Education," pp. 529-36.

131
Thomas Sharpe and Robert Mikeal, "Patient Compliance with Antibiotic Regimens," American Journal of Hospital Pharmacists 31 (May 1974): 479-84.

132
Marian Siefert, Consumer Participation in Health Care: How It's Working, Human Services Institute for Children and Families, Inc. (May 1975); Jonathan Metsch and James Veney, "Consumer Participation and Social Accountability," Medical Care 14 (April 1976): 283-93; Howard Corbus and R. W. Connell, "The Patient's Needs--Does Anyone Care?," Hospitals 48 (16 January 1974): 46-49.

Appendix A

RESEARCH AGENDA

Suggested research topics are presented in hopes of stimulating the development of a more comprehensive research strategy for health care quality assurance. Research findings should enable policymakers to understand the potential gains in health status and reductions in expenditures that result from quality assurance and rationally allocate funds for the development and operation of health care quality assurance programs.

Research needs fall into three general categories: research to develop more reliable and valid assessment tools to measure the level of quality; research to foster the improvement or assurance of quality, which involves the development of better methods for altering the behavior of both health care providers and consumers; and research to develop better evaluation measures to determine the extent to which resources devoted to quality assurance activities have succeeded in improving the health status of the population.

Research topics are categorized according to the major divisions of the summary in Chapter 1.

GENERAL RESERARCH AND EVALUATION NEEDS

A systematic evaluation of the effectiveness of both federal and privately sponsored health care quality assurance programs should be designed and implemented. The research strategy should include geographic areas with and without quality review programs, as well as areas of otherwise similar characteristics but different types of review. Specific research questions and measurement needs are presented throughout this appendix.

Improved methods are needed to identify and aggregate the effects on health status that result from health care. Summary measures must be developed to relate improvements in health status to the activities or resources involved in producing them, and thus permit an assessment of the additional benefit from continuing medical education, quality assurance, and other activities designed to improve the quality of care.

The systematic accumulation of data to describe current patterns of medical care in all settings (hospital, long-term, and ambulatory) is an important research priority. Special attention should be given to unusual methods of

treatment, the extremes of under- and over-utilization, and the reasons for such variation. This information should be used to estimate current levels of inappropriate care and the margin by which care might reasonably be improved. It would then be possible to determine the required magnitude of quality assurance activites, identify particular patients, providers, or conditions in need of special attention, and design quality assurance mechanisms to meet those needs.

Research is needed to determine the extent to which factors determined by public policy, but outside the process of care, influence the quality of care and health status. Such factors include the availability and accessibility of care, links between levels of care, the comprehensiveness of benefits and reimbursement policies of insurance carriers, and the organizational arrangements in which health care is provided.

Better methods are needed to assess unmet health needs and under-utilization of services so that quality assurance programs can extend their responsibilities to deal with these problems.

Methods are needed to integrate information on care provided in all settings so that quality assessment can be based on all services provided to a person over time.

Alternative data sources are needed to expand the information captured by the minimum data sets for hospital, ambulatory, and long-term care and avoid undue reliance on the medical record. The costs of routinely retrieving such data should be determined, as well as the benefits which accrue from their availability.

Experimental curricula should be developed and tested for courses in health care evaluation for all health care professionals.

Better techniques are needed to determine the impact of quality assurance programs on utilization and cost of medical care. In this regard, several specific studies are needed, as listed below.

Factors which affect changes in admission rates and length of stay should be analyzed, including existing length of stay, occupancy rate, demand for beds in the facility and elsewhere in the community, provider and consumer characteristics, case mix, and the relationship of revenues to costs. The interrelationships among these factors may suggest areas for concentration in quality or utilization review.

Factors affecting the effectiveness of quality assurance systems should be delineated and their relative contributions assessed. Factors may include: methods of review, corrective action programs, existing levels of quality, the influence of discharge planning, availability of appropriate alternative care, peer and community pressure, and the role of planning, rate setting, and monitoring agencies.

Better methods must be developed to estimate total costs and unit costs for quality assurance activities by function and activity, including costs of services obtained gratis or below true costs. Better methods are needed to allocate joint costs and to measure work units required by management for purposes in addition to quality assurance.

The relative cost and effectiveness of various quality assessment techniques applied to different provider and consumer groups should be assessed, including: prior authorization and second opinions; targeted reviews determined on the basis of provider, patient, and diagnosis; and corrective action programs (singly or in combination) for both consumer and provider.

Better methods are needed to estimate societal savings from quality reviews, based on capital expenditures avoided and other deterrent effects.

Better methods are needed to estimate bed days saved from both admissions denied and length of stay reduced, which take into account:

- cost of alternative care required as a result of either admission denials or reductions of length of stay;
- short-term and long-term changes in per diem associated with: changes in occupancy rates, by initial rate and size of change; level of per diem; proportion of variable costs to total costs; type of facility and organization; amount of revenues in excess of costs; population changes within a geographic area; and characteristics of outside authorities, such as planning and rate-setting agencies;
- short-term and long-term community effects from interhospital shifts, based on case studies and simulations; and
- capital expenditures avoided.

The assumptions regarding incentives for hospitals to conduct meaningful utilization review programs should be examined to determine whether new incentive arrangements should be developed and tested.

Analyses of the range of costs for hospital PSRO activities should be conducted and related to the effectiveness of review. The manner in which costs are reported before and after hospitals affiliate with PSROs deserves special attention.

The cost and cost-effectiveness of different arrangements for delegating PSRO review requirements to hospitals should be determined, including fully delegated hospitals, partially delegated hospitals, and non-delegated hospitals, taking into consideration both the type of review which is delegated (concurrent, medical care evaluations, or profile analysis) and the review personnel which are delegated (physician advisors or review coordinators).

Criteria should be developed for categorizing successful and unsuccessful MCEs and isolating factors associated with success, so that more effective MCEs may evolve. Data bases must be developed to describe current MCEs, so that a more definitive, future assessment of effectiveness can be made.

A wide range of innovation and evaluation should be encouraged. The effectiveness of concurrent and prospective MCEs that permit direct intervention in the process of care where warranted should be tested. The relative merits of areawide MCEs, as opposed to individual hospital-based MCEs, should be assessed. This will require the resolution of an apparent dilemma. The success of MCEs has been said to rest on medical staff involvement in selecting topics, establishing criteria, and reviewing the results. Yet, without the involvement of an external monitor, such efforts could be self-serving. Experimentation with a mix of internally and externally initiated MCEs may result in an optimal balance.

ASSESSMENT OF HEALTH OUTCOMES

Better measures for assessing health outcomes in terms of both health status and patient satisfaction should be developed. Proxy (substitute) outcome measures are needed, such as immunization levels, as well as proximate or intermediate outcomes, which occur closer in time to the provision of care than end-result outcome measures.

The relationship between process, intermediate outcome, and final outcome measures should be established.

Special studies are needed to develop and evaluate simplified methods for including outcome assessments in the routine PSRO review requirements.

Additional research to establish the natural history of diseases and the efficacy of medical procedures and therapies should be funded. For research findings to be useful in quality assessment, determinations of efficacy should be made under average, as well as ideal, treatment situations at various points in time and should include a broad range of outcome measures. As an initial step, a review of current knowledge of the efficacy of common medical procedures should be conducted to assist in establishing research priorities.

The multiple factors that influence patient outcome and health status should be better specified. To accomplish this, undesirable outcomes could be identified in a large population and traced backwards through the process of care, using record reviews, interviews of patients and providers, and other techniques, to isolate reasons for poor outcome. Reasons attributable to the medical care process should be considered in designing medical care and quality assurance programs.

Experimental projects in which patients and physicians jointly establish outcome objectives for patient care should be conducted in order to determine

the extent to which patient involvement influences patient satisfaction and health.

AMBULATORY CARE

Probability sampling techniques must be developed for ambulatory quality assessment based on claims review, so that review can focus on patients and providers who fall at the extremes of distributions of care patterns and at the same time give estimates of the broader spectrum of care provided to the total population.

In a computerized ambulatory claims review system, the costs and effectiveness of different screens and rejection rates should be analyzed using: only physician claims; physician and prescription claims; physician, prescription, and laboratory claims; all ambulatory claims; non-physician reviewers; physician reviewers; and both non-physician and physician reviewers.

Methods for supplementing information on the ambulatory claim form should be developed and tested, using the Minimum Ambulatory Care Data Set as a base. One project should test the value of diagnostic, patient, and laboratory registries to facilitate problem identification over time.

Quality assessment techniques which appropriately address the unique aspects of primary ambulatory care should be developed. This requires attention to classification of signs and symptoms, rather than diagnoses. Clinical skills should be assessed, including elicitation of signs and symptoms and their history, performance of a physical exam, the synthesis of information into recommendations for care, and determination of the appropriate point for referral. Techniques for assessing the coordination of care for a single individual over time should also be developed, since the coordination function is one of the key components of primary care.

LONG-TERM CARE

Demonstration projects to create community-based long-term care quality assurance programs, as described in the body of this report, should be funded and evaluated. They should include representatives of all groups and facilities involved in providing long-term care. Review should emphasize functional assessments.

The proposed Minimum Data Set for Long-Term Care should be tested and evaluated. Developmental work is needed to further refine the definitions for mental functioning, social functioning, certain aspects of physical functioning, and the events or reasons for use of services other than diagnoses.

Experimental reimbursement demonstrations should be funded to test reimbursement policies that provide incentives to improve the appropriateness

and quality of long-term care. Reimbursement based on capitation might enable the individual patient to move from one level of care to another without being penalized. Alternatively, facility reimbursement rates based on the usual mix of patients, rather than specific patients, might permit patients to be moved from one level of care to another, depending on their conditions.

Longitudinal research is needed to determine the effect of the availability of different long-term care supportive services on patient outcome. Comparable groups of persons receiving different combinations of long-term care services should be evaluated to determine whether outcomes achieved are similar and at what relative costs. The influence of state Medicaid regulations and benefits on quality of long-term care should be assessed.

More basic research is needed to develop more appropriate techniques for quality assessment that consider both the health service and quality of living aspects of long-term care.

IMPLICATIONS FOR PROVIDER PERFORMANCE

Extensive research is needed to devise methods for encouraging improvements in patient care, once deficiencies are identified. Relevant literature from the social sciences, as well as from medical education, should be utilized. Existing quality deficiencies should be categorized to assist in determining the reasons for their occurrence and the design of appropriate corrective actions. All methods for improvement should be carefully evaluated to determine the extent to which they result in lasting behavior change.

Factors associated with effective continuing medical education should be identified, so that more successful programs can be developed.

Hypotheses about optimal learning conditions in other fields should be further explored in medical settings. Research on the diffusion of medical information may identify potential points of intervention to hasten the process of information exchange.

Different methods for informing physicians about instances in which their care differs from local norms should be evaluated, including simple unstructured feedback of information, a more targeted response concentrating on particular areas, or the provision of incentives for review and change. The reasons for failure to change should be explored.

The influence of the organization of health care resources on quality needs detailed analysis. The impact of working arrangements which make performance more visible and facilitate the sharing of information should be evaluated. The potential for informal learning in medical practice should be examined.

For instances in which clearly inappropriate care is identified and behavior does not change, sanctions which are less drastic than permanent loss of licensure may be more readily applied. Experimentation with intermediate

sanctions should be conducted, including temporary curtailment of privileges, licensing with restrictions on specified areas of practice, mandatory supervision of medical practice, remedial education, or curtailment of privileges for certain procedures (perhaps surgical) which are seldom performed.

Demonstrations should test the effectiveness of equipping PSROs with a wider range of sanctions for clearly inappropriate behavior, including more direct links with licensing bodies or perhaps authorizing the PSRO to remove a license with due cause.

The feasibility and effectiveness of publicizing instances of persistently poor quality by individual practitioners in public media should be explored.

CONSUMER INVOLVEMENT IN QUALITY ASSURANCE

Additional work is needed to identify dimensions of health care that are important from the consumers' perspective, which can then be incorporated into valid and reliable instruments for assessing patient expectations and satisfaction. Similarly, additional work is needed to relate expectations and satisfaction to compliance with medical instructions and to health outcome.

Experimental quality assurance programs should include consumer or patient boards to hear patient complaints and evaluate their validity and causes. The use of patient questionnaires in assessing quality should be explored. Patient expectations upon seeking care might be determined and used as the basis for providing patient education and instituting treatment; the influence of expectations on compliance and outcome could then be determined. A more direct involvement of consumers with providers in assessing the quality of care should be tested.

Additional research is needed to identify factors associated with effective health education. Attention should be given to the effect of alternative media, differing levels of patient and family involvement, the duration of behavior change and whether reinforcement is needed, the potential contribution of motivational research, and patient factors which may influence effectiveness, such as emotional state, demographic characteristics, and health status. Different approaches may be required for different patient conditions, ranging from preventive care to acute illnesses and chronic conditions.

In elementary and secondary schools, experimental health education programs should be incorporated in the basic curricula. The influence on the health behavior of students and adults with whom they have contact should be evaluated.

Analyses are needed of the decision-making processes by which a consumer elects to adopt a healthful lifestyle, seek appropriate medical care, or comply with medical instructions.

The manner in which the American lifestyle may contribute to national health problems should be examined so that the feasibility of encouraging healthful habits in a society that simultaneously encourages unhealthful habits might be better analyzed.

The experiential factors in being sick should be examined so that factors which induce unnecessary stress might be reduced in quality medical care.

Because the treatment process by definition involves a health care provider, additional research is needed to explore the psycho-social perspective of the provider and, in particular, to identify factors associated with provider satisfaction or stress. The influence of patients' mannerisms and conduct on physician behavior should be further explored. Greater understanding of these factors may improve the patient-provider relationship and health outcomes.

Changes in the content of the medical curriculum and inclusion of material about the relationship between patient and provider should be evaluated. Alternative models of the patient-physician relationship should be tested to determine whether certain models are more or less appropriate for particular patients or conditions.

Opportunities in existing legislative requirements to further health education should be exploited. On an experimental basis, the requirement for informed consent may provide a unique chance to educate the patient regarding many aspects of his condition, rather than simply obtaining an unthinking agreement to treatment.

The consumer's role in governance and policy-making needs careful documentation and analysis, so that more responsible, comfortable, and effective relationships with health care professionals may evolve.

APPENDIX B

QUALITY ASSURANCE PROGRAMS VISITED

Bethesda Lutheran Medical Center
St. Paul, Minnesota

Foundation for Health Care Evaluation
Minneapolis, Minnesota

Colorado Foundation for Medical Care
Denver, Colorado

Utah Professional Standards Review Organization
Salt Lake City, Utah

Multnomah Foundation for Medical Care
Portland, Oregon

Medical Care Foundation of Sacramento
Sacramento, California

Foundation for Medical Care of San Joaquin
Stockton, California

San Joaquin Area Professional Standards Review Organization
Stockton, California

The Permanente Medical Group
Oakland, California

Kaiser Foundation Health Plan, Inc.
Los Angeles, California

University of California, Los Angeles - EMCRO
Los Angeles, California

Indian Health Service
Tucson, Arizona

State Department of Public Welfare
Austin, Texas

Overlook Hospital
Summit, New Jersey

The Mount Sinai Hospital
New York, New York

Columbia Medical Plan
Columbia, Maryland

National Capital Medical Foundation
Washington, D. C.

APPENDIX C

DESCRIPTORS OF QUALITY REVIEW SYSTEMS

DESCRIPTION OF QUALITY REVIEW SYSTEM (to be obtained through written material and telephone conversations in advance of potential site visit):

I. Origins and Summary of Review System

A. General objectives and goals

B. Groups, events and motivations stimulating interest in quality assurance and reasons for selecting the chosen approach to review (Note involvement of health professionals, administrators, third parties, and consumers.)

C. Dates

1. Date developmental activities began

2. Date on which review activities were ongoing on a routine basis

II. Structure of the System

A. Sponsorship, administrative unit, and financial support (developmental and operational)

B. Inter-relationships between the review system and involved groups or parties external to the system (Note specific involvement of consumers, public agencies, or other persons external to the program under review.

C. Scope of system

1. Population variables

- Geographical or institutional base

- Type of population included

- Extent to which review focuses on a population of potential users; questions of access, non-utilization, and under-utilization; and a system of health care beyond the immediate episode of illness

2. Provider variables

- Single vs. multiple institutions

- Numbers and types of providers included

D. Organization chart

III. Review Process

A. Types of health care problems included

B. Unit of analysis

C. Types of review

D. Criteria for assessment

E. Data requirements (including confidentiality measures and requirements)

F. Corrective action

1. Mechanisms

2. Process for notification and appeals

3. Monitoring methods

G. General description of review process

1. Personnel involved and their responsibilities, including specific reference to involvement of patient/consumers

2. Summary of the process and flow of information

H. Cost of conducting review

IV. Results

A. Procedures to assess attainment of goals and methods for revising goals

B. Evidence of goal attainment

1. Impressions and anecdotes

2. Numbers of occasions in which further review appeared warranted on the basis of initial screening

3. Numbers and types of occasions where corrective action was instituted

4. Changes in aggregate utilization and other statistics

5. Other evidence of impact or results of special studies

6. Cost-effectiveness

C. Awareness of, and reactions to the review system on the part of patient/consumers, public agencies, and physicians outside the administrative structure of the program

V. Long-Range Implications

A. Responsiveness to potential need for change brought about through:

1. Increased scientific knowledge and changing medical practice

2. Social and economic needs

B. Expectations of future status 2-5 years from now

C. Underlying problems noted by the program (either generic or specific to the setting) which require further deliberation; examples of issues that they would have handled differently if they had the chance

SUBJECTIVE ASSESSMENT BY SITE VISITORS

I. Current status and accomplishments to date

A. Impressions and anecdotes

II. Unique characteristics which may be influential in determing the system's effectiveness

III. Unresolved issues (administrative, substantive/methodological, policy) within system

IV. Required follow-up

V. Unanticipated factors which may have influenced IOM's ability to get information

A. On-site

B. Follow-up

APPENDIX D

A Comparison of Three Approaches to Medical Care Evaluation Studies

	PSRO	JCAH	Patient Care Audit
Definition	An Essential component of the PSRO system through which the quality and utilization of services is assessed for groups of patients, usually retrospectively, in order to identify problems in the process and outcome of that care, so that improvement programs may be directed at the causes of the problems.	The evaluation of the quality of patient care based on explicit and measurable outcome criteria that can be applied to significant numbers of patient records for the purpose of documenting and improving provider performance and overall quality of care.	A "needs assessment" mechanism which provides an objective basis for CME programming and also assesses the quality of patient care and assures that any deficiencies which may occur will be identified, analyzed, and rectified.
Purpose	To assure that health care services are appropriate to the patient's needs and are of optimal quality and that health care organization and administration support the timely provision of care.	To demonstrate that the quality of care provided to all patients is consistently optimal by continuously evaluating it through reliable and valid measures. Where the quality of patient care is shown to be less than optimal, improvement in quality shall be demonstrated.	To further the efforts of physicians toward continuously improving the quality of patient care by encouraging and assisting the staff of each hospital to develop a simple patient care audit process linked to continuing medical education.
Type of Criteria	Process and outcome	Predominately outcome	Process and outcome
Sponsor	Department of Health, Education, and Welfare	Joint Commission on Accreditation of Hospitals	California Medical Association and Hospital Association

Number of Audits Required Each Year	Hospitals with less than 2,500 admissions -4 2,500 - 4,999 -6 5,000 - 9,999 -8 10,000 - 19,999 -10 20,000 or more -12	Hospitals with less than 2,500 admissions -4 2,500 - 4,999 -6 5,000 - 9,999 -8 10,000 - 19,999 -10 20,000 or more -12	Must meet JCAH and PSRO requirements
Requirement of an acceptable MCE	1) Focus on a well defined topic 2) Develop explicit objectives 3) Utilize written criteria and standards 4) Collect data on a sample of all patients in an institution 5) Analyze any discrepancies between the written criteria and actual health care practices 6) Develop written recommendations to improve the quality of care and promote more effective and efficient utilization of facilities and services 7) Develop a plan for follow-up evaluation to determine what changes have occurred 8) Complete the follow-up evaluation within one year of the original study.	1) Establish valid criteria that permit objective review of the quality of care provided all patients 2) Measure actual practice against the criteria 3) Analyze results of measurement 4) Take action to correct the problems identified 5) Follow-up corrective action 6) Report results of patient care evaluation	1) Select an audit topic 2) Set criteria 3) Ratify criteria 4) Review charts 5) Identify variations 6) Analyze problems 7) Develop solutions and remedial actions 8) Implement the solution 9) Evaluate and re-audit
Sanctions	PSRO may provide technical assistance or rescind delegation of the MCE study function	Results must be used in reappointment and re-privileging of medical staff members	Emphasizes educational value of auditing

APPENDIX E

Recommended Uniform Basic Data Sets*

Ambulatory Care Encounter Data Set	Proposed Long-Term Care Data Set
Demographic Data	
Name and unique ID number	Name and/or unique ID number
Address and ZIP code	Address and ZIP code or census tract a. Latest non-institutional domicile b. Current domicile (if different)
--	Living arrangements a. Type of domicile b. Availability of able and willing personal "caregiver"
Date of birth	Date of birth
Sex	Sex
--	Current marital status
--	Race/ethnicity
Individual Attributes	
Reason for enounter (principal problems, complaints, symptoms in patient's own words)	Events/reasons for use of services other than diagnoses (as determined by responsible agency)
Principal and other diagnoses and/or problems occasioning current encounter or requiring treatment	Principal and other diagnoses occasioning current use of services or influencing current status
Findings	Physical impairments
--	Physical functioning/disability
--	Mental functioning/disability
--	Social functioning/disability
--	Performance of independent living activities
--	Distress/mood/pain/self-perception

APPENDIX E

Ambulatory Care Encounter Data Set	Proposed Long-Term Care Data Set
Service and Administrative Elements	
Place of encounter by type (office, clinic or center, OPD, ER, other)	Principal facility/agency/provider ID and/or unique number
Provider name, professional address, and unique ID number	Last principal provider ID (within 12 months)
Professional category and specialty of provider	--
Encounter date	Admission/entry date (when appropriate)
--	Discharge/termination date (when appropriate)
--	Assessment date
All services and procedures performed or ordered during encounter	Category of services provided since last assessment date or currently (preventive, acute episodic, evaluative, rehabilitative, supportive)
Disposition	Disposition (when appropriate)
Expected source of payment	Sources of payment (medical insurance, social services, and income maintenance)
Itemized charges	Costs/charges/prices per unit or episode of services

* Jane H. Murnaghan, "Review of the (Long-Term Health Care Data) Conference Proceedings," Medical Care 14 Supplement (May 1976): 16.