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PRACTICE GUIDELINES

Overview of Agency for Health Care Policy and Research Efforts

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to report on clinical practice guidelines sponsored by the Agency for Health Care Policy and Research (AHCPR). In 1989, the Congress created AHCPR within the Public Health Service as the federal government's focal point for effectiveness and outcomes research.[1] As part of this effort, the Congress directed the agency to sponsor the development of clinical practice guidelines. Ideally, the widespread use of clinical practice guidelines can optimize care, eliminate waste, and avoid unnecessary procedures. These guidelines are designed to help medical practitioners and patients make decisions about prevention, diagnosis, and treatment of specific clinical conditions. Typically, AHCPR guideline development entails a consensus of expert medical opinion, a synthesis of current scientific evidence, or a combination of these approaches. The guidance is disseminated with the understanding that the local medical community will tailor it to meet their particular practice needs and the individual circumstances of patients.

In light of congressional concerns regarding AHCPR, you asked us to examine the efficiency and effectiveness of the agency's clinical practice guideline efforts. My remarks today are based on our ongoing work on the use of AHCPR's clinical practice guidelines to improve health care quality and control costs. We contacted numerous physician organizations, managed care organizations, researchers, and providers to learn of their experiences with AHCPR's guidelines. We also reviewed the agency's legislative and budgetary history, as well as recent studies on AHCPR's practice guidelines.[2]

In brief, we found that during AHCPR's first 5 years, its performance has received mixed reviews from potential users of clinical practice guidelines. On one hand, the agency has demonstrated strengths in the difficult process of guideline development. It has been praised for its use of a rigorous, evidence-based methodology, multidisciplinary panels, and emphasis on health care consumers. On the other hand, however, weaknesses in the guidelines themselves make them not very user-friendly. Specifically, the agency has been criticized for the broadness of the guideline topics selected and the formats in which they are

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[1]The Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) created AHCPR. In addition to guidelines, other agency activities include funding health outcomes research and rural health demonstration projects, providing technical assistance to states involved in health care reform, and conducting the National Medical Expenditure Survey.

[2]Studies reviewed include those issued by the Institute of Medicine, the Office of Technology Assessment, the Physician Payment Review Commission, and the George Washington University.

published. The agency is aware of these criticisms and plans to modify its guideline development efforts to improve the timeliness and presentation of its clinical practice guidelines.

For these and other reasons, questions remain as to the extent to which health care practitioners implement the guidelines sponsored by AHCPR. Our discussions with primary care physicians indicate that AHCPR's earliest guidelines are not widely used. This may be changing, however, as the guidelines become more well-known and accepted. Also, medical directors of health plans that create their own guidelines told us that AHCPR products are used regularly by their guideline-drafting committees. To better track the use of its guidelines, the agency has recently started to collect information from user groups. Some of these groups have claimed cost savings and improved patient outcomes from implementing the guidelines.

BACKGROUND

Today, there is a wide range of potential developers and users of clinical practice guidelines. Individual physicians, nurses, health plans, insurers, and regulators have become increasingly interested in using guidelines to improve patient outcomes, control costs, decrease liability, and reduce variation in physician practice patterns. They may choose from over 24,000 guidelines developed by over 75 organizations.[3] In addition to physician organizations and private research groups, there are multiple federal sources of guidelines, including the U.S. Preventive Services Task Force, the National Institutes of Health, and the Centers for Disease Control and Prevention.[4]

To date, AHCPR has sponsored the development of 16 clinical practice guidelines, ranging from preventing pressure ulcers in adults to post-stroke rehabilitation, and 6 more are under way (see app. I). The agency organizes a panel of 15 to 20 clinicians and experts to develop each of its guidelines. AHCPR's clinical practice guidelines have taken between 18 to 42 months to complete depending on the scope and complexity of the topic. AHCPR's contribution to the guideline development process is primarily financial and administrative; agency officials do not participate

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[3]Questions have been raised about whether topics selected by AHCPR duplicate guideline efforts of other public and private groups. However, some experts believe that duplication of topics reflects concerns that guidelines may vary in quality or need to be updated.

[4]The U.S. Preventive Services Task Force issues guidelines that focus on preventive care, the National Institutes of Health publishes consensus statements on preferred medical practices, and the Centers for Disease Control and Prevention publishes guidelines on public health topics.

in the panel's deliberations or in the writing of the guidelines that it sponsors.

More than 15 million copies of AHCPR's guidelines have been distributed by mail to national and state medical and nursing societies, consumer groups, and other interested parties. The guidelines are also available on-line, through the agency's fax-on-demand service, and on CD-ROM.

AHCPR operates with a budget of about $163 million and a staff of approximately 270 full-time equivalents. Funding for its clinical practice guideline development activities is estimated to be $6 million or 3 percent of its total budget per annum. This amount may understate the total resources devoted to clinical practice guideline activities because other separately funded activities indirectly support the guideline effort (see app. II).

AHCPR'S GUIDELINE DEVELOPMENT PROCESS SETS METHODOLOGY STANDARD

We found support for AHCPR's guideline development process. In particular, users had praise for its conduct of extensive literature reviews, the balanced composition of its panels, and the explicit recognition of consumer interests. They contended that the agency is in a unique position to foster unbiased evaluations of the scientific literature and that this role enhances the efficiency of local guideline development efforts.

Developing valid clinical practice guidelines requires in-depth and objective analysis of the scientific evidence on a topic. (Where the scientific evidence is absent or incomplete, the guideline recommendations reflect the professional judgment of panel members and consultants). For example, to develop the guideline on human immunodeficiency virus (HIV) early evaluation and management, the panel had to assess the soundness of all the scientific research written on the topic, which amounted to about 36,000 references. The Office of Technology Assessment estimates that AHCPR's literature reviews have taken up to 9 months and have cost up to $235,000. Because this is such a time-consuming and resource-intensive process, few private organizations that develop clinical practice guidelines can undertake such an exhaustive review.

AHCPR's methodology for guideline development is also perceived as being more open and less biased than the process in private organizations because each panel represents broad interests.[5] Panels are composed of experts from diverse

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[5]In spite of its efforts to be relatively inclusive, AHCPR's guidelines are subject to criticism by affected parties. For example, some eye surgeons disagreed with AHCPR's cataract

backgrounds and clinical expertise and also include consumer representatives. For example, the panel that developed the low back pain guideline included orthopedists, osteopaths, an emergency medicine physician, a radiologist, a chiropractor, an occupational health nurse, a physical therapist, a community health nurse, a physiatrist, and a patient representative. In addition, the agency also has the unique ability to attract nationally recognized experts who can serve as opinion leaders to encourage acceptance of the guidelines.

In contrast, private groups that develop clinical practice guidelines, such as physician organizations, generally limit participation in guideline development to physicians only. A survey of internists suggested that confidence in a guideline is more likely if produced by their physician organization.[6] However, some health plan representatives told us that they would be concerned about using a guideline developed by these groups because they perceive a potential conflict of interest.

Another notable feature of AHCPR's efforts is its emphasis on consumers. Few private organizations involve consumers of health care services in the guideline development process or consider them as guideline users. In contrast, AHCPR includes a consumer representative on each panel that develops guidelines.[7] Furthermore, AHCPR publishes a patient guide on each topic that supplies consumers with information about the medical condition, treatment alternatives and their risks and benefits, and suggests questions to discuss with physicians.

While there is general agreement on the high quality of the guideline development process, there is some criticism regarding its efficiency and expense. As noted earlier, guideline development is a resource-intensive and time-consuming process. However, establishing select panels for each guideline results in a loss of expertise in performing the tasks associated with guideline

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guideline recommendation that a patient's level of visual dysfunction rather than the presence of a cataract alone should dictate the need for surgery. In the case of AHCPR's low back pain guideline, a company that manufacturers a device that is used in back fusion surgery disagreed with the recommendation that most uncomplicated back pain did not require surgery.

[6]Sean R. Tunis and others, "Internists' Attitudes About Clinical Practice Guidelines," Annals of Internal Medicine, Vol. 120, No. 11 (June 1, 1994), pp. 956-63.

[7]AHCPR publishes a request for consumer representatives in the Federal Register. Representatives are selected based in part on their familiarity with the guideline topic and whether they or a close relative have the condition or disease.

development. The assessment of the scientific literature is complex and expensive and requires experience and skill to perform well. By having inexperienced members convene for each guideline, the panel process compromises timeliness and cost-effectiveness.

GUIDELINES ARE NOT USER-FRIENDLY

Criticisms have been voiced that the guidelines generated in the AHCPR process are not user-friendly and therefore difficult to implement. Potential users have noted problems with the topics selected, the readability of the information presented, and the discussion of treatment options. These and other impediments may contribute to the slow adoption of AHCPR guidelines into medical practice.

Clinical practice guideline experts and a variety of users report that AHCPR's topics are too broad and often result in guidelines that are too long, difficult to follow, and vague. In its 1995 report, the Institute of Medicine noted that focusing on more narrow topics would better address the problems of most interest to clinicians and other users, and would ease the implementation and evaluation of guideline use.[8] For example, the agency might develop a clinical practice guideline on the pharmacological management of a heart attack rather than a heart attack in general. Similarly, a 1995 George Washington University study found that because AHCPR's practice guideline topics focus on broad medical conditions rather than on specific medical services, they generate longer, more complex issues to be dealt with in the guidelines.[9] In fact, the length and complexity of the guidelines are one reason physicians do not implement them in their daily practices.

One of the most widely voiced criticisms we heard about AHCPR's clinical practice guidelines was that the texts require too much time to read. One physician told us that it takes about 5 hours to read the long version of a guideline and that the shorter clinician's version (AHCPR's Quick Reference Guide) is not clear by itself. Furthermore, AHCPR's practice guidelines are long in comparison to guidelines developed by other sources. For example, AHCPR's guideline for depression is 2 volumes and 327 pages, while

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[8]Institute of Medicine, Setting Priorities for Clinical Practice Guidelines (Washington, D.C.: National Academy Press, 1995).

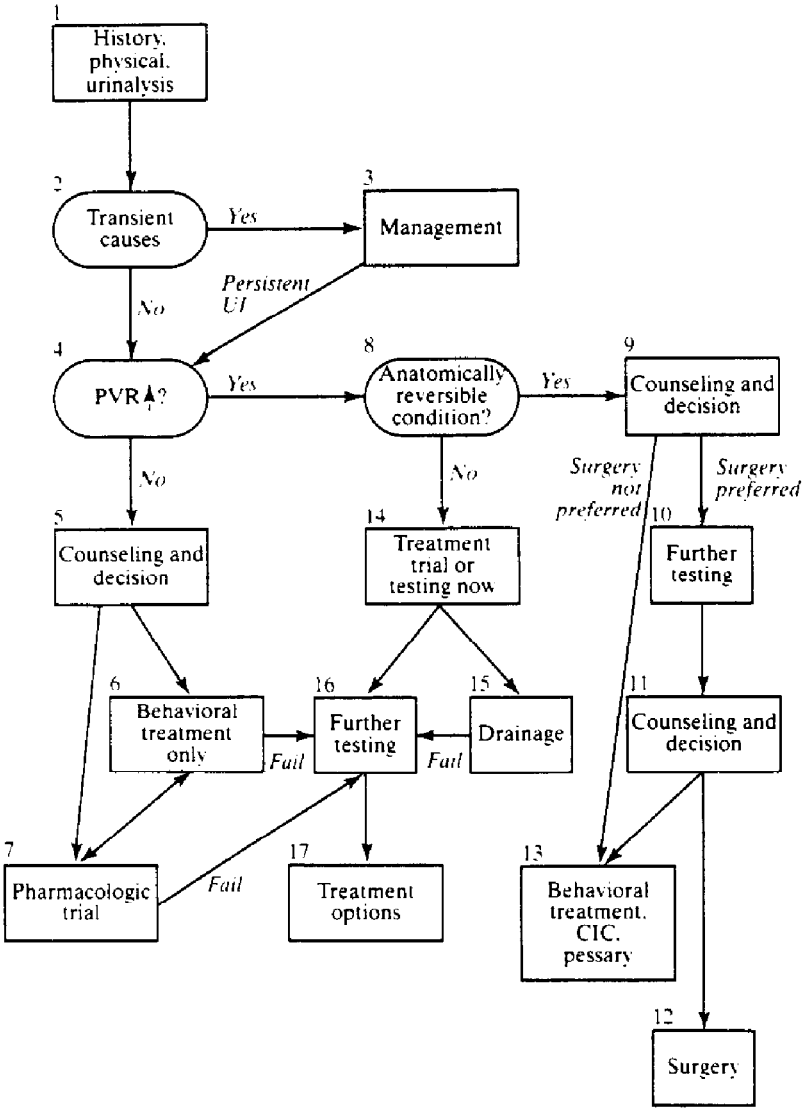
[9]Center for Health Policy Research, Development of Designs for Evaluation of the Process of Clinical Guideline Development (Washington, D.C.: The George Washington University, 1995).

a large health maintenance organization developed a guideline for depression that is 1 volume and 44 pages.[10]

Further complicating their implementation and use, AHCPR's clinical practice guidelines are not always presented in ways that physicians find clear and easy to understand. For example, many physicians prefer graphics, such as algorithms or tables, for the presentation of information, and AHCPR's practice guidelines rely mostly on text. Furthermore, when graphics are used in AHCPR's guidelines, the flow of information, such as from one treatment decision to another, is sometimes confusing. For example, figure 1 shows a flow diagram from AHCPR's urinary incontinence guideline.

[10]Jonathan Brown and others, "The Paradox of Guideline Implementation: How AHCPR's Depression Guideline Was Adopted at Kaiser Permanente Northwest Region," Journal on Quality Improvement, Vol. 21, No. 1 (Jan. 1995), pp. 5-21.

Figure 1: Excerpt from AHCPR's Guideline on Urinary Incontinence in Adults



Note: The numbers in the figure correspond to paragraphs in the accompanying clinical practice guideline text.

Source: AHCPR, Urinary Incontinence in Adults, March 1992.

We also learned that the agency's guideline recommendations are sometimes confusing to providers because they are not explicit. For example, the otitis media practice guideline states that "tympanotomy tubes are to be inserted in a child's ears to manage bilateral otitis media with effusion that has lasted a total of 4 to 6 months." The word "total" can be interpreted in two ways: some might interpret it to mean the child has an intermittent problem that adds up to 4 to 6 months; others interpret it to mean 4 to 6 months of a continuous problem.

Another criticism of AHCPR's guidelines is that the guidelines generally do not include specific information about the cost-effectiveness of alternative therapeutic approaches in their guideline recommendations. For example, AHCPR's urinary incontinence guideline recommended that biofeedback techniques be considered as treatment alternatives to surgery. However, the guideline did not discuss the cost savings that might be realized with biofeedback techniques. This information is important to many guideline users, especially managed care organizations. Harvard Community Health Plan, for example, always considers cost-effectiveness during its guideline development process. In its 1992 report, the Institute of Medicine recommended that a clinical practice guideline should include information on both the health and cost implications of alternative treatment strategies.[11]

AHCPR PLANS TO STRENGTHEN GUIDELINE PRODUCTS AND PROCEDURES

AHCPR plans several changes to its clinical practice guidelines and the development process. In particular, the agency intends to sponsor more narrowly focused guideline topics and to streamline its development process. Through these changes, AHCPR hopes to make its guideline development process more efficient and its guidelines more user-friendly. The agency's proposed changes include

-- modifying guideline topic selection so that topics are of greater value, have sufficient scientific evidence to minimize reliance on expert opinion, and are easier to implement;

-- developing more user-friendly guidelines by making them shorter and clearer, including specifics for implementation in clinical settings, and incorporating information on costs of treatment options;

-- establishing standing guideline development panels on several broad areas of medicine (core panel members will focus on the

[11]Institute of Medicine, Guidelines for Clinical Practice: From Development to Use, 1992.

evaluation and analysis of evidence; they will be supplemented by specialists as necessary); and

-- expanding public/private partnerships for the development and dissemination of new practice guidelines (private organizations could include disease associations, pharmaceutical companies, or managed care organizations).

ANECDOTAL EVIDENCE SUGGESTS AHCPR'S GUIDELINES MAY BE BENEFICIAL

Anecdotal evidence indicates that providers who implement AHCPR's clinical practice guidelines improve patient outcomes and achieve cost savings. The following are examples:

-- Preliminary data from one peer review organization showed a 75-percent reduction in prostate surgery and a savings of more than $1.3 million in five hospitals after educating providers and patients about AHCPR's guideline alternatives.

-- A health care system that implemented AHCPR's pressure ulcer prevention guideline for 6 months reported savings of $240,000 in one California hospital.

-- A California medical center reported that AHCPR's pain management guideline helped decrease the average length of stay for chest surgery patients by 5 to 7 days.

-- One year after adopting AHCPR's urinary incontinence and pressure ulcer guidelines, a Tennessee nursing home reported lowering the number of incontinent patients from 52 to 18 and those with pressure ulcers from 14 to 5.

-- A home health care agency in Omaha reported that primary care physicians are more aggressively identifying and treating depression in homebound, elderly patients because of AHCPR's depression guideline.

-- A training center in New Orleans reported using AHCPR's HIV guideline to train physicians and nurses in Louisiana, Mississippi, and Arkansas to treat patients in a primary care setting rather than a more costly setting.

Health care experts caution that not all clinical practice guidelines result in cost savings and could increase costs. For example, officials in North Carolina reported increased costs when the state adopted AHCPR's recommendation to test all newborns for sickle cell disease. While some health care analysts believe that widespread use of clinical practice guidelines may not initially decrease health care spending, others contend that over time, more effective health care through implementation of guidelines will slow the rate of health care cost growth.

At your request, we are currently conducting a study to determine if and how managed care organizations use clinical practice guidelines and how AHCPR's future guidelines can best serve this segment of the health care market. We expect to report the results of this work in early 1996.

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Mr. Chairman, this concludes my formal remarks. I would be happy to answer any questions from you and other members of the committee.

For more information on this testimony, please contact Rosamond Katz, Assistant Director, at (202) 512-7148. Other major contributors included Mary Ann Curran, Jennifer Grover, Donna Bulvin, and Anita Roth.

APPENDIX I

AHCPR'S CLINICAL PRACTICE GUIDELINES PUBLISHED AND UNDER DEVELOPMENT

Published	Date
Acute Pain Management: Operative or Medical Procedures and Trauma	March 1992
Urinary Incontinence in Adults	March 1992
Pressure Ulcers in Adults: Prediction and Prevention	May 1992
Cataracts in Adults: Management of Functional Impairment	February 1993
Depression in Primary Care: Volume I: Detection and Diagnosis	
Volume II: Treatment of Major Depression	April 1993
Sickle Cell Disease: Screening, Diagnosis, Management and Counseling in Newborns and Infants	April 1993
Evaluation and Management of Early HIV Infection	January 1994
Benign Prostatic Hyperplasia: Diagnosis and Treatment	February 1994
Management of Cancer Pain	March 1994
Unstable Angina: Diagnosis and Management	March 1994
Heart Failure: Evaluation and Care of Patients with Left Ventricular Systolic Dysfunction	June 1994
Otitis Media with Effusion in Young Children	July 1994
Quality Determinants of Mammography	October 1994
Low Back Problems in Adults	December 1994
Treatment of Pressure Ulcers	December 1994
Post Stroke Rehabilitation	May 1995

Under Development

Cardiac Rehabilitation
Recognition and Initial Assessment of Alzheimer's and Related Dementias
Smoking Prevention and Cessation
Screening for Colorectal Cancer
Chronic Pain: Headache
Urinary Incontinence in Adults - Update

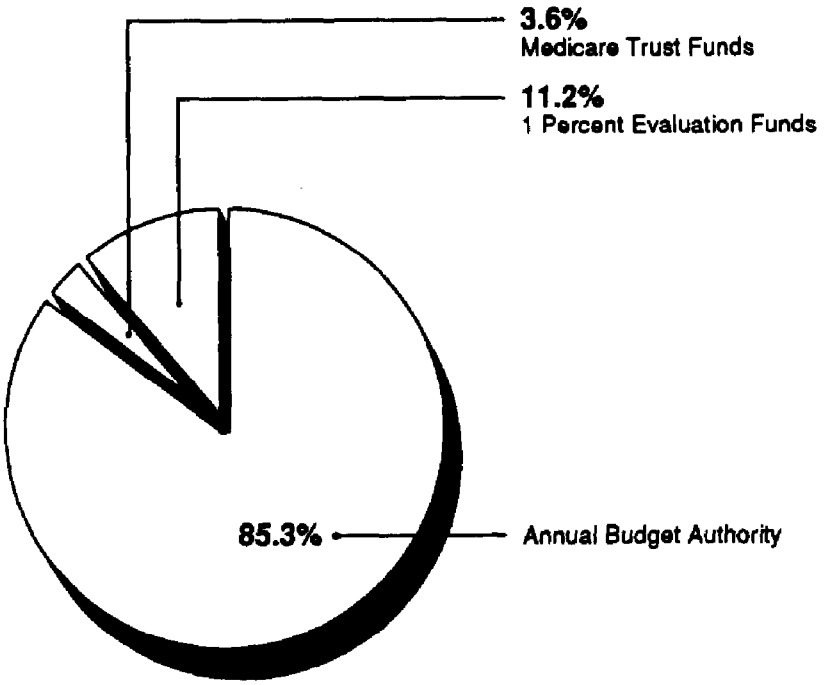
AHCPR'S FISCAL YEAR 1995 BUDGET

AHCPR was created by the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) as part of the Public Health Service. AHCPR's activities are concentrated in three areas. First, AHCPR awards numerous grants and contracts for research on health care costs, quality, and access issues. Second, it collects and analyzes data on policy issues of immediate concern to health policymakers, most particularly for the National Medical Expenditure Survey (NMES), which provides information on the availability of health care and health care expenditures. Finally, the agency supports a variety of activities within its Medical Treatment Effectiveness Program, including the development of clinical practice guidelines.

In fiscal year 1995, AHCPR had a staff of 271 full-time equivalents, and a total budget of $163 million,[12] provided through three sources. The agency receives the majority of its funding through an annual budget authority. This amount is supplemented with Medicare trust funds and a portion of 1-percent evaluation funds from the agencies of the Public Health Service that receive appropriations. In fiscal year 1995, the agency's budget authority was $139 million. AHCPR received an additional $5.8 million from the Medicare trust funds to support research relating to the health care needs of the Medicare population. In addition, the agency received $18.2 million from 1-percent evaluation funds to support NMES and other studies. Figure II.1 shows AHCPR's funding sources for fiscal year 1995.

[12]Excludes reimbursements of approximately $9 million and excludes a proposed recision of $3.132 million.

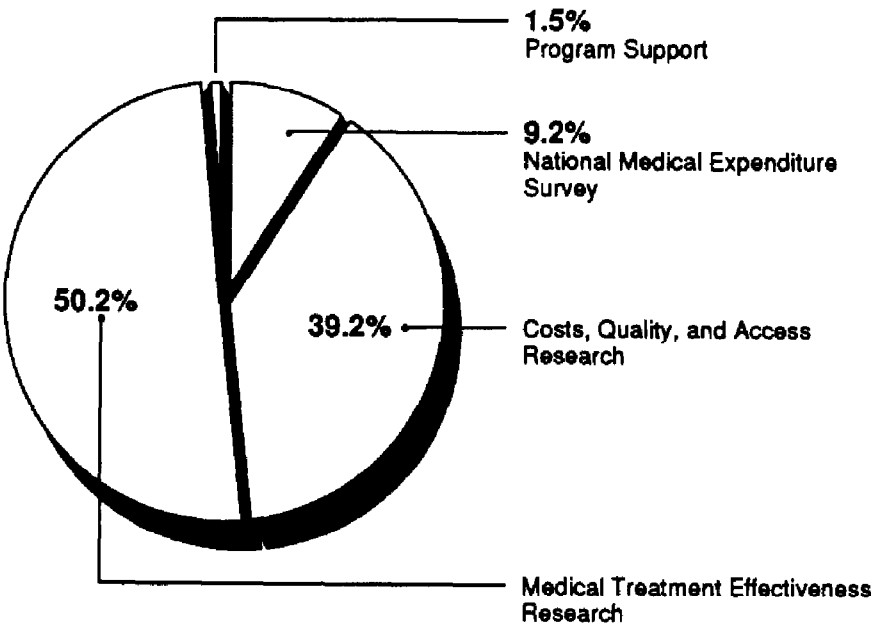
Figure II.1: AHCPR Fiscal Year 1995 Funding Sources



Note: Excludes reimbursements of approximately $9 million and excludes a proposed recision of $3.132 million.

Most of AHCPR's expenditures are made for medical effectiveness research and research on costs, quality, and access. In fiscal year 1995, the agency will spend $15 million on NMES; $64 million on costs, quality, and access research; $82 million on medical treatment effectiveness research; and $2.4 million on program support. Figure II.2 shows AHCPR's expenditures for fiscal year 1995.

Figure II.2: AHCPR Fiscal Year 1995 Expenditures



Most of the agency's expenditures are made in the form of research grants and contracts. In fiscal year 1995, these expenditures are estimated to be $127.1 million. The agency will support an estimated 167 large grants, generally in the amount of $250,000 or more annually. AHCPR will also award 14 small grants, which are usually 1-year grants for about $30,000 each, to new investigators. The agency will support 26 dissertations at about $20,000 to $25,000 each. AHCPR also will support 97 contracts and interagency agreements in fiscal year 1995, which include the clinical practice guideline contracts. Table II.1 shows a summary of the grants and contracts to be supported by the agency in fiscal year 1995.

Table II.1: Grants and Contracts to Be Supported in Fiscal Year 1995

Types of grants and contracts supported	Number supported	Estimated cost
Large grants	167	$72.1 million
Small grants	14	1.0 million
Dissertations	26	0.5 million
Contracts and interagency agreements	97	53.5 million
Total	304	$127.1 million[a]

[a]Estimated dollars; excludes support for research management, and not adjusted for a proposed fiscal year 1995 recision.

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