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Jennifer J. Johnson,

*Deputy Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Health Care Policy and Research

#### Nominations of Outcomes and Effectiveness Research Priority Topics

The Agency for Health Care Policy and Research (AHCPR) is inviting suggestions for priority topics for research related to prevention, diagnosis, treatment and/or management of common diseases and clinical conditions. These suggestions will be considered in AHCPR's plans for future research on the outcomes and effectiveness of health care services. The process AHCPR will employ in establishing priorities and selecting topics for outcomes/effectiveness research is described below.

#### Background

AHCPR is charged under Title IX of the Public Health Service Act (42 U.S.C. 299-299c-6) with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHCPR accomplishes these goals through scientific research that promotes improvements in clinical practice (including the prevention of diseases and other health conditions) and improvements in the organization, financing, and delivery of health care services. Section 1142 of the Social Security Act (42 U.S.C. 1320b-12) enhances and elaborates on AHCPR's program of outcomes and effectiveness research. Outcomes of care and effectiveness research constitutes a major portion of AHCPR's health services research agenda.

#### Outcomes and Effectiveness Research Program

The outcomes and effectiveness research program grew out of awareness of significant unexplained variations in clinical (medical, nursing, and allied health) practice and the inadequacy of scientific evidence to support many common treatments and procedures. Outcomes and effectiveness research encompasses three main areas of emphasis for the prevention, diagnosis, treatment, and management of illness: (1) Determination of the clinical

interventions that are most effective, cost effective, and appropriate; (2) development of methods and data to advance effectiveness research; and (3) dissemination and evaluation of the impact of research findings on clinical practice and outcomes. Other distinctive characteristics of outcomes and effectiveness research include its multidisciplinary nature; use of a variety of research designs (e.g., observational studies, prospective trials, database studies) and analytical methods (e.g., decision analysis, utility analysis, and cost-effectiveness analysis); incorporation of both objective and subjective measures of outcomes; and emphasis on policy relevance.

To date, AHCPR's outcomes and effectiveness research has focused on conditions that meet the following criteria:

- High incidence or prevalence in the general population or in major population subgroups, as defined by age, gender, or ethnicity;
- Controversy or uncertainty about the effectiveness and relative effectiveness of available clinical strategies;
- High cost, whether due to the number of people needing care, high unit cost of care, or high indirect costs;
- Needs, of the Medicare and Medicaid programs; and
- Data available, or readily developed.

In addition, all outcomes and effectiveness research is expected to be:

- Generalizable: Outcomes and effectiveness research is concerned with the outcomes that can be expected in typical patients, receiving care in typical clinical situations, not with outcomes that can be achieved only in selected patients and in controlled clinical situations. Thus, critical features of all outcomes and effectiveness research projects are that the questions have broad applicability and the research designs support wide generalizability of findings.
- Pragmatic: Outcomes and effectiveness research projects address questions that have high clinical and policy significance and are designed with attention to the eventual implementation of findings. They strengthen the science base in ways that can directly contribute to improved patient outcomes and decisionmaking processes (including practice guidelines), and to a more equitable and cost-effective health care system. The usefulness of outcomes and effectiveness research stems, in part, from the requirement that the clinical problems and practices addressed are

common and costly, and from attention to the realities of clinical practice.

- *Patient-Centered:* Outcomes and effectiveness research evaluates health care in terms of outcomes that emphasize the patient's experience and perspective. In addition to survival, morbidity, and complications, outcomes and effectiveness studies consider patient-reported symptom relief, functional capacity, quality of life, satisfaction with care, and economic burden. Demographic, social and cultural characteristics, as well as personal preferences, are important independent variables.

- *Multidisciplinary:* Outcomes and effectiveness research requires theoretical and practical understanding of a wide range of clinical and non-clinical variables that determine the structure, processes, and outcomes of health care. Studies typically involve teams of researchers who bring together the knowledge and methodological expertise of both the clinical and social sciences, plus understanding of the perspectives of patients, providers, and policymakers.

Since 1989, AHCPR has supported significant advances in medical effectiveness research, especially through the set of special projects known as Patient Outcomes Research Teams (PORTs). PORTs are large-scale, 5-year studies designed to determine "what works best" in clinical treatment for common diseases and conditions. PORTs have succeeded in (1) documenting the scientific basis for many common clinical practices, (2) demonstrating the relative benefits of different interventions, and (3) identifying areas for further research. The following clinical conditions addressed by the AHCPR PORT program meet the criteria of being common, costly, and feasible to study:

- Acute Myocardial Infarction
- Ischemic Heart Disease
- Low Back Pain
- Total Knee Replacement
- Hip Fracture and Osteoarthritis
- Low Birth Weight Prevention
- Cataract
- Community-Acquired Pneumonia
- Childbirth
- Schizophrenia
- Stroke Prevention
- Type II Diabetes
- Biliary Tract Disease
- Prostate Disease

In July 1993, AHCPR introduced a new generation of PORT research, known as PORT II. A program announcement inviting applications for PORT IIs was published in the May 13, 1994 "NIH Guide for Grant and

Contracts," Vol. 23, No. 18. Like the original PORTs, PORT IIs are pragmatic, methodologically sophisticated, multidisciplinary projects that focus on patient outcomes for common clinical problems. They differ from the original PORTs by their individualized research strategies and are also distinguished by their expected impact on clinical practice, patient outcomes, and health care policy. PORT IIs focus on the establishment of direct linkages between practice and outcomes and on research methods that facilitate direct comparisons of two or more distinct clinical strategies. Clinical conditions addressed to date by the AHCPR PORT II program include:

- Localized Breast Cancer
- Cardiac Arrhythmia
- End-stage Renal Disease
- Depression
- Prostate Disease
- Infant Dehydration
- Cataract: Preoperative Testing
- Pelvic Inflammatory Disease

In addition to PORTs and PORT IIs, AHCPR has funded approximately 130 other outcomes and effectiveness research clinical studies. For clinical subjects as diverse as AIDS, dental disease, emergency medicine, and cancer, these studies document patterns of practice, describe the natural history of diseases, synthesize the evidence for various clinical strategies, or answer relatively discrete effectiveness questions. Major ongoing program areas focus on pharmaceutical therapy, minority health, and primary care.

#### AHCPR Process for Determining Priority Topics

Topic selection for the original PORT projects was guided by work of the Institute of Medicine (IOM) which was described in the 1990 IOM publication entitled "National Priorities for the Assessment of Clinical Conditions and Medical Technologies." A new process to identify priorities for future outcomes research was discussed at a November, 1995 expert panel meeting. During this meeting, the AHCPR conferred with health services and effectiveness experts, representing multiple disciplines, specialties, and institutions. Alternative approaches for prioritizing topic areas and identification of populations whose major health conditions have not yet been adequately addressed (e.g., young children, the very elderly, women, and ethnic minorities) were considered.

Based on the IOM work and expert discussions, AHCPR has initiated a three stage process for identifying topics:

1. Develop a preliminary list of priority topics and reasons for importance, representing the views of health care providers, insurers, medical and health specialty societies, consumers, and the general public;

2. Convene an expert panel to review and assess the preliminary research priorities and suggested criteria; and

3. Identify which topic areas can be most appropriately addressed using outcomes and effectiveness research methods.

This Notice initiates the first step, that is, a solicitation of topics from health care providers, insurers, health-related societies, consumers, and the public. Written suggestions for research topics that fit within the parameters of AHCPR's outcomes and effectiveness research program are invited.

For each suggestion, the nominee should provide a clear rationale and supporting evidence for the topic's importance and clinical relevance. Responses should be submitted by July 29, 1996 to: Carolyn Clancy, M.D., Acting Director, Center for Outcomes and Effectiveness Research, Agency for Health Care Policy and Research, Suite 605, 2101 East Jefferson Street, Rockville, Maryland 20852. All responses will be available for public inspection at the Center for Outcomes and Effectiveness Research, Telephone (301) 594-1485, weekdays between 8:30 a.m. and 5 p.m. The AHCPR will not reply to individual responses, but will consider all submissions in developing the research priorities.

For further information on the outcomes and effectiveness research program, contact: Carolyn Clancy, M.D., Acting Director, Center for Outcomes and Effectiveness Research, Agency for Health Care Policy and Research, Suite 605, 2101 East Jefferson Street, Rockville, Maryland 20852; Telephone (301) 594-1485.

Dated: May 16, 1996.  
Clifton R. Gaus,  
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## Centers for Disease Control and Prevention

### [ANNOUNCEMENT 648]

#### National Institute for Occupational Safety and Health; Fatality Surveillance and Field Investigations at the State Level Using the NIOSH Fatality Assessment and Control Evaluation (FACE) Model

##### Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for cooperative agreements to build State capacity for conducting traumatic occupational fatality surveillance, investigation, and intervention activities through the National Institute for Occupational Safety and Health (NIOSH) Fatality Assessment and Control Evaluation (FACE) Model.

The CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Occupational Safety and Health, and Surveillance and Data Systems. (To order a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

##### Authority

This program is authorized under section 20(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)) and sections 301 (42 U.S.C. 241) and 317 (42 U.S.C. 247b) of the Public Health Service Act, as amended.

##### Smoke-Free Workplace

The CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

##### Eligible Applicants

Eligible applicants are State Departments of Health, Departments of Labor, Departments of Industry, etc., located within any State or territory of the United States. Program activities, however, may not be carried out by departmental divisions that are responsible for enforcement of occupational safety and health standards. Awards will be limited to