women and 504 children and their parents (half will be 1 year old and half will be 5 years old) will be involved in the data collection. Because a small proportion (20%) of patients will be asked to vising another practice participating in the pilot study in order to test the ability of practices to collect and manage data on non-member patients, the NCS will require some providers to collect data on some patients they do not normally care for.

The method of data collection for the patient assessment includes self-administered questionnaires, physical examination, and collection of a urine sample.

The practice will contact potential participants through a mailing and a phone call. Non-respondents will not be contacted again.

ESTIMATED ANNUAL RESPONDENT BURDEN

Data collection	Number of respondents	Estimated time per respondent in hours	Estimated total burden hours	Average hourly wage rate	Labor rates
Pregnant woman: Data collected at their current practice.	432	3.5	1,512	$17.18 ..... (*see footnotes) ..	$25,976.0 0
Pregnant woman: Data collected at a practice other than usual source of care.	108	4.5	486	17.18 ..... (*see footnotes) ..	8,350.00
Parent of a 1 year old or 5 year old: Data collected at their current practice.	432	3.5	1,512	17.18 ..... (*see footnotes) ..	25,976.0 0
Parent of a 1 year old or 5 year old: Data collected at a practice other than usual source of care.	108	4.5	486	17.18 ..... (*see footnotes) ..	8,350.00
1 year old or 5 year old: Data collected at their usual practice.	432	3.5	1,512	0	0.00
1year old or 5 year old: Data collected at their usual practice.	108	4.5	486	0	0.00
Total	1620	24	5994	.....	68,652.0 0

Footnotes: *based on the average hourly wage across private and public sector jobs in the United States, National Compensation Survey, July 2002. U.S. Bureau of Labor Statistics.

Estimated Costs to the Federal Government

The total cost to the government for activities directly related to this data collection is estimated to be $780,411 for the pilot study.

Request for Comments

In accordance with the above cited legislation, comments on the AHRQ information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ, including whether the information will have practical utility;

(b) the accuracy of the AHRQ's estimate of burden (including hours and cost) of the proposed collection of information;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. all comments will become a matter of public record.

Dated: February 17, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–4098 Filed 2–24–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Nominations of Topics for Evidence-based Practice Centers

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Nominations of topics for evidence reports and technology assessments.

SUMMARY: AHRQ invites nominations of topics for evidence reports and technology assessments relating to the prevention, diagnosis, treatment and management of common diseases and clinical conditions, as well as, topics relating to the organization and financing of health care. Previous evidence reports can be found at *http://www.ahrq.gov/clinic/epcix.htm*

DATES: Topic nominations should be submitted by April 16, 2004, in order to be considered for this fiscal year. In addition to timely responses to this request for nominations, AHRQ also accepts topic nominations on an ongoing basis for consideration for future years. AHRQ will not reply to individual responses, but will consider all nominations during the selection process.

ADDRESSES: Topics nominations should be submitted to Kenneth Fink, MD, MGA, MPH, Director, Evidence-based Practice Centers (EPC) Program, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850. Electronic submissions are preferred. They may be sent to Dr. Fink at *epc@ahrq.gov.*

FOR FURTHER INFORMATION CONTACT: Kenneth Fink, MD, MGA, MPH, Center for Outcomes and Evidence, AHRQ, 540 Gaither Road, Rockville, MD 20850; Phone: (301) 427–1617; Fax: (301) 427–1640; E-mail: *epc@ahrq.gov.*

Arrangement for Public Inspection: All nominations will be available for public inspections at the Center for Outcomes and Evidence, telephone (301) 427–1600, weekdays between 8:30 a.m. and 5 p.m. (Eastern time).

SUPPLEMENTARY INFORMATION:

1. Background

Under Title IX of the Public Health Service Act (42 U.S.C. 299a–299c–7) as amended by Public Law 106–129 (1999), AHRQ is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHRQ accomplishes these goals through scientific research and through the promotion of improvements in clinical

practice and health systems practices, including the prevention of diseases and other health conditions.

2. Purpose

The purpose of this **Federal Register** notice is to encourage participation and collaboration of professional societies, health systems, payors, and providers, with AHRQ as it carries out its mission to promote the practice of evidence-based health care. AHRQ serves as the science partner with private-sector and public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care delivery in the United States, and to expedite the translation of evidence-based research findings into improved health care services. In this context, AHRQ awards task order contracts to its Evidence-based Practice Centers (EPCs) to undertake scientific analysis and evidence syntheses on topics of high-priority to its public and private healthcare partners and the health care community generally. The EPCs produce science synthesis—evidence reports and technology assessments—that provide to public and private organizations the foundation for developing and implementing their own practice guidelines, performance measures, educational programs, and other strategies to improve the quality of health care and decision-making related to the effectiveness and appropriateness of specific health care technologies and services.

The evidence reports and technology assessments also may be used to inform coverage and reimbursement policies. As the body of scientific studies related to organization and financing of health care grows, systematic review and analysis of these studies, in addition to clinical and behavioral research, can provide health system organizations with a scientific foundation for developing or improving system-wide policies and practices. Thus, EPC reports may address and evaluate topics such as risk adjustment methodologies, market performance measures, provider payment mechanisms, and insurance purchasing tools, as well as measurement or evaluation of provider integration of new scientific findings regarding health care and delivery innovations.

3. Evidence-based Practice Centers (EPCs)

The EPCs prepare evidence reports and technology assessments on topics for which there is significant demand for information by health care providers, insurers, purchasers, health-related societies, and patient advocacy organizations. Such topics may include the prevention, diagnosis and/or treatment of particular clinical and behavioral conditions, use of alternative or complementary therapies, and appropriate use of commonly provided services, procedures, or technologies. Topics also may include issues related to the organization and financing of care. AHRQ widely disseminates the EPC evidence reports and technology assessments, both electronically and in print. The EPC evidence reports and technology assessments do not make clinical recommendations or recommendations of reimbursement and coverage policies.

4. Role/Responsibilities of Partners

Nominators of topics selected for development of an EPC evidence report or technology assessment assume the role of Partners of AHRQ and the EPCs. Partners have defined roles and responsibilities. AHRQ places high value on these relationships, and plans to review Partners' past performance of these responsibilities, at such time, as AHRQ is considering whether to accept additional topics nominated by an organization in subsequent years. Specifically, Partners are expected to serve as resources to EPCs as they develop the evidence reports and technology assessments related to the nominated topic; serve as external peer reviewers of relevant draft evidence reports and assessments; and commit to (a) timely translation of the EPC reports and assessments into their own quality improvement tools (*e.g.,* clinical practice guidelines, performance measures), educational programs, and reimbursement policies; and (b) dissemination of these derivative products of their membership. AHRQ also is interested in members' use of these derivative products and the products' impact on enhanced health care. AHRQ will look to the Partners to provide these use and impact data on products that are based on EPC evidence reports and technology assessments.

AHRQ will review topic nominations and supporting information including the need and the nominators' commitment to partnership roles described above; seeking additional information as appropriate to determine final topics. AHRQ is very interested in receiving topic nominations from professional societies and organizations comprised of members of minority populations, as well as nomination of topics that have significant impact on the health status of women, children, ethnic and racial populations.

5. Topic Nomination and Selection Process

The processes that AHRQ employs to select topics nominated for analyses by the EPCs is described below. Section A addresses AHRQ's nomination process and selection criteria for clinical and behavioral topics. Section B addresses AHRQ's nomination process and selection criteria for organization and financing topics.

A. Clinical and Behavioral Topics

1. *Nomination Process for Clinical and Behavioral Topics.* Nominations of clinical and behavioral topics for AHRQ evidence reports and technology assessments should focus on specific aspects of prevention, diagnosis, treatment and/or management of a particular condition, or on an individual procedure, treatment, or technology. Potential topics should be carefully defined and circumscribed so that the relevant published literature and other databases can be searched, evidence systematically reviewed, supplemental analyses performed, draft reports and assessments circulated for external peer review, and final evidence reports or technology assessments produced within a timely and reasonably responsive manner. Some reports and assessments can be completed within six months, if there is a small volume of literature to be systematically reviewed and analyzed. Other evidence reports and technology assessments may require up to 12 months for completion due to complexity of the topic, the volume of literature to be searched, abstracted, and analyzed, or completion of the external peer review process. Topics selected will not duplicate current and widely available syntheses, unless, new evidence is available that suggests the need for revisions or updates. For each topic, the nominating organization must provide the following information:

a. Rationale and supporting evidence on the clinical relevance and importance of the topic;

b. Plans for rapid translation of the evidence reports and technology assessments into clinical guidelines, performance measures, educational programs, or other strategies for strengthening the quality of health care services, or plans to inform development of reimbursement or coverage policies;

c. Plans for dissemination of these derivative products, *e.g.,* to membership; and

d. Process by which the nominating organization will measure the use of these products, *e.g.,* by their members,

and impact of such use. Specifically, nomination information should include:

- Defined condition and target population.
- Incidence or prevalence, and indication of the disease burden (*e.g.,* mortality, morbidity, functional impairment) in the U.S. general population or in subpopulations (*e.g.,* Medicare and Medicaid populations). For prevalence, the number of cases in the U.S. and the number of affected persons per 1,000 persons in the general U.S. population should be provided. For incidence, the number of new cases per 100,000 a year should be provided.
- Costs associated with the clinical or behavioral condition, including average reimbursed amounts for diagnosis and therapeutic interventions (*e.g.,* average U.S. costs and number of persons who receive care for diagnosis or treatment in a year, citing ICD9–CM and CPT codes, if possible).
- Impact potential of the evidence report or technology assessment to decrease health care costs or to improve health status or clinical outcomes.
- Availability of scientific data and bibliographies of studies on the topic.
- References to significant differences in practice patterns and/or results; alternative therapies and controversies.
- Plans of the nominating organization to incorporate the report into its managerial or policy decision making (*e.g.,* rapid translation of the report or assessment into derivative products such as clinical practice guidelines or other quality improvement tools, or to inform reimbursement or coverage about a particular technology or service).
- Plans of the nominating organization for disseminating derivative products *e.g.,* to its membership.
- Process by which the nominating organization will measure use of the derivative products, and measure the impact of such use, on clinical practice.

2. *Selection Criteria for Clinical Topics.* Factors that will be considered in the selection of clinical topics for AHRQ evidence report and technology assessment topics include:

a. High incidence or prevalence in the general population and in special populations, including women, racial and ethnic minorities, pediatric and elderly populations, and those of low socioeconomic status;

b. Significance for the needs of the Medicare, Medicaid and other Federal health programs;

c. High costs associated with a condition, procedure, treatment, or technology, whether due to the number of people needing care, high unit cost of care, or high indirect costs;

d. Controversy or uncertainty about the effectiveness or relative effectiveness of available clinical strategies or technologies;

e. Impact potential for informing and improving patient or provider decision making;

f. impact potential for reducing clinically significant variations in the prevention, diagnosis, treatment, or management of a disease or condition, or in the use of a procedure or technology, or in the health outcomes achieved;

g. Availability of scientific data to support the systematic review and analysis of the topic;

h. Submission of nominating organization's plan to incorporate the report into its managerial or policy decision making, as defined above; and

i. Submission of nominating organization's plan to disseminate derivative products, and plan to measure use of these products, and the resultant impact of these products on clinical practice.

B. Organization and Financing Topics

1. Nomination Process for Organization and Financing Topics. Nominations of organization and financing topics for AHRQ evidence reports should focus on specific aspects of health care organization and finance. Topics should be carefully defined and circumscribed so that relevant databases may be searched, the evidence systematially reviewed, supplemented analyses performed, draft reports circulated for external peer review, and final evidence reports produced in a timely and reasonable manner. Reports can be completed within six months if there is a small volume of literature for systematic review and analysis. Some evidence reports may require up to 12 months to completion due to the complexity to the topic and the volume of literature to be searched, abstracted, analyzed. Topics selected will not duplicate current and widely available research syntheses, unless new evidence is available that suggests the need for revisions or updates. For each topic, nominations should provide:

a. Rationale and supporting evidence on the importance and relevance of the topic including:

- Defined organizational/financial arrangement or structure impacting quality, outcomes, cost, access or use.
- Three to five focused questions to be answered.
- If appropriate, description of how the organizational/financial arrangement or structure is particularly relevant to delivery of care for specific vulnerable populations (*e.g.,* children, persons with chronic disease) or certain communities (*e.g.,* rural markets).
- Costs potentially affected by the organizational/financial arrangement, to the extent they can be quantified.
- Impact potential of the evidence report to decrease health care costs or to improve health status or outcomes.
- Availability of scientific and/or administrative data and bibliographies of studies on the topic.
- References to significant variation in delivery and financing patterns and/or results, and related controversies.

b. Plans for use of the evidence report and indicate how the report could be used by public and private decisions makers including:

- Nominator's plan for use of an evidence report on the topic.
- Nominator's plan for measuring the impact of the report on practice.

2. Selection Criteria for Organization and Financing Topics. Factors that will be considered in the selection of topics related to the organization and financing of care include the following:

a. Uncertainty about the impact of the subject organizational or financing strategy;

b. Potential for the subject organizational or financing strategy or the proposed research synthesis to significantly impact aggregate health care costs;

c. Policy-relevance to Medicare, Medicaid, and/or other Federal and State health programs;

d. Relevance to vulnerable populations, including racial and ethnic minorities, and particular communities, such as rural markets;

e. Availability of scientific data to support systematic review and analysis of the topic;

f. Plans of the nominating organization to incorporate the report into its managerial or policy decision making; and

g. Plans by the nominating organization to measure the impact of the report on practice.

Dated: February 17, 2004.

Carolyn M. Clancy,

Director.

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