

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*Agency for Healthcare Research and Quality’s (AHRQ) Guide To Improving Patient Safety in Primary Care Settings by Engaging Patients and Families—Evaluation.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by October 11, 2016.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

#### FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Proposed Project

*Agency for Healthcare Research and Quality’s (AHRQ) Guide To Improving Patient Safety in Primary Care Settings by Engaging Patients and Families—Evaluation*

There is a substantial evidence base showing that engaging patients and families in their care can lead to improvements in patient safety. Since the 1999 release of *To Err is Human*, there has been an undeniable focus on improving patient safety and eliminating patient harm within acute care. What is not as well documented is

how to achieve these improvements in primary care settings.

Patient and Family Engagement (PFE) strategies for acute care settings include, among others: Patient and family advisory committees; membership on patient safety oversight bodies at both operations and governance levels; consultation in the development of patient information material; engaging patients in process improvement or redesign projects; rounding with patients and families; patient and family participation in clinical education programs, and welcoming patients and families to work alongside providers and health systems employees on transparency, culture change and high reliability organization initiatives.

Although the field of PFE in patient safety for hospitals and health systems is maturing, leveraging PFE to improve patient safety in non-acute settings is in its infancy. Building sustainable processes and practice-based infrastructure are crucial to improving patient safety through patient and family engagement in primary care.

In response to the limited guidance available for primary care practices to improve safety through patient and family engagement, the AHRQ has funded the development of a *Guide To Improving Patient Safety in Primary Care Settings by Engaging Patients and Families* (hereafter referred to as the Guide). This comprehensive Guide will provide primary care practices with interventions that they can use to engage patients and families in ways that lead to improved patient safety. It will include explicit instructions to help primary care practices, providers, and patients and families adopt new behaviors. The Guide and its development are prefaced on several key insights relevant to primary care including:

- Active engagement requires organizational commitment to hearing the patient and family voice and action by leadership to include them as central members of the health care team.
- Patients and families expect and increasingly demand meaningful engagement in harm prevention efforts.
- Institutional courage is required to openly share patient safety vulnerabilities and proactively engage patients in developing solutions that prevent harm.
- Supportive infrastructure is needed to hardwire PFE into all facets of care delivery across the care continuum.
- When done well, patient engagement yields important and measurable results. When not done well, PFE activities may disenfranchise patients, contribute to

misunderstanding about risk, create fissures among members of the clinical care team, and result in lack of trust between patients and providers.

With these insights as a basis, three precepts undergird our approach to development for the Guide. The Guide interventions must yield:

- *Meaningful relationship-based engagement* for patients and families and primary care providers.
- *Innovation and enabling technologies* to support engagement, shared decision making and patient safety.
- *Workable processes* yielding sustainable engagement opportunities for patients, families, providers, and practice staff.

The Guide will be principally (but not exclusively) meeting the needs of practices that have not already implemented effective PFE structures or processes. An environmental scan revealed several promising interventions for consideration for inclusion in the Guide. The four interventions selected as part of the Guide include:

- Teach-back.
- Be Prepared to Be Engaged.
- Medication Management.
- Warm Handoff.

The interventions will be compiled into the Guide for adoption by primary care practices. The environmental scan also yielded several important implications for Guide development including:

- Engagement efforts in primary care to date have focused on the patient as the agent of change with limited guidance to providers on how to support patients in these efforts.
- Many interventions are focused heavily on educational efforts alone, either for the patient, the provider, or the practice.
- Few of the tools and interventions identified are immediately usable without the need for additional development or enabling materials to support sustainable adoption.
- Health equity and literacy considerations are limited. Tools for patients are often at a relatively high level of literacy, and/or health literacy is required for use.
- Current interventions, tools, and toolkits have a high level of complexity that may impede adoption.

Existing evidence-based interventions are being refined to reduce complexity and enhance the opportunity for implementation. Implementation development activities are currently underway. Field testing of the Guide will evaluate the implementation challenges faced by primary care

practices whereby offering an opportunity to revise the Guide materials for optimal implementation success prior to widespread dissemination.

The Guide will be made publicly accessible through the AHRQ Web site for easy referral, access, and use by other health care professionals and primary care practices. AHRQ recognizes the importance of ensuring that the Guide will be useful and feasible to implement and ultimately able to improve patient safety by engaging patients and families. Thus, the purpose of the Field Testing evaluation is to gain insight on the implementation challenges identified by the twelve primary care practices field testing the Guide. The Guide materials will be revised in an effort to overcome these implementation challenges prior to broad dissemination.

The specific goals of the proposed Guide field testing evaluation are to examine the following:

- The feasibility of implementing a minimum of two of the four Guide interventions within 12 medium or large primary care practices.
- The challenges to implementing the interventions at the patient, clinician, practice staff, and practice level.
- The uptake and confidence among primary care practices to improve patient safety through patient and family engagement.
- How the implementation of two of the four Guide interventions changes the perception of patient safety among patients, clinicians, and practice staff.
- How the implementation of two of the four Guide interventions changes the perception of patient and family engagement among patients, clinicians, and practice staff.
- Whether primary care practices will continue to use the Guide (or its interventions) beyond the period of field testing and evaluation (*i.e.* examine sustainability).
- What changes patients, clinicians, and practice staff would recommend to the interventions and the Guide to enhance sustainability.

This study is being conducted by AHRQ through its contractor, MedStar, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

### Method of Collection

To achieve the goals of the project, the following data collections will be implemented during the Field Testing evaluation:

1. Baseline Practice Assessment of Primary Care Practices. This pen and paper survey will be administered to the 12 primary care practice champions immediately following the recruitment as part of the Guide Field Test and prior to commencing implementation of the Guide. Information collected includes: (i) Practice name and location (*e.g.*, city and State); (ii) non-identifying demographic information about the practice (*e.g.*, number of clinicians by type, number of patients served by the practice, payer mix of patients served by practice, race and ethnicity of patients served by practice); (iii) general descriptive information on the practice's experience with patient safety and quality improvement activities (*e.g.*, current experience with Guide interventions, patient safety culture routinely measured); (iv) information related to the practice's affiliation with larger health system; and (v) information related to any competing priorities or practice improvement initiatives (*e.g.*, patient centered medical home designation, etc.).

2. Post-Implementation Focus Groups for Patients and Families. Information from patients on their experiences with the Guide and its interventions will be solicited twice during the Field test—once at 3-months and again at 6-months post-implementation of the Guide. Each patient and family focus group will aim to recruit between six to eight participants and solicit feedback from patients and family members on their experiences with the Guide materials. Information collected will include: (i) Perceptions of patient safety in primary care practices; (ii) perceptions of patient and family engagement in primary care practices; (iii) feedback from the patient perspective on the Guide materials and their general use; (iv) feasibility of adopting the patient and family focused intervention materials in practice; (v) feedback on the patient and family experiences of the Guide and its relation to patient safety.

3. Baseline Practice Readiness Assessment. Information from primary care practices about their readiness to adopt patient and family engagement strategies will be solicited through telephone interviews with practice staff champions. Information collected will include: (i) Descriptive information on the person completing the interview (*e.g.*, position in the practice, length of employment, experience in

implementing patient safety improvements); (ii) description of the patient safety culture of the primary care practice (*e.g.*, teamwork, communication, patient safety culture, etc.); (iii) perceptions of patient and family engagement within the practice; (iv) perceptions of change management strategies, challenges, and barriers (*e.g.*, leadership support, competing initiatives, other production pressures); (v) capacity for ongoing internal measurement and assessment of the intervention. This process will also solicit general information the interviewee would like to share about the practice's readiness to implement the Guide strategies.

4. Post-Implementation Interviews of Primary Care Clinicians. Information from primary care clinicians (*e.g.*, physicians, nurses, nurse practitioners, social workers, etc.) on their experiences with the Guide and its interventions will be solicited twice during the Field test—once at 3-months and again at 6-months post-implementation of the Guide. Interviews with two or three primary care clinicians per practice will be conducted during Field Testing to solicit feedback on their experiences with the Guide materials. Information collected will include: (i) Perceptions on patient safety in primary care practices; (ii) perceptions of patient and family engagement in primary care practices; (iii) feedback from the clinician perspective on the Guide materials and their general use; (iv) feasibility of adopting the intervention materials in practice; (v) feedback on the clinicians' experiences of the Guide and its relation to patient safety.

5. Post-Implementation Focus Groups for Practice Staff Members. Information from practice staff members (*e.g.*, practice administrators, medical assistants, schedulers, practice facilitators, other non-clinical staff, etc.) on their experiences with the Guide and its interventions will be solicited twice during the Field test—once at 3-months and again at 6-months post-implementation of the Guide. Focus groups with between six to eight primary care practice staff will be conducted in each practice during Field Testing to solicit feedback on their experiences with the Guide materials. Information collected will include: (i) Perceptions on patient safety in primary care practices; (ii) perceptions of patient and family engagement in primary care practices; (iii) feedback from the practice staff perspective on the Guide materials and their general use; (iv) feasibility of adopting the intervention materials in practice; (v) feedback on the

practice staff's experiences of the Guide and its relation to patient safety.

6. Monthly Telephone Interviews with Practice Champions. This survey will be completed over the phone on a monthly basis with the practice champions from the twelve primary care practices engaged in the Field Testing of the Guide. Information collected will include: (i) Current progress towards implementation of the intervention(s); (ii) movement towards target goals set in the prior meeting; (iii) barriers to implementation; (iv) facilitators of implementation; (v) perceived impact on patient safety; (vi) perceived impact on patient and family engagement; (vii) plans for the coming weeks/months.

The Guide will be tested to evaluate the feasibility of adopting it in primary care practices. A mixed-methods approach will be used to identify barriers and facilitators to uptake and

sustainability, and to answer the question "How and in what contexts do the chosen interventions work or can they be amended to work", rather than "Do they work?" Testing will occur at up to 12 primary care sites and feasibility will be assessed at the patient, provider, and practice levels. The Guide will be revised based on these findings.

#### Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this evaluation of the Guide during field testing. Two formative evaluations will be conducted during field testing in twelve primary care practices in at least two geographic regions of the United States. Evaluation efforts will include collection of baseline practice level data prior to Guide implementation and two

separate rounds of focus groups and interviews conducted 3 months and 6 months after Guide implementation. Baseline assessments will be conducted on paper via phone consultation between the Contractor and the local practice champion and will take between 30 to 60 minutes. Patient focus groups will be conducted at the 3- and 6-month evaluation periods; each lasting between 60 to 90 minutes. Practice staff focus groups will be conducted during each of the site visits, conducted outside regular practice hours, and last between 60–90 minutes. Primary care clinician interviews will last approximately 45 minutes. We estimate that approximately 12 individuals will participate in the monthly telephone interviews over the 9-month implementation and evaluation period.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Baseline Practice Assessment .....	12	1	1	12
Post-Implementation Focus Group for Patients and Family Members .....	72	2	1.5	216
Interview Guide—Baseline Practice Readiness .....	12	1	.75	9
Post-Implementation Interview Protocol—Providers .....	24	2	.75	36
Post-Implementation Focus Group Protocol—Practice Staff .....	72	2	1.5	216
Topic guide for Telephone Protocol—Guide Practice Champions .....	12	6	.5	36
Total .....	204	NA	NA	525

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in this

project. The total cost burden is estimated to be \$18,629.16.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Baseline Practice Assessment .....	12	12	<sup>a</sup> 37.40	448.80
Post-Implementation Focus Group for Patients and Family Members .....	72	216	<sup>c</sup> 23.23	5,017.68
Interview Guide—Baseline Practice Readiness .....	12	9	<sup>a</sup> 37.40	336.60
Post-Implementation Interview Protocol—Providers .....	24	36	<sup>b</sup> 94.48	3,401.28
Post-Implementation Focus Group Protocol—Practice Staff .....	72	216	<sup>a</sup> 37.40	8,078.40
Topic guide for Telephone Protocol—Guide Practice Champions .....	12	36	<sup>a</sup> 37.40	1,346.40
Total .....	204	525	.....	18,629.16

\* National Compensation Survey: Occupational wages in the United States May 2015, "U.S. Department of Labor, Bureau of Labor Statistics." [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).

<sup>a</sup> Based on the mean wages for Miscellaneous Health care Worker (Code 29–9090).

<sup>b</sup> Based on the mean wages for Internists, General (Code 29–1063).

<sup>c</sup> Based on the mean wages for All Occupations (Code 00–0000).

#### Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's 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 AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including

hours and costs) of the proposed collection(s) 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 Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**Sharon B. Arnold,**  
Deputy Director.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-16-16AWP; Docket No. CDC-2016-0075]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed study to examine the facilitators and barriers to receiving clinical preventive services among newly insured medically underserved women who had previously been served by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The purpose of this survey is to assess if newly insured women receive appropriate clinical preventive health services, what barriers and facilitators these women experience, and if they are able to maintain consistent health insurance coverage.

**DATES:** Written comments must be received on or before October 11, 2016.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0075 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.
- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for

Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to

generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

#### Proposed Project

Women's Preventive Health Services Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) provides free or low-cost breast and cervical cancer screening and diagnostic services to low-income, uninsured, and underserved women. The NBCCEDP is an organized screening program with a full complement of services including outreach and patient education, patient navigation, case management, professional development, and tracking and follow-up that contribute to the program's success. Compared to when the NBCCEDP was established, more women are eligible for insurance coverage but there are still many women who are not insured and many insured women not obtaining preventive services that they are eligible to receive. Currently, the NBCCEDP not only provides screening services to uninsured and underinsured, but has expanded its services to include population-based activities that prevent missed opportunities and ensure that all women receive appropriate breast and cervical cancer screening.

Previous research suggests that access to health care through insurance alone does not ensure adherence to cancer screening, as many individual, cultural, and community factors serve as barriers to preventive service use. With recent increases in the numbers of women who are insured, there is a need to understand the experiences of women who had been served by the NBCCEDP and become newly insured. This project will inform the development of future activities of the NBCCEDP so that all women receive the information and support services needed for obtaining clinical preventive services.