

Dated: March 22, 2010.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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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: "Studying the Implementation of a Chronic Care Toolkit and Practice Coaching In Practices Serving Vulnerable Populations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on February 1, 2010 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

**DATES:** Comments on this notice must be received by April 30, 2010.

**ADDRESSES:** Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by e-mail at [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) (attention: AHRQ's desk officer).

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 e-mail at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### **Proposed Project**

#### *Studying the Implementation of a Chronic Care Toolkit and Practice Coaching In Practices Serving Vulnerable Populations*

An important part of AHRQ's mission is to disseminate information and tools that can support improvement in quality and safety in the U.S. health care community. This proposed information collection supports that part of AHRQ's mission by further refining the practice coaching delivered in conjunction with a previously developed toolkit, Implementing Integrating Chronic Care and Business Strategies in the Safety Net: A Toolkit for Primary Care Practices and Clinics. AHRQ requests that the Office of Management and Budget approve, under the Paperwork Reduction Act of 1995, AHRQ's intention to collect information needed to determine whether practice coaching is effective in facilitating adoption of the Chronic Care Model (CCM) for improving treatment and management of chronic medical conditions by primary care physicians, especially those who care for underserved populations. This project is being conducted 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 quality measurement and improvement and with respect to clinical practice, including primary care and practice-oriented research. 42 U.S.C. 299a(a)(2) and (4). This project will be conducted by AHRQ through a contract with the University of Minnesota.

Although 1,500 physician practices in the U.S. and internationally have been involved in CCM quality improvement efforts, most patients still do not receive their chronic care in accordance with CCM. One factor affecting CCM implementation has been that having teams attend collaborative meetings (three two-day meetings over a nine-month period) is burdensome, especially for under-resourced providers. An attempt to use the Internet as a virtual collaborative met with disappointing results. Another barrier to adoption of the CCM in settings that serve vulnerable populations is the scarcity of resources to implement and sustain the CCM. In 2006 AHRQ contracted with the RAND Corporation, Group Health's MacColl Institute, and the California Health Care Safety Net Institute (SNI) to develop a toolkit that informs safety net providers on how to redesign their systems of care along the lines of the Chronic Care Model while attending to their financial

realities. The result was Implementing Integrating Chronic Care and Business Strategies in the Safety Net: A Toolkit for Primary Care Practices and Clinics. The Toolkit was piloted in two California safety net clinics. Recognizing that merely distributing the Toolkit was unlikely to foster adoption of CCM, the intervention included six months of practice coaching delivered by the MacColl Institute. Practice Coaches (PC) are health care or related professionals who help primary care practices in a variety of quality improvement and research activities. PCs made two site visits to each site and participated in weekly team meetings by phone. They also interacted with the sites through e-mail and phone contact.

The lack of documentation available on coaching led to the development of a practice coaching manual, which was funded by AHRQ through a contract with the RAND Corporation. Development of the Coaching Manual entailed conducting a literature review, interviewing practice coaching experts, and incorporating evaluation results from the coaching provided in conjunction with the Toolkit. The Coaching Manual was published in the winter of 2009. The literature review and interviews revealed that there are a number of different models of practice coaching. However, knowledge is scant about how practice coaching is best performed, under what conditions practice coaching is most successful, and the costs of coaching and being coached. Pilot testing the Toolkit with a low-intensity practice coaching strategy proved insufficient to encourage practices to use the Toolkit independently. The Toolkit was subsequently streamlined based on pilot sites' reports that the initial Toolkit was not easy to use. This project will explore the implementation of the revised Toolkit along with a more intensive practice coaching strategy, providing lessons on methods to improve chronic care in clinical practices that serve vulnerable populations.

### **Method of Collection**

This project will include the following data collections:

(1) Key Informant Interviews with providers, staff and practice coaches from 20 safety net practices that participate in the practice coaching intervention. These will be used to describe the process and content of practice coaching, perceived changes from the coaching intervention at the practice, provider and patient levels, factors that impeded or facilitated the coaching intervention and implementation of practice changes

through the coaching process, overall satisfaction with practice coaching, and recommendations for improvement.

(2) Primary Care Practice Profile (PCPP). This questionnaire will be completed by a single individual at each site, either the medical director or chief administrator, and will provide an overview of each replication site that will help place intervention activities and outcomes in context for each site. It covers demographics of patients served, patient flow, disease health outcomes, most frequent diagnoses, most frequent referrals, number of staff by discipline, staff and patient satisfaction, processes of care, and organizational processes.

(3) Physician Practice Connections-Readiness Survey (PPC-RS)—This questionnaire asks about the presence of 53 practice systems in 5 of the 6 domains of the Chronic Care Model: Clinical information systems (information systems, presence of registry or organized database, and systematic monitoring of patient population); decision support (clinician reminders and alerts for lab tests, and visits or guidelines related to individual patient care), delivery system redesign (services for managing patients with chronic illness involving multiple clinicians and care between visits), health care organization (performance tracking and feedback, process of using clinical information systems to aggregate and report on key indicators, and use of data for benchmarking performance and informing QI activities), and clinical quality improvement (presence of formal processes to assess care, develop interventions, and use data to monitor the effects).

(4) Assessment of Chronic Illness Care (ACIC)—The ACIC is contained in the Toolkit and yields subscale scores and a total score. Subscale scores reflect CCM components and include: Community linkages, self-management support, decision support, delivery system design, information systems, and organization of care.

(5) Change Process Capability Questionnaire (CPCQ)—The CPCQ assesses 30 factors and strategies that experienced quality improvement leaders ranked as most important for successful implementation. A recent validation study found good predictive validity. Items correlating with the PPC-RS were eliminated after the initial validation study so there is little to no overlap across the two measures. In addition to changes in the content of

care (CCM components), these also include organizational will for change (Priority) and capacity and skill in the conduct of the actual change processes and strategies.

(6) Patient Assessment of Chronic Illness Care (PACIC)—The 20-item PACIC consists of five subscales which assess components of the CCM: Patient activation, delivery system design/decision support, goal setting, problem-solving/contextual counseling, and followup and coordination.

(7) Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult—This questionnaire assesses patient experiences in three areas: Getting appointments and healthcare when needed; how well doctors communicate, and courteous and helpful office staff.

(8) Primary Care Staff Satisfaction Survey—This questionnaire assesses staff satisfaction with their work environment. It consists of 8 4-point likert scale items and 2 open-ended questions, and was developed by the Institute for Healthcare Improvement.

(9) Chart Audits—Chart audits will be conducted at baseline, the end of the 10-month coaching intervention, and at 3-month follow-up to assess changes in patient care quality over the course of the intervention. A chart abstraction form will be developed to collect these data. This data collection will be performed by the project staff and will not impose a burden on the participating sites. Therefore, OMB clearance is not required for this data collection.

Clinic staff will be provided with a paper version of the surveys as well as the option to complete the surveys on line using a secure on-line survey program. With the exception of the staff surveys, no special information technology will be used to collect information, since many of the data collection forms are standardized instruments available in hard-copy form, and special permission from the developers would be required to create electronic versions of these forms. The information collection is a one-time only project; thus, there would be little benefit in reduced burden from automated information collection tools for the other instruments.

#### **Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this two-year study. Key informant interviews will be conducted with practice coaches at midpoint in the

intervention and again at the end of the intervention. Key informant interviews will also be conducted with up to 3 primary care providers and 2 other staff members from each of the 20 practices (10 per year) prior to start of the intervention, and again at 3-month follow-up after the intervention is completed. Each interview takes about 1 hour.

The Primary Care Practice Profile will be administered once and will be completed by one staff person from each practice and takes 30 minutes to complete. The Physician Practice Connections-Readiness Survey (PPC-RS) will be completed pre, post and at 3-month follow-up by three individuals from each of the 20 practices (individuals with the appropriate knowledge to complete the survey will be identified by the medical director of each site). It takes 90 minutes to complete. The Assessment of Chronic Illness Care (ACIC) will be completed by 4 staff and 4 primary care providers per practice at pre, post and 3-month follow-up and takes 30 minutes to complete. The Change Process Capability Questionnaire (CPCQ) will be completed by 4 staff and 4 primary care providers per practice at pre, post and 3-month follow-up and takes 15 minutes to complete. The Primary Care Staff Satisfaction Survey (PCSSS) will be completed by 4 staff and 4 primary care providers per practice at pre, post and 3-month follow-up and takes 15 minutes to complete. The Patient Assessment of Chronic Illness Care (PACIC) will be completed by 3,000 adult patients (1,500 annually) with chronic illness and requires 15 minutes to complete. The Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult (CAHPS) will be completed by 3,000 adult patients (1,500 annually) with chronic illness and requires 45 minutes to complete. Both patient surveys will be administered to adult patients with a chronic disease who receive care at the practices during a 2-day data collection period immediately before, immediately after, and at 3-month follow-up. The surveys will be administered during the post visit period in the wait room, by a bi-lingual Spanish-English research assistant. The total annualized burden hours are estimated to be 1,984 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this study. The total annualized cost burden is estimated to be \$60,714.

## EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Key informant interviews with practice coaches .....	2	2	1	4
Key informant interviews with providers (3 per practice interviewed twice) ...	10	6	1	60
Key informant interviews with staff (2 per practice interviewed twice) .....	10	4	1	40
Primary Care Practice Profile (PCPP) .....	10	1	30/60	5
Physician Practice Connections—Readiness Survey (PPC-RS) (3 per practice × 3 times) .....	10	9	1.5	135
Assessment of Chronic Illness Care (ACIC) (8 per practice × 3 times) .....	10	24	30/60	120
Change Process Capability Questionnaire (CPCQ) (8 per practice × 3 times) .....	10	24	15/60	60
Primary Care Staff Satisfaction Survey (PCSSS) (8 per practice 3 × times) .....	10	24	15/60	60
Patient Assessment of Chronic Illness Care (PACIC) .....	1,500	1	15/60	375
Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult (CAHPS) .....	1,500	1	45/60	1,125
Total .....	3,072	na	na	1,984

## EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Key informant interviews with practice coaches .....	2	4	\$42.00	\$168
Key informant interviews with providers .....	10	60	77.64	4,658
Key informant interviews with staff .....	10	40	32.64	1,306
Primary Care Practice Profile (PCPP) .....	10	5	77.64	388
Physician Practice Connections—Readiness Survey (PPC-RS) .....	10	135	77.64	10,481
Assessment of Chronic Illness Care (ACIC) .....	10	120	**55.14	6,617
Change Process Capability Questionnaire (CPCQ) .....	10	60	**55.14	3,308
Primary Care Staff Satisfaction Survey .....	10	60	**55.14	3,308
Patient Assessment of Chronic Illness Care (PACIC) .....	1,500	375	20.32	7,620
Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult (CAHPS) .....	1,500	1,125	20.32	22,860
Total .....	3,072	1,984	na	60,714

\* Based upon the mean of the average wages, May 2008 National Occupational and Wage Estimates accessed on December 14, 2009 at: [http://www.bls.gov/oes/current/oes\\_nat.htm#b29-0000](http://www.bls.gov/oes/current/oes_nat.htm#b29-0000).

National Compensation Survey:

\*\* Average for 4 staff (\$32.64/hr) and 4 physician clinicians (\$77.64/hr).

### Estimated Annual Costs to the Federal Government

research. The total cost over two years is estimated to be \$600,000.

Exhibit 3 shows the estimated total and annualized cost to conduct this

## EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development .....	\$162,744	\$81,372
Data Collection Activities .....	92,994	46,497
Data Processing and Analysis (20%) .....	92,994	46,497
Publication of Results .....	23,248	11,624
Project Management .....	92,994	46,497
Overhead .....	135,026	67,513
Total .....	600,000	300,000

### Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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 healthcare research and healthcare 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.

Dated: March 19, 2010.

**Carolyn M. Clancy,**

*Director.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Agency for Healthcare Research and Quality**

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**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: "Reductions of Infection Caused by Carbapenem Resistant Enterobacteriaceae (KPC) Producing Organisms through the Application of Recently Developed CDC/HICPAC Recommendations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by June 1, 2010.

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

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#### **SUPPLEMENTARY INFORMATION:**

#### **Proposed Project**

##### *Reductions of Infection Caused by Carbapenem Resistant Enterobacteriaceae (KPC) Producing Organisms Through the Application of Recently Developed CDC/HICPAC Recommendations*

Healthcare Acquired Infections (HAIs) caused almost 100,000 deaths among the 2.1 million people who acquired infections while hospitalized in 2000, and HAI rates have risen relentlessly since then. On March 20, 2009, the Centers for Disease Control (CDC) and the Healthcare Infections Control Practices Advisory Committee (HICPAC) developed infection control (IC) guidance for *Klebsiella pneumoniae* carbapenemase-producing (KPC) isolates, as they have been rapidly emerging as a significant challenge in healthcare settings. The danger of these bacteria is that they are resistant to carbapenem (a class of beta-lactam antibiotics with a broad spectrum of antibacterial activity) and cannot be treated by the most commonly prescribed antibiotics. Limited treatment options mean that infections caused by carbapenem resistant bacteria result in substantial mortality and morbidity.

The CDC and HICPAC recommendations draw on infection control strategies which have been applied to these pathogens in other settings, and other evidence based strategies in infection control. There has been little research, however, on the implementation of control strategies to prevent the spread of these KPC infections. The goal of this project is to understand how these recommendations can best be implemented and how effective these recommendations will be in practice. This research will advance private and public efforts to improve health care quality by improving measures to control the spread of a dangerous organism. This research will also provide data for the development of an implementation toolkit that hospitals can use to prevent the spread of carbapenem resistant bacteria. The toolkit may include the following types of resources: General information about the implementation of evidenced-based clinical practices, resource materials, and tools and methods that users can adopt to conduct point prevalence surveys, protocols and tools that users can adopt to specify when active KPC surveillance is needed, and resources for approaching the problem as a team-based quality-improvement effort.

OMB clearance will be sought for this toolkit once it is developed.

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

#### **Method of Collection**

This project will include the following data collections from the intensive care unit (ICU) staff within each of three participating hospitals:

(1) Pre-intervention focus groups will be conducted separately with managers and staff. The purpose of these focus groups is to identify potential problems in the implementation that can be addressed through various means (*e.g.*, additional education, other changes in process). Another purpose is to understand the existing approach to quality improvement, the connection(s) between overall approach to quality improvement and to KPC infection control practices, current practices at the hospital of quality reporting and accountability, and constraints and obstacles to quality improvement as seen in their roles. Staff members identified for the focus groups will be those with the most first-hand knowledge of existing quality improvement efforts, and KPC infection control practices.

(2) Clinical staff survey. Factors identified in the pre-intervention focus groups will be used to inform the development of a self-administered survey of staff knowledge of and attitudes toward KPC surveillance and infection control procedures. Respondents will be health care workers on the units where these new guidelines have been implemented. Findings from the survey will be used to assess barriers perceived by the staff, potential differences across units, and potential differences by employee/occupational group.

(3) Post-intervention focus groups (6 months after implementation of new KPC IC guidelines) will be conducted separately with managers and staff. The purpose of these focus groups is to identify actual problems experienced in the initial implementation and possible measures to address, and to identify successful practices to include in a toolkit that hospitals can use to implement the CDC and HICPAC recommendations.

In addition to developing a toolkit, AHRQ plans to disseminate the lessons