

SUPPORTING STATEMENT

Part A

**Assessing the Feasibility
of Disseminating Effective Health Care Products through a
Shared Electronic Medical Record Serving Member Organizations
of a Health Information Exchange**

Version: May 17, 2012

Agency of Healthcare Research and Quality (AHRQ)

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A. JUSTIFICATION

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, the Healthcare Research and Quality Act of 1999 (see <http://www.ahrq.gov/hrqa99.pdf>), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care;
2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve under the Paperwork Reduction Act of 1995 this Information Collection Request to collect information from users of work products and services initiated by the John M. Eisenberg Clinical Decisions and Communications Science Center (Eisenberg Center).

AHRQ is the lead agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ's Eisenberg Center is aimed at improving communication of findings to a variety of audiences ("customers"), including consumers, clinicians, and health care policy makers. The Eisenberg Center compiles research results into useful formats for customer stakeholders. The Eisenberg Center also conducts investigations into effective communication of research findings in order to improve the usability and rapid incorporation of findings into medical practice. The Eisenberg Center (EC) is one of three components of AHRQ's Effective Health Care (EHC) Program. From 2005 until September 2008, the EC operated through a contract with the Oregon Health and Science University (EC-OHSU), Department of Medicine, located in Portland, Oregon. In September 2008, the contract to operate the EC was awarded to Baylor College of Medicine (EC-BCM), located in Houston Texas.

The collections proposed under this clearance include activities to assess the feasibility of disseminating materials developed by the EC-BCM through the use of an electronic medical record (EMR) shared by a network of clinical care providers that are part of a Health Information Exchange (HIE) operating in multiple sites in several states. Our Community Health Information Network (OCHIN) members include 30 clinical care organizations operating more than 230 primary care clinics in six states. Data will be gathered from three OCHIN-member clinical care systems representing a total of 10 primary care clinics.

This research has the following goals:

- 1) Identify facilitators and barriers to successful efforts to implement processes that: a) support use of EHC Program products by clinicians in practice, and b) place relevant clinical information in the hands of patients and family members in languages and formats that are appropriate to patients' information needs;
- 2) Examine ways in which EHC Program products can be used in concert with other support programs and products (e.g., *healthwise*® resources available through the EMR; brief patient instructions and letters, including those designed for use with persons having very low literacy skills);
- 3) Assess the extent to which EHC Program products are used (e.g., accessed by clinicians, provided to patients in relevant formats) in settings where use is supported by automated EMR features, such as on-screen prompts and reminders; and
- 4) Document the perceived value of integrating EHC Program products into systems of care supported by an EMR system as self-reported by clinicians involved in direct care of patients and clinic support personnel who interact with patients.

To achieve the goals of this project the following data collections will be implemented:

- 1) Automated Data Capture from EMR Usage Logs. Electronic usage data will be collected to determine the extent to which EHC Program guides for clinicians and patients were accessed to support shared decision making and patient education. The data will be retrieved from the existing EMR-linked database operated by the Kaiser Permanente staff in their coordination of activities related to the OCHIN HIE. Data will include: a) number and frequency of retrieval of EHC resource materials; b) specific types of materials retrieved; and c) health topic or condition targeted in the EHC materials. These data will inform the development of follow-up questions to be administered to clinicians and patients in the interviews and surveys described below. Because the data will be obtained using automated systems already in place, no special effort will be needed to generate these data, and thus this task is not included in the burden estimates in Section 12.
- 2) Interviews with Clinicians. Interviews will be held with clinical service providers for the following purposes: a) obtain perceptions of the overall value, relevancy, currency and appropriateness of EHC Program products in addressing the health service needs of patients treated in clinical settings; b) assess ease of use of the materials in terms of access via the EMR; c) determine perceived success of efforts to employ EHC Program products and

related materials in addressing the needs of patients with limited language skills and/or low literacy levels; and d) describe the relative success of efforts to use the EHC Program products in concert with other tools (e.g., *healthwise*® resources) in promoting patient engagement in their own health care or in the care of family members. The guide for the clinician interviews is included in Attachment A.

- 3) Interviews with Support Staff. Interviews will be held with non-clinical support staff to characterize perceptions of how the introduction of EHC Program products: a) affected clinic workflows and influenced the work that staff was required to do in supporting clinician-patient interactions; and b) facilitated or impeded efforts to inform patients about actions they could take in being more fully involved in their own health care. The guide for the support staff interviews is included in Attachment B.
- 4) Interviews with Patients. Interviews will be held with recruited patients to determine if they: a) viewed the EHC Program products that they were provided as useful to them in understanding their health issues; b) were able to understand the EHC Program-related information that was provided to them sufficiently to take actions in their own health care; and c) have suggestions about how the EHC Program materials could be changed or the delivery of them done in a different way to make the materials more useful and/or accessible to patients. The guide for the patient interviews is included in Attachment C.
- 5) Survey of Clinicians. A questionnaire will be administered to clinical care providers near the end of the study to gather quantitative data around their assessments of: a) the relevancy of the EHC Program materials to the patients they serve; b) the appropriateness of the products in addressing specific clinical issues; c) the ease of use of the system created to provide access to EHC Program products through the EMR; and d) overall ratings of the approach in addressing patient needs with regard to specific conditions addressed by the products available. See Attachment D for the questionnaire.

The interviews with clinicians, clinical staff, and patients will be conducted throughout the project period, approximately every three months with different sets of participants, to inform and refine delivery mechanisms and monitor progress.

This study is being conducted by AHRQ through its contractor, the Eisenberg Center - Baylor College of Medicine, pursuant to AHRQ's statutory authority to conduct and support research, and disseminate information, 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 clinical practice. 42 U.S.C. 299a(a)(1) and (4).

2. Purpose and Use of Information

This information will provide insight into the feasibility of efforts aimed at distributing clinician and consumer guides, as well as other EHC products, using EMRs as the primary vehicle for providing product access at the point of care and will be used to inform the development of additional studies to identify factors that encourage or deter effective integration of EHC

products into care processes using electronic tools and care delivery support systems, like the EMR, that are increasingly common in clinical work settings.

3. Use of Improved Information Technology

Improved electronic technology (e.g., Web-based materials) will be used whenever possible to reduce the burden on the public. Much of the data gathered through this project will be generated from usage logs that are generated through the EMR database structure for purposes of identifying usage rates of specific information items. The retrieval of log data can be completed with very modest personnel time required to complete programming needed to query the database.

In some instances, however, the most appropriate methodology will involve oral responses to interview queries to gain an in-depth understanding of participants' perception and experiences. In addition, a self-administered questionnaire will be used to gather data from clinical personnel who have been engaged in using the EMR-delivered guides and related materials for clinicians and patients. The questionnaire will be devised to be completed online to facilitate ease of response and decrease paper usage.

4. Efforts to Identify Duplication

In preparing for this project, key project staff made inquiries with AHRQ personnel and with personnel at the HIEs, including the OCHIN HIE which was finally selected. These inquiries revealed that, while AHRQ was indeed planning to fund a number of activities related to implementation of electronic medical records (EMRs) and support for the formation and/or operation of HIEs, none of these projects were designed to examine, in a specific fashion, facilitators or barriers to integration of Effective Health Care (EHC) Program products into the EMR-supported health care delivery setting in ways that would help to determine the feasibility of broader applications of this approach. In addition, perusal of the literature on EMR use in varied clinical settings revealed no studies that specifically described methods designed to foster use of EMRs as vehicles for delivery of information resources designed for both the clinician and the patient. The focus of virtually all reported research in this area was on the interaction between providers and patients and not on the provision of supporting resources, as is the case with project described here. This project will explore an area of interest—assessing the technical and operational feasibility of using an EMR shared across a multisite delivery system as the primary vehicle for promoting use of publically funded, evidence-based resources—on which the professional literature is lacking at present. Examination of other AHRQ-supported projects, as described in published materials, revealed no efforts that duplicated the type of data collections described for this project.

5. Involvement of Small Entities

The survey instruments and procedures for administering the instruments are designed to minimize the burden on all respondents and will not have a significant impact on small businesses or other small entities. The OCHIN-member organizations that will be engaged have been involved in project development since the early stages, and have provided input on the

types of data collections that can be implemented with minimal impact on work burden for personnel in these care environments.

The overall intent of the project is to identify strategies for fostering access to EHC Program products without disruption of the workflows of these clinics.

6. Consequences if Information Collected Less Frequently

These information collections are appropriate vehicles to examine customer experiences, perceptions, and factors that contribute to or detract from accessing and using products and services developed by the EC-BCM. Inability to collect these data would inhibit efforts to determine how emerging technologies, like EMRs, can be effectively leveraged to maximize capabilities of the EC-BCM in delivering comparative effectiveness research-based products to clinicians and patients in environments where these products can be used most effectively in guiding decisions about clinical treatment.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d) (2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on *(date and page number of 60 day notice)* for 60 days (see Attachment E).

8.b. Outside Consultations

No outside agencies will participate as consultants. However, the information technology team at Kaiser-Permanente will be assisting in collecting and verifying the integrity of data tracked within the HIE system. Kaiser Permanente functions as the primary grantee for the OCHIN Health Information Exchange and it supports the electronic medical record (EMR) services for the clinical service organizations that are members of the OCHIN HIE. For this project, Kaiser Permanente will operate as a paid subcontractor in assisting with EMR-related activities, including retrieving data from the EMR related to electronic access of patient and clinician guides and information products.

9. Payments/Gifts to Respondents

Modest remuneration will be given to clinicians, clinical support staff, and patients who agree to participate. Patients will be reimbursed for their time in the amount of \$20 for assessments that require initiating contact with EC-BCM researchers (i.e., the telephone interviews). Clinicians will be reimbursed up to \$250 for provision of feedback via interview and \$100 for completion of the online questionnaire, and clinical support staff will receive \$125 for interviews. These

professionals have limited time availability and are accustomed to receiving similar levels of recompense for their valuable input, which is essential to effective product development and testing. Discussions with OCHIN leadership confirmed that these amounts seemed reasonable based on remuneration typically received by these physicians for participation in other studies.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

Respondents will be advised that interviews, surveys and/or other data collection activities in which they may be asked to participate are entirely voluntary, and that any information they provide will be combined and summarized with information provided by others and no individually identifiable information will be released. In instances where respondent identifiers are needed (e.g., for issuance of payment), information collection will fully comply with all requirements of the Privacy Act.

11. Questions of a Sensitive Nature

No questions of a sensitive nature are anticipated under this project-specific clearance. Although some data gathering may deal with specific health conditions, the focus of the query items will be on the method of delivery of the information, rather than on any personal issues around a health condition or how it is managed.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in this research. Up to three rounds of interviews will be conducted during the project period with separate sets of participants to assess progress and adjust methods or refine materials as needed. Interviews will be conducted with 90 patients, 50 clinicians and 50 clinical support staff across the three clinical care systems. Each interview is estimated to last no more than 30 minutes. All clinicians in each participating clinic will have access to the EMR and will be invited to participate in an online questionnaire. We estimate that approximately 200 clinicians will complete the 10-minute questionnaire.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annual cost burden is estimated to be \$6,167.

Exhibit 1. Estimated annualized total burden hours

Type of Data Collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
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Interviews with Clinicians	50	1	30/60	25
Interviews with Support Staff	50	1	30/60	25
Interviews with Patients	90	1	30/60	45
Survey of Clinicians	200	1	10/60	33
Total	390	na	na	128

Exhibit 2. Estimated annualized total cost burden

Type of Data Collection	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Interviews with Clinicians	50	25	\$83.59	\$2,090
Interviews with Support Staff	50	25	\$14.31	\$358
Interviews with Patients	90	45	\$21.35	\$961
Survey of Clinicians	200	33	\$83.59	\$2,758
Total	390	128	na	\$6,167

Based upon the mean wages for clinicians (29-1062 family and general practitioners), clinical team members (31-9092 medical assistants) and patients/consumers (00-0000 all occupations), National Compensation Survey: Occupational wages in the United States May 2010, “U.S. Department of Labor, Bureau of Labor Statistics.”

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

The maximum cost to the Federal Government is estimated to be \$217,351 annually for two years. Exhibit 3 shows the total and annualized cost by the major cost components.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	\$153,750	\$76,875
Data Collection Activities	\$162,265	\$81,133
Data Processing and Analysis	\$33,563	\$16,781
Project Management	\$22,625	\$11,313
Overhead	\$62,500	\$31,250
Total	\$434,703	\$217,351

15. Changes in Hour Burden

This is a new information collection request.

16. Time Schedule, Publication and Analysis Plans

Timeline for Data Gathering to Assess the Feasibility of Using Electronic Medical Record Systems Shared Across Member Organizations of a Health Information Exchange (EHC) as Vehicles for Promoting Clinician

and Consumer Access to Findings and Products of the AHRQ Effective Health Care (EHC) Program*																									
Major Data Gathering Tasks to Be Completed	2010-2011												2011-2012												
	Pre-OMB Approval												Post-OMB Approval												
Complete process of integration of EHC products into the OCHIN EMR system	█	█	█	█	█	█	█	█	█	█	█	█													
Coordinate implementation efforts, including planned data gathering efforts with clinic staff													█	█	█	█									
Initiate and sustain activities to promote EHC Program resource access in clinics																									
Submit initial OMB clearance request to gather data as indicated in this document																									
Work with OMB representatives in revising and refining clearance request																									
Complete the public comment period required for OMB clearance																									
Conduct 3 rounds of follow-up interviews with clinical personnel at OCHIN member clinics																									
Complete brief online survey of clinical care providers related to issues around EMR-delivered resources																									
Conduct telephone interviews with patients provided EHC-related information																									
Analyze data and prepare final report on feasibility																									
Publish results via the Effective Health Care Program Web site and in journal article(s)																									
*NOTE: The project timeline was extended with approval from the AHRQ contracting officer to allow for completion of substantive reorganization efforts within the OCHIN HIE that resulted from significant ARRA-related grant awards and new obligations for OCHIN and its clinical service member organizations.																									

Most data will be analyzed using descriptive statistics, and it is unlikely that the results can be generalized to the larger population. Some quantitative data are being collected in the form of the questionnaire surveys. These data will be summarized primarily using descriptive statistics. Limited inferential statistics could be applied if we see a large numbers of responses to the questionnaires; and these would likely consist of comparisons across demographic categories on various indices of satisfaction. Because many of the data points will be measured using a 5-point Likert-type scale, nonparametric techniques will likely be warranted.

The analyses of the interviews will entail qualitative methodologies and consist mostly of narrative summaries of the discussions. These data will be analyzed thematically, and the results of thematic analyses will be summarized in reports prepared for the project. Summary information on action steps taken to improve processes or materials delivered through the EMR capabilities of the OCHIN network will also be included in reports, indicating the nature of the information generated to support actions, interpretation of the significance of these findings, and any relevant caveats or other issues that are significant in terms of future efforts to implement similar projects.

The results of these findings will be summarized and include in a relevant publication format (e.g., brief report, topical white paper) on the AHRQ Effective Health Care (EHC) Program Web site. In addition, the results will be prepared in manuscript format for submission to a peer

reviewed journal. A number of journals will be considered, including *Patient Education and Counseling*, *The Journal of Health Communication*, and the *Journal of Health Care for the Poor and Underserved*. The latter journal may be of special interest since all of the clinical sites in which project activities will be carried out are federally-funded clinics addressing the needs of medically underserved populations. Final decisions about publication will be made once data are gathered and the suitability for publication in a specific venue is determined.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Interview Guide for Clinicians

Attachment B: Interview Guide for Support Staff

Attachment C: Interview Guide for Patients

Attachment D: Questionnaire for Clinicians

Attachment E: [Federal Register]