SUPPORTING STATEMENT

Part A

Improving Quality through Health IT: Testing the Feasibility and Assessing the Impact of Using Existing Health IT Infrastructure for Better Care Delivery

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Agency for 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 Attachment 1), 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; and

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.

AHRQ proposes to assess how the use of health information technology (IT) can improve care delivery and outcomes in community health centers. AHRQ is specifically interested in improving the quality of care provided in a community clinic setting through better management of laboratory information. The study will measure the impact of health IT tools on two problems: duplicate laboratory tests and the failure to follow up on laboratory test results of HIV patients and women screened for cervical cancer (see attachment 3). In addition, AHRQ will measure the impact of health IT on compliance with evidence-based guidelines for laboratory tests. The study will also investigate whether disparities between vulnerable populations and the general population exist in both laboratory screening rates and rates of abnormal laboratory test results without follow up. To assess the extent of these problems and the impact of health IT, AHRQ will evaluate both quantitative and qualitative components. The qualitative component will use interviews with key informants in two community health centers to gather data on laboratory information processes, laboratory information communication problems and use of health IT tools (see attachment 4). The target populations for this study consist of one chronic disease population – patients with HIV/AIDS, and one preventive screening population – women in need of cervical cancer screening. Both of these populations represent AHRQ priority groups. In addition, the intervention will be

implemented at "safety net" clinic that serve primarily low-income, minority population that often experience disparities in health services from the general population.

This research will provide invaluable information for organizations struggling to maximize the benefit from a sizeable investment in IT systems. In addition, this study will fill some important gaps in the literature. For instance, while the impact of certain types of health IT systems, such as computerized order entry (CPOE) systems, has been well documented, there are fewer studies examining the impact of specific health IT tools such as decision support in lab results systems or chronic disease management tools. There is also a dearth of knowledge about the impact of these IT systems in an ambulatory care environment and an even greater lack of research in safety net clinics. Finally, our ability to track specific patient characteristics such as socioeconomic status, race/ethnicity, and language presents a unique opportunity for our study to contribute to a growing body of evidence on health disparities and to determine whether health IT can contribute to the goal of reducing the health disparities gap by targeting quality improvement interventions.

This study also supports AHRQ's special interest in minority populations, women and low-income groups. The target population for this study includes one chronic disease population, patients with HIV, and one preventive screening population, women in need of cervical cancer screening. Patients will be drawn from two clinics that are part of the Alliance of Chicago Community Health Services (the Alliance), Howard Brown Health Center and Heartland Health Outreach. The Alliance is a network of four community health centers serving primarily low-income and uninsured patients and is headquartered on Chicago's north side. Howard Brown services 6,215 patients, predominantly minority and HIV infected populations. Heartland Health Outreach provides primary health care, mental health and addiction services, and oral health care to homeless and low-income Chicagoans at various sites throughout the city and through street outreach. Both Centers implemented a comprehensive Electronic Health Record System (EHRS) in 2006.

To gather information on lab information processes, lab information communication problems and use of health IT tools, interviews will be conducted with key informants in each of the two Centers (see Attachment 6). Key informants will include physicians, nurses, medical assistants, IT personnel, and administrators, among others. This collection of information supports the program mission by providing key information on processes critical to quality of care. The interviews will also probe for how health IT tools are being used to support these processes. Better understanding of these processes and barriers will provide insight into how errors of redundancy and information lost to follow up can be reduced and provide a context for interpreting the quantitative results.

2. Purpose and Use of Information

The information from the interviews will be used extensively by the project team for several purposes. First, the qualitative information gathered via interviews will provide context for the quantitative results of the study. The quantitative component will measure duplicate lab tests, labs lacking follow up and level of compliance with lab order

guidelines. The interviews will provide information on how the processes work and potential problem areas within them. This information will provide insights into why the Centers are experiencing high or low error rates in certain areas.

Secondly, an objective of the study is to learn how health IT can improve the roles of various types of health care practitioners in lab related tasks. This objective will be achieved primarily using the qualitative data. The interviews will be conducted with various staff members and will probe for how health IT is being used or not used by various roles.

Thirdly, the interview data will play a critical role in the development of the Implementation handbook. A particular focus of the handbook will be documentation of best practices on how to implement clinical decision support for chronic disease care. The interviews will gather information on how providers are using the tools within the EHRS and how they respond to the clinical decision support. It will also explore barriers and attempt to elicit suggestions for improvements. This type of information will be incorporated into the handbook in the form of recommendations on how these clinical decision support tools should be designed, how they should be used by different types of providers and what type of impact can be reasonably expected.

3. Use of Improved Information Technology

Information technology will not play a role in the collection of the interview information. In order to establish rapport and encourage participants to speak freely we will conduct the interviews in-person. The questions are structured primarily as open-ended to allow in-depth exploration of issues. Given these goals electronic submission of responses is not a viable option.

4. Efforts to Identify Duplication

We are aware of no in-depth interview data of community clinic staff members regarding lab information processes. This type of information has not previously been gathered at any Alliance Centers. In addition, literature searches have not revealed any substantive information of this nature.

5. Involvement of Small Entities

All potential participants are employees of small, community health centers; thus efforts will be taken to minimize the burden of participation for all interviews. The interview instrument will be honed to a set of only critical questions and we will be diligent in respecting the 90 minute time limit scheduled with each participant. To further minimize the burden to each clinic we will provide $2, 500 compensation for their participation in the interviews. Given we are assuming the interviews will require 1.5 hours for up to 20 participants at each site, it is necessary to alleviate the burden this process would place on the clinic with monetary compensation.

6. Consequences if Information Collected Less Frequently

The interviews represent a one-time collection.

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 February 15th, 2008 for 60 days (see Attachment 2). No comments were received.

8.b. Outside Consultations

The methodology planned for this data collection was developed by members of our multidisciplinary study team. The team includes individuals from academia, staff from the Alliance Health Centers as well as experienced researchers and consultants. The team has no unresolved issues and is in agreement regarding the content to be covered in the interviews and their timing and frequency.

9. Payments/Gifts to Respondents

Individual interviewees will not be compensated in any way for their participation in the interviews. However, each of the two clinics will receive $1,500 to cover clinical and administrative staff informant interview time.

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 (see Attachments 7).

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 4225 U.S.C.552a (Privacy Act of 1974). In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

- While the identity of the interviewees will be known, all individuals will be assured of the confidentiality of their responses and various safeguards will be put in place to protect the privacy of the data.

- All collected interview questionnaire data will be labeled with only the study identifier, and will be kept confidentially secure in locked files with access limited to designated personnel.
- All electronic files will be password protected, and will be accessible only from computers of the research team. The files will not be accessible via the Internet.
- No persons outside the study team will have access to the data.
- Audiotapes and transcripts of interview sessions will remain in the possession of the study investigators at all times, and will be reviewed in seclusion. These will all be secured in a locked office at all times.
- Upon completion of the study, the data and audiotapes will reside with the qualitative study investigator. After three years, all audiotapes and data will be destroyed.

11. Questions of a Sensitive Nature

No questions of a sensitive nature will be asked in the interviews.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours. A total of forty one in-person interviews will be conducted with administrative and clinical personnel: eighteen interviews from administrative personnel and twenty three interviews from clinical personnel. The question set is the same for both clinical and administrative personnel. The estimated time per response is 1.5 hours for a total of 61.5 burden hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to provide the requested data. The hourly rate of $32.13 is a weighted average of the administrative personnel hourly wage of $19.68 and the clinical personnel hourly wage of $41.88. The total cost burden is $1,976.

Exhibit 1. Estimated annualized burden hours

Data Collection	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden Hours
In-person interviews	41	1	1.5	61.5
Total	41	na	na	61.5

Exhibit 2. Estimated annualized cost burden

Data Collection	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate*	Total Cost Burden
In-person interviews	41	61.5	$32.13	$1,976
Total	41	na	na	$1,976

*Based upon the actual site personnel wages. Clinical personnel averages are weighted by the number of physicians, nurses and medical assistants in the sample. Administrative personnel averages are weighted by the

number of administrators, lab, IT and other support personnel. Total average is weighted by relative number of administrative and clinical personnel being interviewed.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

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 total cost to the Federal Government for this project is $393,457 over a two year period. The average annual cost is $196,728. The following is a breakdown of average annual costs:

Direct Costs	
Personnel	$108,320
Consultancies	$24,400
Data support	$5,000
Travel	$2,575
Supplies	$100
IRB review	$125
Indirect Costs	
Indirect costs 40%	$56,208

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Qualitative data analyses will use the constant comparative method of qualitative data analysis, and common techniques to code the data (see Attachments 4 and 5). Using a grounded theory approach, we will read interview transcripts, and discuss findings among investigators as the study progresses. This iterative process will enable us to explore new themes that emerge in subsequent interviews and case studies, and help us to ensure that we reach saturation in our data collection. We will use the Atlas.ti software package (version 4.2) to facilitate coding and data analyses, and the formal exploration of patterns and themes within the data.

The results of the qualitative analysis will be published in various forms. We will seek to disseminate results via peer-reviewed journals such as *Health Affairs*, or the *Joint Commission Journal on Quality and Patient Safety*, as well as via presentations at professional and academic conferences, and at National Association of Community Health Center meetings and other meetings.

The timeline for data collection, analysis and dissemination for the entire project is provided below on the following page (see Table 16-1.).

Table 16-1. Project Timeline.

		Year 1												Year 2											
	Mos.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	Sept. 2007	October, 2007	November,	December,	January, 2008	February,	March, 2008	April, 2008	May, 2008	June, 2008	July, 2008	August, 2008	September,	October,	November,	December,	January, 2009	February,	March, 2009	April, 2009	May, 2009	June, 2009	July, 2009	August, 2009	September,
Project Approval																									
Administrative Meetings (11/9/07, 12/17/07, Fall 2008 and Early 2009)																									
Quantitative Component																									
Report of existing infrastructure (10/28/07)																									
Submit plan for intervention and assessment (study protocol) (11/28/07)																									
Refine measurement set																									
Final assessment plan (1/28/08)																									
Identify population (3/28/08)																									
Gather data																									
Analyze data																									
Cost effectiveness analysis																									
Review preliminary findings and draft interim reports																									
Interim Implementation and Assessment Reports (9/28/08)																									
Qualitative Component																									
Draft OMB/IRB packages																									
Develop interview instrument																									
OMB clearance/IRB review*																									
Final implementation plan																									
Pilot test interview instrument*																									
Recruitment and scheduling for interviews*																									
On-site interviews*																									
Review qualitative findings and draft final assessment report																									
Submit Final Assessment Report																									
Dissemination Activities																									
Document and package best practices (implementation handbook); submit draft (3/28/09)																									
Final Implementation Handbook (5/28/09)																									
Final Dissemination Plan (5/28/09)																									
Disseminate through HRET and Alliance networks (complete at least 2 activities – includes presentations and publications) (7/28/09)																									
Submit draft manuscript to CO and TOO for comment																									
Disseminate best practices through HRET and Alliance electronic sources																									
Final Report (9/28/09																									

*6-9 months allowed for OMB/IRB clearance. Timeline for subsequent implementation activities is dependent on obtaining clearance.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments

Attachment 1	AHRQ Authorizing Legislation
Attachment 2	60-Day Federal Register Notice
Attachment 3	Quantitative Evaluation Protocol
Attachment 4	Qualitative Evaluation Protocol
Attachment 5	Code Book
Attachment 6	Interview Guide
Attachment 7	Informed Consent
Attachment 8	Recruitment Letter