SUPPORTING STATEMENT

Focus Groups on Consumer Engagement in
Developing Electronic Health Information Systems

Version: January 7, 2008

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 Attachment A), 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.

This project will consist of focus groups to gain insights into healthcare consumers' awareness and perceptions of Health Information Technology (IT), and how best to engage consumers in the development of these technologies. AHRQ has so far invested significant resources in initiatives to promote the planning and development of new Health IT that should improve healthcare, lower healthcare costs, and improve patient safety. For such benefits to be maximized, it is important understand how consumers view Heath IT and how to engage them in the design and implementation of future innovations.

We will conduct 20 focus groups (in addition to two pretest groups) with healthcare consumers. For this project, we define healthcare consumers as persons who have visited a healthcare provider (either for their own health or the health of a family member) in the previous two years. For the most part, the groups be homogenous with respect to the presence or absence of either of the following characteristics: a) Managing a chronic health condition (or the condition of a close family member), or b) Having visited at least three healthcare providers in the past two years. Consumers with a relatively "heavy" dependence on healthcare might be expected to have a very different frame of reference in considering Health IT, as compared to persons with a lighter use of healthcare. We would expect that both the potential benefits and risks of Health IT will be more immediately clear to those more dependent on healthcare, relative to the latter group.

Participants will be covered by a range of health insurance plans, and we intend to recruit some persons not covered by health insurance as well. However, we will construct several groups to be homogenous with respect to whether or not participants are covered

by an HMO. Approximately two-thirds of physicians who practice within an HMO are using Electronic Medical Records (at least partially), as compared to only about one-fifth of those in practices owned by the physicians themselves.[1] Consumers who avoid HMOs often do so, at least partly, because they want maximum choice and independence with respect to the healthcare providers they visit, and this characteristic may be related to their perceptions of certain aspects of Health IT (e.g., sharing of information among providers).

Participants will be recruited through databases of research volunteers and newspaper ads. Participants will gather together for a 2-hour session with an experienced focus group moderator who will pose the topics and lead the discussion, ensuring that all viewpoints are heard and that the discussion stays on track.

Attachment B provides more information on the locations of the focus groups, and how these groups will be constructed during the participant recruitment process.

2. Purpose and Use of Information

As AHRQ continues to promote and fund efforts to design and implement Heath IT, it is expected that information from the proposed project will be used to better understand the misunderstandings, fears, and other concerns on the part of the people most affected by these efforts: healthcare consumers. AHRQ will also use the information to devise strategies to better engage consumers in the development of Health IT systems, so as to facilitate more effective communication with consumers and address demands for transparent and culturally-sensitive mechanisms for involving consumers. We consider the proposed project an exploratory investigation – we know that engaging consumers in the development of Health IT is necessary in order to maximize its future utility, but it is unclear how best to engage them in this development, and at what points to engage them. Findings from this project will be disseminated to others working in areas related to Health IT (both governmental and private industry) through conference presentations, and possibly publications in scholarly journals.

AHRQ is committed to accelerating the adoption of Health IT throughout the United States, in keeping with the President's goal that most Americans' healthcare involve Health IT by 2014. With this project, AHRQ will better understand the optimum role of consumers in developing Health IT systems. This knowledge should lead to wider acceptance of Health IT by healthcare consumers, which in turn might hasten providers' adoption of Health IT.

3. Use of Improved Information Technology

This project cannot effectively make use of computer or internet-mediated data collection techniques to satisfy the task objectives. Instead, data collection will be done through an established focus group methodology, involving face-to-face interactive discussions between a professional moderator and groups of healthcare consumers.

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[1] Robert Wood Johnson Foundation (2006) *Health Information Technology in the United States: The Information Base for Progress*,

4. Efforts to Identify Duplication

Although a number of statistical surveys of the public have addressed topics relating to Health IT, we are not aware of any in-depth qualitative research that examines healthcare consumers' perceptions of the risks and benefits of Health IT and how consumers may wish to be engaged in its development. This project will be a pioneering effort on this topic.

5. Involvement of Small Entities

This project will collect information from individual healthcare consumers. Thus, the project will place no burden on small businesses or other small entities.

6. Consequences if Information Collected Less Frequently

This is a one-time data collection.

7. Special Circumstances

The data collection from this study, as with any focus group study, will produce findings that cannot readily be statistically generalized to a broader population of persons, including healthcare consumers. The focus groups will be conducted with persons residing in multiple regions of the country, including large cities, medium-sized cities, and rural locations. The participants will have a variety of healthcare needs and health insurance arrangements, such as coverage by HMOs, non-managed care plans, Medicare, Medicaid, as well as persons without health insurance. We will recruit participants varying in gender, age, racial/ethnic background, and education levels. Four focus groups will be with Spanish-speaking participants.

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 December 28th, 2007 for 60 days (see Attachment C). AHRQ received one comment in response to the notice, from the Iowa Foundation for Medical Care (IFMC). The comment informed us of a series of five focus groups that IFMC conducted with healthcare consumers Iowa during 2006. The purpose of their focus groups overlapped to some degree with the purpose of our proposed project. We were very pleased to learn about this project. Their objectives were much narrower, however, being largely concerned with perceptions of privacy and security issues in the electronic exchange of personal health information in Iowa. Learning how to engage consumers in the future development of Health IT does not appear to have been an objective of the IFMC project.

The IFMC memo also pointed to a few logistical considerations:

- *A $50 stipend for a 2-hour session scheduled over a mealtime, with meals provided, was an effective way to engage the consumers.*

We would not necessarily disagree with this point. However, rules enacted by the Department of Health and Human Services in 2007 strictly prohibit us from providing food to focus group participants.

- *Essman recommended no more than 10 persons per session to allow adequate involvement by each participant. Fifteen persons were recruited for each session to allow for "no-shows". If more than 10 showed up, the additional persons were paid and sent home.*

We agree that it is best to have no more than 10 persons per session. We plan to initially recruit 12 persons per session to allow for "no-shows." Experience shows that recruiting 12 persons generally ensures 10 participants. If necessary, we can recruit a greater number of persons for later groups. For any groups where more than 10 people show up, we will pay and send away the additional persons.

- *It was difficult to fit in 4 written consumer exercises in addition to the discussion guide during the 2 hours. Adjustments were made after the first focus group to accommodate this fact (e.g., consumers were asked to write out only 1-2 exercises; the rest were discussed verbally).*

The first two focus groups we plan to conduct are considered the "pretest groups" for the proposed project. Like IFMC, we are prepared to adjust the protocols for conducting the focus group sessions as necessary to fit into a 2-hour timeframe.

The full comment from IFMC is included in Attachment H.

8.b. Outside Consultations

The project officer consulted with former colleagues and experts on issues of health information systems and consumer engagement regarding the need for this work, the lack of availability of data on the topic and the appropriateness of focus groups as a viable method for conducting this work.

Furthermore, the project officer consulted with local groups that perform or have performed focus group work with consumers on topics relating to health to understand the suitability of the methodology and estimated costs.

9. Payments/Gifts to Respondents

We will offer eligible persons $75 as an incentive to participate in the focus groups. In order to take part in the focus groups, participants will have to transport themselves to a specified location (a focus group facility or conference center) at a previously determined time. Some participants will have to make arrangements for childcare or adjust their work schedules to come to the focus group. Although it may be possible to conduct this study while providing a smaller incentive amount to participants, experience suggests that doing so would increase the resources needed for recruiting groups with the desired level of diversity among participants, thus increasing the overall project cost to the government. Furthermore, only people very eager to participate in focus groups could be

recruited using a smaller incentive, which may influence the group discussion in unpredictable ways that color the study's findings.

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.

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.

The data collection will be conducted by AHRQ's contractor, Westat. Westat is a major government contractor with established policies and procedures in place for protecting the confidentially of research participants. All Westat employees and consultants with access to identifiable information are required to read and sign an Assurance of Confidentiality statement (shown in Attachment D). When not in use by project staff, all information or materials that could potentially identify participants in this study will be stored in locked cabinets that are accessible only to persons assigned to work on the project. All materials that identify participants will be destroyed within three months after the project ends.

Written informed consent will be obtained from all focus group participants. A copy of the consent form to be used is shown in Attachment E.

11. Questions of a Sensitive Nature

Focus group participants will not be asked questions of a sensitive nature. A draft discussion guide to be used by moderators leading the focus groups is show in Attachment F.

12. Estimates of Annualized Burden Hours and Costs

Estimates of hour and costs burden to respondents in this project are shown in Tables 1 and 2, respectively. We expect to have to screen approximately 2,200 persons to identify 220 eligible participants across a total of 22 focus groups. We expect that the screener to be used to identify and recruit eligible persons will take approximately 5 minutes to complete (the screening questionnaire is shown in Attachment G). The focus group discussion will take approximately 2 hours, and we have assumed a 20-minute commuting time (each way) per participant. Thus, focus group participation will require 2.67 hours per response. The total estimate of burden hours is 770 hours. The cost to respondents for this burden is estimated to be $13,090, based on an average hourly wage of $17 per hour.

Table 1. Estimated annualized burden hours

Form Name	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden hours
Recruiting Screener	2,200	1	5/60	183
Focus Group Discussion Guide	220	1	2.67	587
Total	2,420	na	na	770

Table 2. Estimated annualized cost burden

Form Name	Number of Respondents	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
Recruiting Screener	2,200	183	$17	$3,111
Focus Group Discussion Guide	220	587	$17	$9,979
Total	2,420	770	na	$13,090

*Based upon the mean hourly wage of full-time workers, third-quarter of 2007. Current Population Survey, U.S. Department of Labor, Bureau of Labor Statistics.

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

Based on the current budget for the project, the total cost to the Federal Government is $257,474 ($251, 114 of contractor costs + $6,360 of travel and time cost for AHRQ employees) for the 18-month period from Oct. 1st, 2007 to March 31st, 2009. The annualized cost is approximately $171,649. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phases of the study. The costs of Federal employees for monitoring the contract are $5,660.

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

The anticipated schedule for this project is shown in Table 3. Analyses will be performed on an iterative basis after a set of four groups to be conducted in each of the five major U.S. geographical regions. Upon completion of all groups, findings across all five regions will be integrated and final analyses will be performed comparing groups in terms of characteristics such heavy versus light use of healthcare, and HMO coverage versus non-HMO coverage. Additional analyses will address issues of particular interest to Spanish-speaking persons and persons living in selected rural areas.

Table 3. Anticipated Schedule

Activity	Time Schedule after OMB Approval
Two Pretest Focus Groups	
Begin recruiting	Immediately
Conduct groups	<1 month
Four Groups in Mid-Atlantic Region	
Begin recruiting	1 month
Conduct groups	2 months
Analysis and In-depth report	2-3 months
Four Groups in West Region	
Begin recruiting	3 months
Conduct groups	4 months
Analysis and In-depth report	4-5 months
Four Groups in Midwest Region	
Begin recruiting	4.5 months
Conduct groups	5.5 months
Analysis and In-depth report	5.5-6.5 months
Four Groups in Northeast Region	
Begin recruiting	6 months
Conduct groups	7 months
Analysis and In-depth report	7-8 months
Four Groups in South Region	
Begin recruiting	7.5 months
Conduct groups	8.5 months
Analysis and In-depth report	8.5-9.5 months
Final analyses and comprehensive report	9.5-11 months
Presentation slides	11.5 months

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: AHRQ's Authorizing Legislation

Attachment B: Locations and Characteristics of Focus Group Participants

Attachment C: 60 Day Federal Register Notice

Attachment D: Westat Assurance of Confidentiality

Attachment E: Consent Form for Focus Group Participants

Attachment F: Focus Group Moderator's Guide

Attachment G: Screener for Recruiting Participants

Attachment H: Public Comment