# SUPPORTING STATEMENT

## Part A

Understanding Development Methods from Other Industries to Improve the Design of Consumer Health IT

Version: July 28, 2011

Agency for Healthcare Research and Quality (AHRQ)

## Table of Contents

## A. Justification

### *1. Circumstances That Make The Collection of Information Necessary*

The mission of the Agency for Healthcare Research and Quality (AHRQ), as 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:

- Research that develops and presents scientific evidence regarding all aspects of health care;

- The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

- 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.

Consumer health information technology (IT) is the collection of tools, technologies, and artifacts that individuals can use to support their health care management tasks (Agarwal and Khuntia, 2009). Consumer health IT can play an important role in patients' efforts to coordinate their care and in ensuring that their personal values and interests help guide all clinical decisions. In order to accomplish this, consumer health IT solutions must take into account the particular needs of the consumer.

Useful consumer health IT products may enhance the quality of health care by empowering individual consumers to take a more active, effective, and collaborative role in their own personal health care. These products could provide the following capabilities to consumers:

- **Information storage, archiving, and retrieval:** the capabilities to search results of past examinations or lab tests, to interact with electronic versions of their health records, and identify when to seek health care services.
- **Health monitoring:** the capability to report data (e.g., blood pressure, weight) from various locations.

- **Information seeking and searching:** the capability to interactively search for a wealth of health-related information.

Despite the potential power of consumer health IT, consumers have not adopted these technologies to the same degree that they have adopted technology products marketed from other consumer product industries. One reason for slow adoption is that the marketplace lacks robust tools that allow for the complexity and diversity of personal health information management (PHIM) practices. These types of practices are influenced by a variety of user and contextual factors, including demographics, personal attitudes, the goals and objectives of users, and the broad range of tasks that users wish to perform. There is no comprehensive list of problems that users encounter as they collect and reflect on personal information; this creates a barrier for design of consumer health IT tools.

New practices for the development of consumer-facing digital tools are emerging in a variety of industries. The success of information management tools in other industries offers much to be learned and applied to the health care field.
In July of 2009, AHRQ held the *Building Bridges: Consumer Needs and the Design of Health Information Technology* workshop. The workshop brought together leaders from multiple disciplines, including health informatics, health sciences, information science, consumer health IT, and human factors to discuss the diverse needs of different consumer groups in managing their personal health information, and how these needs could be incorporated into the design of consumer health IT solutions. The outcome of the workshop was a framework to further the design of consumer health IT systems, based on an understanding of practices that consumers use in their PHIM. The final report also included a set of recommendations for additional work in the health IT field related to research and industry and policy. Recognizing that design plays a key role in consumer use of personal tools, one research–related recommendation that resulted from the workshop was to *investigate the application of design methodologies used in other industries to consumer health IT design*.

This project has the following goals:

1) To investigate the product development approaches, methods, and philosophies from a variety of industries in order to identify promising design and development techniques that will be most applicable to consumer health IT.

2) To disseminate the project findings and recommendations to vendors and developers of consumer health IT products to assist them in developing health IT products that are consumer-focused.

To achieve the goals of this project the following activities and data collection will be implemented:

1) Semi-structured interviews will be conducted with key informants identified as being experts in the design, management, and/or marketing of consumer products that are relevant to consumer health IT products (see Attachment B). The purpose of these

interviews is to gather information related to their experiences in developing consumer products, focusing on the design processes that their company uses, how they segment the market, the role of users in testing during the various product development phases, and the factors that affect the success of their product development approaches.

2) The final report will be provided in PDF format for easy download from the AHRQ National Resource Center for Health IT Web site.

This study is being conducted by AHRQ through its prime contractor, Westat, and two individual consultants (Dr. Enid Montague and Dr. Pascale Carayon) from the University of Wisconsin, 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).

### *2. Purpose and Use of Information*

Information collected by the study will support the development of recommendations for those developers and vendors who design, develop, and market consumer health IT products. The ultimate goal is to improve consumer health IT design and impact the adoption of this technology by consumers. This project will identify principles that led to the success of other consumer products, so that they can be evaluated for extension to the design and development of consumer health IT.

### *3. Use of Improved Information Technology*

AHRQ will collect data through an established qualitative research methodology, which includes telephone conversations with informants from other industries (henceforth called "study participants"). Because most discussion topics are open-ended to allow for in-depth exploration of issues, electronic submission of responses is not a viable option.

### *4. Efforts to Identify Duplication*

In a prior AHRQ project, *Personal Health Information Management and the Design of Consumer Health Information Technology*, AHRQ contractors conducted a literature review and conferred with internal staff and outside health IT experts about ongoing research projects. From these discussions and review, AHRQ has not identified research efforts of a similar nature.

### *5. Involvement of Small Entities*

This research will involve telephone discussions with study participants representing a variety of consumer product and service industries. It is unclear at this time whether any of the 15 study participants will be employed at a small business or other entity.

Interviews will be scheduled at times convenient for the study participants. The interview guide (see Attachment B) illustrates the depth and breadth of questions intended for coverage in each discussion, although not all questions will apply to each study participant. Individual telephone discussions will last no more than 90 minutes. Study participation is voluntary and AHRQ will be respectful of the study participants' time. Contact materials for inviting participation, confirming participation, and thanking study participants for their participation are included as Attachments C, D, and E.

### *6. Consequences if Information Collected Less Frequently*

This is a one-time collection of qualitative interview data.

### *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 January 27th, 2011 for 60 days (see Attachment F).

#### *8.b. Outside Consultations*

AHRQ consulted with its research contractor, Westat, in developing the study protocol. Supporting Statements Parts A and B along with all the attachments were also shared with Lygeia Ricciardi from the Office of the National Coordinator for Health IT for review. Ms. Ricciardi noted that ONC-IT was familiar with this activity and supported it.

### *9. Payments/Gifts to Respondents*

There will be no remuneration to the study participants.

### *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.

All study participant involvement will be voluntary. Only oral consent for participation will be obtained from the study participants. The study will collect information from study participants about their industry's strategies for consumer-focused design. The study participants will be informed that the information they provide may be published; however, the researchers will mark specific feedback as off-limits for reports and publications if requested to do so by the study participant (for example, proprietary information, or opinions that may not be viewed positively by a study participant's organization). This means that AHRQ will be granted access to the information but will not place the information in the public domain.

The contractor staff, subcontractors, and consultants are required to sign a Confidentiality of Data agreement (see Attachment G). Also, all electronic files will be password protected and accessible only from a secured network. When not in use by project staff, all printed information or materials that could potentially identify participants in the study will be stored in locked cabinets that are accessible only to project team members.

### *11. Questions of a Sensitive Nature*

No questions of a sensitive nature will be asked. Further, during the introduction to the discussions, the study participants will be informed that their participation is voluntary and that they can refuse to answer any question.

### *12. Estimates of Annualized Burden Hours and Costs*

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. Semi-structured interviews will be conducted with no more than 15 individuals representing a variety of consumer-focused industries. The average burden will be 90 minutes per interview. The total annual burden is estimated to be 23 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondent's time to participate in this research. The total annual cost burden is estimated to be $1,770.

**Exhibit 1. Estimated Annualized Burden Hours**

| | Number of responses | Number of responses per respondent | Hours per response | Total burden hours |
|---|---|---|---|---|

| | Number of responses | Number of responses per respondent | Hours per response | Total burden hours |
|---|---|---|---|---|
| **Total** | 15 | 1 | 1.50 | 23 |

**Exhibit 2. Estimated Annualized Cost Burden**

| | Number of responses | Total burden hours | Average hourly wage rate* | Total cost burden |
|---|---|---|---|---|
| Semi-structured interviews | 15 | 23 | $76.94 | $1,770 |
| **Total** | 15 | 23 | $76.94 | $1,770 |

*Wage rates calculations were not possible using data from the U.S. Department of Labor, Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the United States, Occupational Employment Statistics (OES). The OES categories are too broad to determine a wage rate for a "Director of Product Development." Instead wage rate calculations are based on information from the Web site www.salary.com which has a tool providing a range of salaries for a variety of specific job titles. The salary for a "Product Development Director" generally ranges from $130,313 (25$^{th}$ percentile) to $189,771 (75$^{th}$ percentile) with an anticipated median of $160,042. Assuming 2,080 hours per year (40 hours per week), the resulting median hourly rate is $76.94.

### *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 the study participants other than their time to participate in the study.

### *14. Estimates of Total and Annualized Cost to the Government*

Exhibit 3 shows the estimated total and annualized cost to the Federal Government for this research project. Since this projects' activities will span a single year the total and annualized costs are identical. The estimated total cost is $409,388.

**Exhibit 3. Estimated Total and Annual Cost* to the Federal Government**

| Cost component | Total cost | Annualized cost |
|---|---|---|
| Administration and Coordination Activities | $91,673 | $91,673 |
| Technical Expert Panel | $74,217 | $74,217 |
| Environmental Scan and Grey Literature Review | $58,413 | $58,413 |
| OMB Submission Package | $11,574 | $11,574 |
| Interviews with Study Participants | $102,018 | $102,018 |
| Recommendations for Health IT Vendors and Developers | $48,612 | $48,612 |
| Dissemination Activities | $14,325 | $14,325 |
| 508 Compliance | $8,556 | $8,556 |
| **Total** | $409,388 | $409,388 |

*Costs are fully loaded including overhead, G&A and fees.

### *15. Changes in Hour Burden*

This is a new collection of information.

### *16. Time Schedule, Publication and Analysis Plans*

**Time schedule and publication plans.** The anticipated schedule for this project is shown in Exhibit 4. Once clearance from the Office of Management and Budget is obtained, AHRQ will begin identifying appropriate industry experts, and scheduling and conducting discussions.

The results of the key informant interviews will be shared with the members of the project's Technical Expert Panel (TEP). During a TEP meeting scheduled to occur in approximately March of 2012, the TEP members will offer their insights and interpretations of the key informant report based on their individual reviews. They will discuss the applicability and generalizability of these results, along with results generated from another project activity – an environmental scan and review of the grey literature – for consumer health IT applications. The TEP members will assist project staff in formulating a set of recommendations targeted to the audiences of developers and vendors who design, develop, and market consumer health IT products. These recommendations will be developed in both report and presentation formats.

The key informant report will be made publicly available to the target audiences of external experts in the field of consumer health IT and consumer health IT designers and vendors who are interested applicability of specific design methods and consumer products. The report will be provided in PDF format for easy download from the AHRQ National Resource Center for Health IT Web site.

**Exhibit 4. Anticipated Schedule**

| Activity | Estimated timeline following OMB clearance |
|---|---|
| Conduct Interviews | Months 1-2 |
| Analyze Results | Months 2-4 |
| Final outline of the interview report | Month 5 |
| Draft report of lessons learned from interviews | Month 6 |
| Final report of lessons learned from interviews | Month 7 |
| Draft recommendations report | Month 8 |
| Final recommendations report | Month 10 |
| Dissemination of findings and recommendations | Month 12 |

**Analysis plans.** Over the course of the approximate two-month data collection period, the project team will review interview notes after each interview has been completed to discuss the key findings, emerging issues and/or themes, and unique points mentioned by the study participant. The team will primarily be tasked with identifying "lessons learned" from the other industries that might be applied to consumer health IT and design approaches that appear most promising and relevant to consumer health IT design.

The interviews with the 15 study participants will be transcribed verbatim. Analysis will begin with a coding process to identify themes that emerge from the raw transcribed data. The team will identify and tentatively group question responses into conceptual categories and name these. The objective is to create descriptive, multi-dimensional categories that will form a preliminary framework for analysis. Responses that appear to be similar will be grouped into the same initial categories. The categories may be gradually modified, subsumed into other categories, or replaced during the subsequent stages of analysis.

The team will analyze findings, then aggregate findings to identify any patterns or themes present across industries, product types, study participant's role in design and development of consumer products, stage of consumer product development (e.g., idea generation, concept development, testing, implementation, and commercialization), and other key dimensions that may emerge as the data are collected.

### *17. Exemption for Display of Expiration Date*

AHRQ does not seek this exemption.

### *References*

Agarwal R, and Khuntia, J. (2009). *Personal Health Information and the Design of Consumer Health Information Technology: Background Report.* (Prepared by Insight Policy Research under Contract No. HHSA29020070072T). AHRQ Publication No. 09-0075-EF. Rockville, MD: Agency for Healthcare Research and Quality.

### *List of Attachments*

Attachment A: Healthcare Research and Quality Act of 1999
Attachment B: Key Informant Interview Guide
Attachment C: Invitation Letter
Attachment D: Confirmation Letter
Attachment E: Thank-you Letter
Attachment F: Federal Register Notice
Attachment G: Confidentiality of Data Agreement