

SUPPORTING STATEMENT

Part A

Innovator Data Collection on Healthcare Innovations for
The Agency for Healthcare Research and Quality Healthcare's
AHRQ Healthcare Innovations Exchange

Version: August 13, 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: 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.

From its National Healthcare Quality Report (NHQR) and National Healthcare Disparities Report, AHRQ has revealed that positive change is happening but at a slow pace. Indeed, in the 2007 NHQR, AHRQ found that the rate of improvement has slowed.¹ In addition, the health care environment is ripe for novel changes to shape how health care is delivered and funded.² Innovation is at the heart of these novel changes and AHRQ seeks to find health service delivery innovations and support accelerated diffusion and adoption of them, with the goal of having a more profound impact on improvements in the quality of the nation's health care and significant reductions in its disparities.

To help meet these goals, the Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve for three years, under the Paperwork Reduction Act of 1995, the collection of information about health care service innovations to support accelerating the diffusion and adoption of innovative health care delivery changes. This information will be collected using the AHRQ Healthcare Innovations Exchange Innovator Email Submission Guidelines (Attachment B) and the AHRQ Healthcare Innovations Exchange Innovator Interview Guide (Attachments C and C2). The descriptions of the innovations will be published on the AHRQ Healthcare Innovations Exchange web site (Innovations Exchange). This work will be performed by Westat in collaboration with AHRQ.

The Innovations Exchange will provide a national-level information hub to foster the implementation and adaptation of innovative strategies that improve health care quality and minimize disparities in the care received by different populations. It is intended to address stakeholder interest in a “one-stop shop” that presents digested and reliable information about health care delivery innovations along with their accompanying

¹ Agency for Healthcare Research and Quality. 2007 *National Healthcare Quality Report*. Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; February 2008. AHRQ Pub. No. 08-0040. <http://www.ahrq.gov/qual/nhqr07/Key.htm>. Accessed 04/23/2008.

² Dougherty D, Conway PH. The “3T’s” Road Map to Transform US Health Care: The “How” of High-Quality Care. *JAMA*, May 21, 2008—Vol 299, No. 19

implementation tools and networking opportunities to share implementation strategies and techniques. Its target audiences, broadly defined, will be current and potential change agents in the U.S. health care system, including clinicians (e.g., physicians, nurses, and other providers), health system administrators, health plan managers, health service purchasers, regulators, and policymakers from relevant Federal and state agencies.

These service innovations will come from many care settings including inpatient facilities, outpatient facilities, long term care organizations, health plans and community care settings. They will also represent many patient populations, disease conditions, and processes of care such as preventive, acute, and chronic care. The innovations must meet six criteria with respect to the nature of the activity, the level of documentation, and the participation of the innovator, which are minimum requirements to participate. The six criteria are:

- The innovation focuses directly or indirectly on patient care.
- The innovation is intended to improve one or more domains of health care quality.
- The activity is truly innovative in the context of its setting or target population.
- Information about the innovation is publicly available.
- The innovator (or a representative) is willing and able to contribute information to the Health Care Innovations Exchange.
- There is reason to believe that the innovation will be effective.

The ultimate decision to publish a detailed profile of the innovation will depend on several factors, including an evaluation by AHRQ, AHRQ's priorities, and the number of similar ideas in the Innovations Exchange. AHRQ's priorities include identifying and highlighting innovations (1) that will help reduce disparities in health care and health status; (2) that will have significant impact on the overall value of health care; (3) where the innovators have a strong interest in participating; and (4) that have been supported by AHRQ.

To develop the target of 750 profiles (250 profiles per year for three years), a purposively selected group of 825 health care innovations will be selected for potential consideration. These 825 innovations will be selected to ensure that innovations included in the Innovations Exchange cover a broad range of health care settings, care processes, priority populations, and clinical conditions. These 825 innovations will be gathered from several sources. Innovators who submit their innovations for possible publication through the email submission guidelines process (Attachment B) will be considered as will innovations identified by project staff through an array of sources that will include: published literature, conference proceedings, news items, list serves, Federal agencies and other government programs and resources, health care foundations, and health care associations. Secondary research will provide background information prior to contacting the innovator.

To collect and verify the information required for the profiles, approximately 825 health care innovators associated with these innovations will be contacted by telephone about their innovative activities and their voluntary interest in participating in the Innovations Exchange. Once their agreement to participate is secured, the innovators will be

interviewed by telephone (Attachment C) about the following aspects of their innovation: health care problem addressed, impetus for the innovation, goals of the innovation, description of the innovation, sources of funding, evaluation results for the innovation, setting for the innovation, history of planning and implementation for the innovation, and lessons learned concerning the implementation of the innovation. The length of the interview will depend on whether the innovators submitted information by email.

Based on the respondent feedback and a determination that the innovation meets the inclusion criteria, a draft profile will be developed based on the email submission and/or interview and sent by email to the innovator for review and approval to publish. After the profile is published, on a yearly basis, innovators will be interviewed to review and update their profiles.

These research activities are not required by regulation, and will not be used by AHRQ to regulate or sanction its customers.

2. Purpose and Use of Information

The AHRQ Health Care Innovations Exchange's use of the interview guide and email submission guidelines will assist in determining if the suggested innovation: 1) meets established eligibility criteria of the Innovation Exchange, 2) addresses AHRQ's priorities, and 3) can be used to prepare and maintain the current nature of a profile.

3. Use of Improved Information Technology

The Innovations Exchange will offer guidelines to innovators on how to submit their innovations by email for the purposes of providing project staff with preliminary information about their innovations. These guidelines will decrease the time required for telephone interviews by conveying important information to project staff who prepare the innovation profiles. Innovators will be provided with an email address to which they are asked to send a description of the innovation that includes:

- name of the main organization, along with any other organizations that are participating in the innovation;
- name, title and contact information of the submitter (e.g, e-mail address and phone number) NOTE: this information is to establish contact between the project team and the innovator and to broker connections between innovators and potential adopters should the innovation be included in the Innovations Exchange; this personal identifying information is NOT retrievable in a searchable database;
- brief description of the innovation;
- brief description of results including any impact on the delivery of patient care;
- description of the health care setting (e.g., hospital, community clinic, nursing home);

- description of the population on which the innovation is focused, if any (e.g., the elderly, children, racial or ethnic group); and
- any funding sources for the innovation.

Innovators will be encouraged to attach documents that support each of the bulleted items above and provide more detail.

4. Efforts to Identify Duplication

Duplication of this effort neither exists with respect to other Federal agencies nor with respect to the private sector. There are a number of websites that present information on health care innovations sponsored by foundations and the private sector. These websites tend to be limited in their focus. They may consider innovations that focus on one or a few diseases, funding sources, patient populations, or theoretical foundations. A list of the healthcare innovations-oriented websites is located in Attachment E.

The Innovations Exchange will be the only readily accessible, single source of information concerning innovations in patient care service delivery, multiple patient populations, multiple care settings, multiple diseases, multiple care processes, and multiple funding sources. For example, the Innovations Exchange will publish profiles representing patient care innovations focusing on population groups that represent all ages, geographic locations (e.g., rural, urban, suburban, nation), ethnicities, genders, and a wide variety of vulnerable population groups (e.g., frail elderly, homeless, illiterate/low-literate, medically uninsured). There will also be profiles focusing on multiple care settings such as ambulatory care, hospital care, managed care; on multiple care processes (e.g., preventative care, diagnosis and treatment, patient-focused processes/psychosocial care); and on all Institute of Medicine (IOM) quality domains.

5. Involvement of Small Entities

While we anticipate that innovators within small entities will be included in the pool of respondents, participation in and submissions to the Innovations Exchange are voluntary. We do not expect that our data collection procedures will result in any significant additional burden for small entities. Rather the data collection efforts are designed to minimize burden on all respondents.

6. Consequences if Information Collected Less Frequently

Without this data collection effort and annual updates, detailed information about current innovations in patient care service delivery would not be available in one location to the target audience: current and potential change agents in the US health care system, including clinicians (e.g., physicians, nurses, and other providers), health system

administrators, health plan managers, health service purchasers, regulators, and policymakers from relevant Federal and state agencies.

7. Special Circumstances

This data collection will be consistent with the general information collection guidelines of 5 CFR 1320.4(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 August 21st, 2008 for 60 days (Attachment F). One comment was received, which is shown below:

what is nih and cdc doing that is duplicative of this work. why are these 3 agencies not working tightly together to get more accomplished for the american tax dollarrs. Instead none of them knows what the other is doing and the american taxpayers gets socked for endless dollars. there needs to be a review of all 3 agencies to correlate their work. no budget money should be spent on this until these 3 agencies start working together.

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The NIH National Center for Minority Health and Health Disparities' Office of Innovation and Program Coordination and AHRQ have been collaborating on how best to capitalize on AHRQ's investment in the Health Care Innovations Exchange (so as not to be duplicative). AHRQ is not aware of any CDC efforts that duplicate this particular AHRQ effort, which has been identified by outside consultations as novel and unique. Note that these outside consultations have included communications with experts in the VA and the DoD's Military Health System.

8. b. Outside Consultations

AHRQ has consulted a broad range of experts, including staff in-house, in other Federal agencies such as the (National Library of Medicine, National Institutes of Health), and in other organizations (Attachment G) who have extensive expertise in health service delivery systems, workflow processes, identifying and disseminating innovative processes across industries, and in health classification systems. Ongoing consultations in these areas are necessary to guide appropriate practices for identifying, organizing, classifying and disseminating innovations that result in health care quality improvements and disparities reduction. Several examples of expert consultations in support of the Innovations Exchange include the following.

- Guided by AHRQ officials, Westat, the contractor for this project, consulted targeted senior AHRQ staff to identify prospective program sources that might yield eligible innovations through AHRQ grant and contract programs. Additionally, AHRQ staff have been instrumental in helping to establish criteria that refine various definitions of innovation, degrees of innovativeness, and applications of innovations in addressing various care processes in diverse clinical and community-based settings.
- Silverchair, a subcontractor to Westat, is a nationally recognized health information technology firm with a substantial track record in developing high-value, information-critical products for the health care community. For the Innovations Exchange, Silverchair's role is to help create domain specific taxonomies, facilitate the adaptation of legacy systems, and integrate established vocabularies. Supported by a cadre of professional medical indexers, Silverchair's capacity is enhanced to provide assistance with taxonomy development and semantic tagging.
- Dr. Brian Mittman, an internationally regarded senior social scientist with expertise in implementation science provided insight into service systems for veterans via his position as Director for the Study of Healthcare Provider Behavior, Department of Veterans Affairs, USA.
- Paul Plesk, a nationally recognized expert in health care innovation has consulted on an ongoing basis relative to criteria development/refinement, positioning of quality improvement innovations and message development to promote adoption of effective practices.
- Dr. Kyu Rhee, Director, Office of Innovation and Program Coordination, National Center on Minority Health and Health Disparities was consulted by AHRQ on approaches that should be undertaken to assess the innovativeness and context for health disparities reduction innovations. Dr. Rhee was also consulted on the appropriate strategies that might be used to identify health disparities reduction innovations among past and current NIH grantees.
- Dr. Rubens Pamies, a nationally recognized expert on disparities reduction issues, continues to be consulted on contextual frameworks for innovations that address priority populations and disparities reduction efforts.
- Dr. Greg Pawlson, an executive leader of the National Committee for Quality Assurance (NCQA)—a premiere quality improvement health care organization—provides leadership to the project as the Chair of the Expert Panel. In this capacity, Dr. Pawlson facilitates dialogue and garners input from a broad range of health care experts in support of the Innovations Exchange.
- Patricia M. Collins, BSN, MN, a senior advisor in the Office of the Chief Medical Officer at the TRICARE Management Activity and program manager for the Military Health System (MHS) Office of Transformation initiative, Effective Patient Partnerships, is consulted for her expertise in military health innovations.

The above descriptions represent a few examples of the experts consulted, the types of issues discussed and queries that have been made. Attachment G provides a more extensive list of other experts who have been engaged during the developmental aspects of the Innovations Exchange project.

9. Payments/Gifts to Respondents

No payments or gifts will be offered to respondents.

10. Assurance of Confidentiality

No assurance of confidentiality will be made to respondents.

11. Questions of a Sensitive Nature

No questions of a sensitive nature are included in the interview guide or email submission guidelines.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents. Approximately 275 innovators will participate in the initial data collection each year for a total of 825 over the three year period. Of the 275 respondents per year we estimate that approximately 15% (41) will submit information via email and will thus be interviewed for a shorter period of time. The remaining 234 respondents that did not submit information via email will be interviewed more extensively to capture the information required. The estimated annualized hours for the respondents' time to participate in the project is 401 hours.

Based on a review of materials from potential innovations we estimate that approximately 10% of the candidate innovations either will not meet the inclusion criteria or their innovators will decide not to continue their participation. Therefore, about 90% (750) of the original 825 profiles will move into the publication stage.

For the 750 published profiles, annual follow-up interviews will be conducted to update the information about the innovation, which will average 30 minutes. Because the profiles will be prepared on a rolling basis over three years, the average number of yearly follow-up reviews per innovator will vary:

- o One third (250) of the profiles will be prepared in the first year and will have 2 annual reviews;
- o One third (250) of the profiles will be prepared in the second year and will have 1 annual review; and,
- o One third (250) of the profiles will be prepared in the third year and will have 0 annual reviews.

Approximately 750 follow-up interviews will be conducted over the 3 years of this project resulting in an annualized average of 250 follow-up interviews per year, even though no follow-up interviews will be conducted in the first year.

Exhibit 1: Estimated annualized burden hours

Form name	Number of Respondents	Number of Responses per Respondent	Hours per response	Total Burden Hours
Email submission	41	1	30/60	21
Health care innovator interview -following email submission	41	1	30/60	21
Health care innovator interview – without email submission	234	1	1	234
Annual follow-up interview	250	1	30/60	125
Total	566	—	—	401

Exhibit 2 shows the estimated annualized cost burden for the respondents. The Bureau of Labor Statistics reported that the average hourly wage for "healthcare practitioner and technical occupations" in the United States was \$29.82 in May 2006. An estimate of \$30 per hour allows for inflation and represents a conservative estimate of the wages of the respondents. Therefore, the total estimated cost burden for respondents is \$12,030, based on the total estimated annualized burden of 401 hours.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of Respondents	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
Email submission	41	21	\$30	\$630
Health care innovator interview - following email submission	41	21	\$30	\$630
Health care innovator interview – without email submission	234	234	\$30	\$7,020
Annual follow-up interview	250	125	\$30	\$3,750
Total	566	401		\$12,030

*Based upon the average wages, "National Compensation Survey: Occupational Wages in the United States, May 2006," 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 total cost to the Government of this data collection is approximately \$116,620 over three years (on average, \$38,873 per year). These costs cover all data collection efforts for preparing and updating the profiles.

Exhibit 3: Estimated Cost

Form name	Total Cost	Annualized Cost
Health care innovator interview -following email submission	\$6,445	\$2,148
Health care innovator interview – without email submission	\$71,813	\$23,938
Annual follow-up interview	\$38,362	\$12,787
Total	\$116,620	\$38,873

15. Changes in Hour Burden

This is a new data collection initiative.

16. Time Schedule, Publication and Analysis Plans

Schedule. This data collection is scheduled for December 2008 through December 2011. The data collection follows a four-week cycle, shown below in Table 3. The Innovations Exchange will publish new profiles to the website every two weeks, averaging 25 publication issues a year. AHRQ will publish approximately 10 profiles per issue for a total of 250 innovations per calendar year. The timeline includes reviewing material from the email submission or identifying the potential innovation and conducting background research, contacting the innovator and conducting the innovator interview, developing the profile, requesting innovator review, and publishing the innovation to the Innovations Exchange.

Table 3: Anticipated schedule

Activity	Time schedule
Background research on innovation	4 weeks prior to publication
Innovator interview	3.5 weeks prior to publication
Develop profile	3 weeks prior to publication
Innovator review	2 weeks prior to publication
Publish profile	Every 2 weeks

Analysis. The Innovations Exchange portfolio of innovations will be systematically reviewed to ensure a broad representation of various settings of care, patient populations, disease conditions, and processes of care.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: Healthcare Research and Quality Act of 1999

Attachment B: Email Submission Guidelines

Attachment C: Healthcare Innovator Interview Guide – Without Email Submission

Attachment C2: Healthcare Innovator Interview Guide – Following Email Submission

Attachment D: Annual Follow-up Guide

Attachment E: List of Websites that Offer Healthcare Quality Improvement and Innovation Information

Attachment F: Federal Register notice

Attachment G: Expert Consultation for the AHRQ Healthcare Innovations Exchange