

SUPPORTING STATEMENT

Part A

**Pretest of Proposed CAHPS® for Cancer Care Questions and
Methodology**

Submitted under AHRQ's Generic Pretesting Clearance 0935-0124

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Agency of Healthcare Research and Quality (AHRQ)

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- Attachment A: CAHPS Cancer Care Questionnaires
- Attachment B: Cover Letter, Reminder Letter, and Phone Invitation Letter
- Attachment C: Phone Call Reminder Script for Mailed Survey Non-respondents

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; 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 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.

This effort, similar to AHRQ's Consumer Assessment of Healthcare Providers and Systems (CAHPS[®]) program, seeks to collect patient experiences of cancer care to measure the quality of cancer care to use for quality improvement and for informed decision-making by cancer patients and their families. AHRQ first launched the CAHPS program in October 1995 in response to concerns about the lack of good information about the quality of health plans from the enrollees' perspective. Numerous public and private organizations collected information on enrollee and patient satisfaction, but the surveys varied from sponsor to sponsor and often changed from year to year. The CAHPS program was designed to standardize patient assessments so that consumers can compare providers and providers can monitor their performance against internal and external benchmarks. Over time, the program has expanded beyond its original focus on health plans to include a range of health care providers and services for special populations. These are the first surveys sponsored by AHRQ's CAHPS program to assess care for a specific class of illness¹. "Cancer" is literally hundreds of diseases, each with its own etiology and treatment strategies. Cancer is the second leading cause of death in the United States and cancer care is becoming increasingly centralized at cancer centers.

¹ These surveys vary by treatment modality only (each survey refers to cancer surgery, radiation, or drug therapy), and they are collectively known as the CAHPS Cancer Care survey

A number of commercial survey vendors offer cancer care satisfaction surveys, but there is no standard survey that will enable patients to compare cancer centers or enable cancer centers to compare their own performance to that of other cancer centers that use different commercial or in-house surveys. AHRQ and its collaborator in this project, the National Cancer Institute, intend this survey to enable the cancer care community to bring order to this chaotic situation, in the same way that other CAHPS surveys have organized and standardized the assessment of health plans, hospitals, ambulatory practices, dialysis centers, and home health agencies among other providers. These other CAHPS surveys, especially those adopted by the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA) have benefited the public and the providers being assessed. Once the survey is completed and a CAHPS trademark is obtained, it is the hope that cancer care organizations, such as the Commission on Cancer, which accredits over 1,500 cancer centers nationwide, will use the survey to standardize the assessment of cancer care and similarly benefit cancer patients and care providers.

Because the CAHPS Cancer Care survey is focused on care for a particular set of clinical conditions, which is unusual for CAHPS surveys, it offers the field of clinical and health services research the opportunity to use CAHPS for additional purposes. It could be used to monitor the quality of care experienced by individual patients in the clinical setting as they transition from one phase of care to the next. Quality of care is also an important outcome measure for studies that compare the effectiveness of new or alternative clinical and delivery system interventions. Compared to previous CAHPS surveys, the cancer survey is particularly suited to use as an outcomes measure in comparative effectiveness research (CER), because it will address a specific set of clinical conditions—cancer—which is one of the 14 sets of priority clinical conditions established by the Health and Human Services for its CER initiative.

The development of a CAHPS Cancer Care survey supports AHRQ’s mission of enhancing the quality, appropriateness, and effectiveness of care by measuring patient experiences of cancer care. Through measuring the care experiences of cancer patients, this project will promote improvements in clinical and health systems practices. These data collection activities are necessary to develop the CAHPS Cancer Care survey and follow the standard protocol for the development of all CAHPS instruments, which the CAHPS program established at its inception in 1995.

This study is being conducted by AHRQ through its contractor, the American Institutes for Research (AIR), 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

We are requesting approval for an initial field test of the survey instrument with 1,800 respondents, all of whom will be cancer patients. AHRQ, NCI, the American Institutes

for Research (AIR), and Mayo Clinic will be participating in the project to develop a reliable and valid questionnaire, which will assess the quality of cancer care from the perspective of the patient. We will use the field test to evaluate the:

- **Survey methodology.** We will assess the response properties and the sampling and survey operations to determine that the planned survey procedures are effective and to select among alternative procedures that will be tested experimentally in the field test, including alternative modes of administration.
- **Psychometric properties.** We will conduct classic psychometric analyses to assess the performance of individual assessment items, develop composite measures from individual items, and provide information about the statistical reliability and validity of the composites and individual global items. On the basis of this analysis, we will revise items and shorten the questionnaire.
- **Case mix adjustment.** We will identify the personal characteristics of patients that should be used to adjust the raw survey results so that the cancer providers being assessed are not held accountable for characteristics of patients that are both associated with the CAHPS scores and beyond the control of providers.

These preliminary research activities are not required by regulation, and will not be used by AHRQ (or any other federal agency) to regulate or sanction anyone. They will be entirely voluntary and the confidentiality of respondents and their responses will be preserved.

The information collected will be used to design, test, and revise the survey instrument described in section 1. The result will be an improvement in information collection instruments and in the quality of data collected, a minimization of respondent burden, and improved responsiveness to the cancer patient and cancer provider communities.

AHRQ believes that several rounds of testing may be necessary to address all of the methodological challenges due to the shift to a disease-specific rather than a provider-specific focus before being approved as a final CAHPS survey. This OMB clearance request is for one round of testing. If additional rounds are needed they will be submitted under a separate clearance. We believe this survey is a much greater challenge in general, because there are many more dimensions of care that were not at issue in the provider-specific focus of previous CAHPS instruments (e.g., type of provider, disease stage, care continuum, location of care). At the contract conclusion, AIR will provide the field test results, revised instrument and recommendations for additional testing (if any) to AHRQ. AHRQ would then decide whether to give this tested survey to a subsequent contractor or the CAHPS Consortium for additional work and finalization of this survey.

3. Use of Improved Information Technology

Experience with previous CAHPS[®] surveys shows that a combination of mail and telephone data collection works well for respondents, vendors, and health care organizations.

4. Efforts to Identify Duplication

AHRQ published a Call for Measures in the Federal Register (Vol. 75, No. 42, Thursday March 4, 2010) and conducted an environmental scan, neither of which revealed a standardized assessment of the quality of cancer care in the public domain. Discussions with experts revealed the existence of two proprietary surveys that are used by some cancer centers on a subscription basis, neither of which were submitted in response to the Call for Measures or meet the need for a standardized survey in the public domain. Thus, the work to be carried out under this clearance is needed to develop the CAHPS Cancer Care survey and does not duplicate any other survey being done by AHRQ, Federal agencies, or commercial firms. During the development of these voluntary instruments, groups within and outside of AHRQ have been and will continue to be consulted (see section 8.b).

5. Involvement of Small Entities

We will recruit 6 cancer centers to provide sampling frames for the field test. Each organization must be large enough to identify a sample of approximately 800 eligible patients. Organizations of this size are necessarily large, so no small organizations will be involved in the study. Survey data will be collected only from individual cancer patients.

6. Consequences if Information Collected Less Frequently

This is presumed to be an initial (see section 2 above) data collection; additional data collections may be needed to finalize instrument if methodological issues remain.

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

Since this project is being submitted under AHRQ's Generic Pretesting Clearance 0935-0124 publication in the Federal Register is not required.

8.b. Outside Consultations

Similar to other CAHPS® survey development efforts, AHRQ is working with a variety of outside organizations and persons to develop the CAHPS Cancer Care survey. Chief among these organizations is the National Cancer Institute, which has played an integral role in every step of survey design, including providing input on the availability of data, frequency of collection, the clarity of instructions, and reporting, and the data elements to be recorded, disclosed or reported. In addition, AHRQ has contracted with the American Institutes of Research and the Mayo Clinic for development of the survey (see Attachment A for the draft instruments) and organized a Technical Expert Panel

composed of cancer patients, cancer clinicians, and representatives of cancer care organizations to provide feedback on technical issues. Informal discussions about the need for and possible use of the survey have been held with the American College of Surgeon's Commission on Cancer, which accredits over 1,500 cancer centers; the American Society of Clinical Oncology, which represents cancer clinicians such as medical oncologists, radiation oncologists, and surgeons among others; the American Society for Therapeutic Radiology and Oncology, which represents radiation oncologists; the American Cancer Society, which represents cancer patients; and four community cancer centers to assure that the strategic approach we are taking will meet the needs of the broad cancer community. The Commission on Cancer has expressed its interest in considering this survey for use in its accreditation process for cancer centers, if the final product meets its needs; we are continuing to consult with them on this possibility.

9. Payments/Gifts to Respondents

Survey participants will not be compensated.

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.

AIR and Mayo Clinic will request HIPAA waivers of authorization from their Institutional Review Boards (IRBs) and, where possible obtain them from participating cancer centers to enable cancer treatment centers to share contact information as part of the sampling and survey operations processes. Wherever HIPAA waivers cannot be obtained, the cancer centers will supply AIR and Mayo Clinic with de-identified sampling frames using a study ID generated by the cancer center. AIR and Mayo Clinic will draw the sample, supply the cancer centers with the sampled IDs and unaddressed envelopes containing questionnaires and cover letters, and the cancer centers will address and mail the envelopes (see Attachment B: Cover Letter, Reminder Letter, and Phone Invitation Letter and Attachment C: Phone Call Reminder Script for Mailed Survey Non-respondents.) See Supporting Statement Part B for more details of data collections procedures.

As a covered entity under HIPAA, Mayo Clinic meets all standards of the HIPAA Privacy and Security Rules. As a health services research and technical assistance organization, AIR often obtains protected health information (PHI) from covered entities for research purposes using Data Use Agreements and Business Associate Agreements and has established privacy and security policies and procedures for these data that comply with the HIPAA Privacy and Security Rules.

11. Questions of a Sensitive Nature

All questions will pertain to the patient’s experience of cancer care (see Attachment A: CAHPS Cancer Care Questionnaires). No questions will be asked about sexual behavior, religious or political beliefs, substance use, social behavior, or illegal activity. The law and most individuals consider health care to be a private matter. Because cancer is a particularly emotion-laden condition and because it can affect private bodily functions, such as sex and elimination, many patients find it to be a sensitive topic. However, this study focuses on the patient’s experience of cancer *care*, not patient’s experience of cancer. Thus, the questions will address provider behaviors and they will be general enough to be applicable to patients with a wide variety of cancers; questions will not focus on issues that patients might find embarrassing or sensitive.

12. Estimates of Annualized Burden Hours and Costs

The length of the survey estimate of 20 minutes is based on the written length of the survey and AHRQ’s experience with previous CAHPS® surveys of comparable length that were fielded with a similar, although not identical, population (see Exhibit 1).

The Bureau of Labor Statistics reported the average hourly wage for civilian workers in the United States was \$21.29 from 2010. An estimate of \$22 per hour allows for inflation and represents a conservative estimate of the wages of the respondents (see Exhibit 2).

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
CAHPS Cancer Care Questionnaires	1,800	1	20/60	600
Total	1,800	na	na	600

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
CAHPS Cancer Care Questionnaires	1,800	600	\$22.00	\$13,200
Total	1,800	600	na	\$13,200

*Based upon the average hourly earnings. Data is based on the National Compensation Survey: Occupational Earnings in the United States, 2010. (Jul 2010).

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

Exhibit 3 shows the estimated total and annualized cost for this 2 year project. The total cost is estimated to be \$846,830.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Management	\$121,261	\$60,630
Draft Survey	\$289,818	\$144,909
Cognitive Testing	\$57,380	\$28,690
Plan Field Test	\$140,411	\$70,205
Field Test and Analysis	\$237,960	\$118,980
Total	\$846,830	\$423,414

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

We have presented on the project at one professional conference and expect to present at one more by the end of the project. As time allows, we plan to write an article for a health services research journal and a cancer care journal as in-kind contributions by AIR and Mayo Clinic. Potential journals include *Health Services Research*, *Medical Care*, *Journal of Clinical Oncology*, and *Supportive Care in Cancer*.

We plan to use the following analytical techniques to describe survey development and testing:

1. Psychometric analysis using classical test theory to address item functioning, identify composites, evaluate the measurement properties of the final composite scales, and evaluating individual and interunit reliability.
2. Investigation of potential case-mix adjusters.
3. Methodological experiments to compare the modes of mail and telephone administration.

These are the standard analytic tasks for the development of CAHPS surveys and will use the same methods that have been used for other CAHPS surveys.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.