Evidence-based Practice Center Systematic Review Protocol

Project Title: Models of Survivorship Care: Technical Brief

I. Background and Objectives for the Technical Brief

The Increasing Population of Cancer Survivors and the Challenge of Transitioning From Cancer Treatment to Followup Care

As of January 2012 in the United States, there were nearly 14 million cancer survivors, among whom 59 percent were aged 65 years or older.[1] The number of survivors is projected to grow to 18 million by 2020.[2] Survivors have unique physical, psychological, social, and spiritual health needs.

Relative to pediatric cancer survivors, adult survivors are under studied.[3] Further, their health care needs differ from those of pediatric survivors—for example, they have an increased risk for comorbidities, which present unique care coordination challenges. Consequently, this technical brief seeks to increase knowledge regarding survivorship care models for adult cancer survivors (age ≥19).

As described in the Institute of Medicine report *From Cancer Care to Cancer Survivor: Lost in Transition*,[4] survivorship care (i.e., the delivery of medical care services specifically designed for cancer survivors) ideally includes (1) prevention and detection of new (primary) cancer; (2) cancer spread and recurrence surveillance; (3) interventions for illnesses secondary to cancer and their treatment (including physical consequences of symptoms including pain and fatigue), psychological distress experienced by cancer survivors and their caregivers, and concerns related to employment, insurance, and disability; and (4) coordination between specialists and primary care providers (PCPs)[a] to ensure the fulfillment of all health needs of the survivors.

Developing appropriate health care programs that provide needed supports and enhance outcomes for individuals with cancer following completion of acute (i.e., potentially curative) cancer treatment can be difficult. Current cancer survivorship care often involves medical oncologists following survivors for prolonged periods of time after treatment ends, which may or may not represent the preferred model for cancer survivors or for oncologists. Barriers to optimal care for cancer survivors may include differing perspectives, lack of communication, or lack of clear expectations among PCPs and oncologists on their roles in delivering survivorship care.[5] These may result in inadequate care coordination, leading to the duplication or omission of prevention, detection, surveillance, or treatment services.[6] This fragmentation of care may have significant adverse consequences for cancer survivors, including delayed detection of recurrences, suboptimal identification of symptom causes and treatments, and worse outcomes including health-related quality of life. Furthermore, survivors may feel poorly informed regarding psychological, social, and sexual health issues[7] and their risk for recurrence[8] and may be dissatisfied with care following cancer treatment.[9]

[a] Primary care providers (PCPs) include physicians, nurse practitioners, and physician assistants.

The challenges associated with the transition of cancer survivors to followup care may be exacerbated by the concerns PCPs may have about their ability to deliver survivorship care;[5] the rapidly growing number of cancer survivors in the United States; the projected shortage of oncologists;[10,11] and possible changes related to the Affordable Care Act[12] (e.g., the development of Accountable Care Organizations may influence where and by whom cancer survivorship care is delivered[13]).

Models of Care Intended To Enhance Outcomes and Provide Supports Among Cancer Survivors

It is unlikely that cancer survivorship care will have a "one size fits all" model. Many factors may influence which model will be most effective, such as the number and type of survivors being served; available health care providers, services, and resources; risk of recurrence and level of symptoms following cancer treatment; and patient preference regarding the type and source of survivorship care. Different models of survivorship care have been described; a subset of the characteristics of these models is discussed in the Guiding Questions below. Types of survivorship care models include community-based shared-care models, academically based comprehensive survivor program models, nurse practitioner–led shared care, and multidisciplinary programs for high-risk populations.[14] These models are based on the providers delivering the care and the structure of the program or services being offered for survivorship care. For example, an academically based program may be offered for specific disease groups where that may not be possible in other settings. Resources for survivors may be offered within a program or be services available within the community to address unmet needs. For example, a comprehensive survivorship program may offer exercise programs or a smaller program may partner with a local YMCA to offer the LIVESTRONG℠ program for survivors.

According to a recent report on survivorship care from the American Society for Clinical Oncology (ASCO), "Because no uniform standards for the care of survivors exist, significant efforts are required to understand the needs of survivors and to develop models of comprehensive, coordinated care that meet those needs."[15, p.2] As discussed in this ASCO report, additional research is needed to "expand the evidence base required to define optimal care delivery, including the type or components of care delivered, the manner in which that care is delivered and by whom, and the efficacy of the various models of care."[15, p.2]

A number of previous studies have described different models for delivering survivorship care and summarized research efforts in this area.[4,15,16] However, few publications have described the process or outcomes of survivorship care models. Therefore, the purpose of this technical brief is to describe different existing and proposed models of and services for survivorship care to promote understanding of the differences in care delivery and survivor outcomes associated with these models. The Technical Brief will also present information on studies of survivorship care models and their outcomes, explore the breath of information available on these models and gaps in this literature, discuss potential issues that are important to key stakeholders, and identify areas of future research needs.

II. Guiding Questions

1. **Overview of cancer survivorship care**
   - What are the different models of cancer survivorship care that have been most widely

used?
- What are the components of cancer survivorship care?
- What is the nature of usual care for survivors of cancer?
- What are the potential advantages and disadvantages of these models, when compared with one another and with usual care?
- What are the potential safety issues and harms?

2. **Context in which cancer survivorship care is used**
   - What information do patients, clinical care providers, or other decisionmakers receive about survivorship programs or components of those programs?
   - How do models of care vary based on the following?
     - Setting
     - Organizational structure
     - Provider type and responsibilities of varying provider types in medical care for survivors, including providers involved in the patient transition from acute cancer treatment to ongoing survivorship
     - Payment considerations
     - Patient characteristics such as age, race/ethnicity, cancer type, stage of disease and other risk-stratification issues
   - What associated supportive care resources are commonly incorporated in or needed for survivorship care programs?
   - How is risk stratification being (or could be) applied to cancer survivor programs?
   - What kinds of resources (e.g., health information technology) are available or needed to share information among health care providers and with patients?
   - What are important considerations for evaluating appropriate resource utilization, cost, quality of care, and outcomes for survivorship programs?
   - How widely is survivorship care offered? For how long?
   - What kinds of training and staffing are required? What modifications to current training and staffing are in development?

3. **Current evidence on cancer survivorship care**
   - Characteristics of patients enrolled (age, race/ethnicity, cancer type, stage of disease)
   - Type of survivorship model, if defined
   - Setting
   - Organizational structure of the health care entities involved in survivorship care and in the transition from acute care treatment to survivorship care
   - Provider type
   - Payment considerations
   - Study design and size
   - Comparator used in comparative studies
   - Concurrent or previous treatments
   - Length of followup
   - Cost and resource utilization
   - Outcomes measured

- Adverse events and unintended consequences of survivorship care

4. **Gaps in knowledge and future research needs**
   - What are the key decisional uncertainties?
   - What are the implications of the current level of diffusion and/or further diffusion of cancer survivorship care, given the current state of the evidence?
   - Are there models of survivorship care that are planned but have yet to be implemented?
   - What are the differences between existing models of survivorship care and new and emerging models of survivorship care?
   - What are possible areas of future research?

III. Methods

The Technical Brief protocol will integrate discussions with Key Informants (KIs), a search of the gray literature, and a search of the published literature.

A. Discussions with Key Informants. KIs are particularly vital to shaping the Technical Brief because little empirical evidence exists about a gold standard model of survivorship care. Therefore, KIs can contribute to an understanding of which components of the models are most effective across cancer types, where the models might fit into clinical care, and potential advantages or concerns related to the development and implementation of these models. Specifically, responses to Guiding Questions (GQs) 1, 2, and 4 will be based on KI discussions.

In consultation with our team and AHRQ, we identified distinct perspectives that need to inform the development of a Technical Brief in this area. Specifically, we will seek to recruit the following as KIs: patient advocates, clinicians offering survivorship services, PCPs, policymakers, management and administration, financing and reimbursement, and researchers.

We will adhere to all Office of Management and Budget (OMB) requirements and limit our standardized questions to no more than nine nongovernment-associated individuals so that we will not need to obtain OMB clearance for the interview activities.

After review and approval of the completed Disclosure of Interest forms for proposed KIs by the Agency for Healthcare and Quality (AHRQ), we will hold interviews with the selected KIs. The interviews may be held with individual KIs or with a group of KIs based on availability and concordance of perspectives. Each interview will be summarized in writing and submitted to AHRQ within a week of the interview for documentation.

B. Gray literature search. GQs 1 and 2 above will rely primarily on information from published narrative reviews and information in the gray literature. Sources for the gray literature include the following:

- LexisNexis® Academic: This source provides mostly full-text access to general, regional, and international news; company news and financial information; legal

information (including law reviews, case law, and legal rulings); and other topics such as biographical information. LexisNexis Academic is a Web-based service that provides access to most of the information formerly available on the LexisNexis® Educational Program (approximately 75 percent of the titles).

- ProQuest Dissertations & Theses: This source indexes U.S. dissertations from 1861 to as recently as the last semester with full text available from 1997 on. Master's theses are covered more selectively and some full text is available. The database covers work done at more than a thousand institutions, primarily in the United States but also in Canada and Great Britain, and at other European universities for recent years. In addition to this database, the full text of most of the theses and dissertations completed at the University of North Carolina at Chapel Hill (UNC) from 2006, and all beginning in 2008, are freely available electronically from the UNC Health Sciences Library.

- NIH RePORTER database: The information found in RePORTER is drawn from several extant databases (eRA databases, MEDLINE®, PubMed® Central, the NIH Intramural Database, and iEdison), using newly formed linkages among these disparate data sources. The comprehensiveness of these databases varies, as does the quality of the linkages formed among them. We expect that the quality of RePORTER data will improve over time as a result of changes in both data collection (e.g., implementation of the NIH Public Access policy) and the increased ability to identify missing information that comes from making these data accessible to more people.

- HSRProj (Health Services Research Projects in Progress): HSRProj contains descriptions of research in progress funded by Federal and private grants and contracts for use by policymakers, managers, clinicians, and other decisionmakers. It provides access to information about health services research in progress before results are available in a published form.

We will also include a Web site search of relevant organizations such as ASCO, the American Cancer Society (ACS), and the National Coalition for Cancer Survivorship (NCCS). We will use the gray literature to identify additional model components that are in piloting stages or not yet fully implemented.

C. Published Literature Search

1. *Criteria for Inclusion/Exclusion of Studies in the Review.* Table 1 describes our inclusion and exclusion criteria.

2. *Searching for the Evidence*: We will systematically search, review, and analyze the available information for each guiding question. To identify articles for this review, we will conduct focused searches of PubMed and the Cochrane Library. PubMed, a service of the National Library of Medicine, covers journal articles about medicine, nursing, dentistry, veterinary medicine, and public health from 1950 to the present. The Cochrane Database of Systematic Reviews (CDSR) is the leading resource for full-text systematic reviews in health care. The Excerpta Medica database

(EMBASE®), produced by Elsevier, is a major biomedical and pharmaceutical database indexing thousands of international journals in the following fields: drug research, pharmacology, pharmaceutics, toxicology, clinical and experimental human medicine, health policy and management, public health, occupational health, environmental health, drug dependence and abuse, psychiatry, forensic medicine, and biomedical engineering/instrumentation.

Table 1. Proposed eligibility criteria for survivorship care

Criterion	Inclusion	Exclusion
Population	• Age 19 and above • Survivor of adult cancer (any cancer type) • Currently in remission	• Age 18 and younger • Adult survivor of childhood cancer • In relapse at enrollment in a survivorship study • Individuals with metastatic cancer
Intervention	• Two or more service(s) for survivorship care within one or more of the four core IOM survivorship care components (prevention, coordination, surveillance, intervention intended to facilitate survivors' experience • Formal referrals to service(s) that facilitate survivors' experiences	• Treatment with curative intent • Studies of a single service • Studies that provide information only on patient characteristics associated with use of survivor services
Comparator	• Active comparison with other survivorship care models • Active comparison of components of survivorship care • Usual care • No comparator (for case series)	• None
Outcomes	• Any patient outcomes related to the survivorship care model • Intermediate patient health outcomes • Morbidity • Mortality • Quality of life • Satisfaction with care • Cost and resource utilization • Adverse events	• Outcomes attributable to the cancer treatment (except for adverse events and other long-term consequences potentially resulting from cancer treatment) • Outcomes among health care providers
Timing	• All timing	• None
Setting	• All care settings	• Acute care inpatient
Study design	• Systematic reviews • Randomized controlled trials • Nonrandomized controlled trials • Prospective and retrospective cohort studies • Case-control studies • Case series	• Case reports • Opinions • Commentaries • Nonsystematic reviews[a] • Letters to the editor with no primary data
Other	• English language	• Non-English language

[a]Nonsystematic reviews may be used to inform our responses on Guiding Questions 1, 2, and 4.
IOM = Institute of Medicine

An experienced research librarian will use a predefined list of search terms and medical subject headings (MeSH®), when applicable. Table 2 lists search terms and limits. We will review the reference lists of identified papers and reviews and add any previously unidentified relevant papers.

Table 2. Search terms

Search #1	Query	Items found
#9	Search "Survivors"[Mesh] OR survivorship OR survivor Filters: Humans; English	498,795
#10	Search "Neoplasms"[Mesh] Filters: Humans; English	1,609,728
#11	Search (("Aftercare"[Mesh]) OR "Continuity of Patient Care"[Mesh]) OR "Delivery of Health Care"[Mesh] Filters: Humans; English	586,760
#12	Search (("Patient Care Planning"[Mesh]) OR "Models, Nursing"[Mesh]) OR "Health Services/utilization"[Mesh]) OR "methods" [Subheading]) OR "standards" [Subheading] Filters: Humans; English	1,801,900
#13	Search (#9 AND #10 And #11 and #12) Filters: Humans; English	1,575
#14	Search (#9 AND #10 And #11 and #12) Filters: Humans; English; Adult: 19+ years	972
#17	Search (#9 AND #10 And #11 and #12) Filters: Editorial; Comment; Case Reports; Humans; English; Adult: 19+ years	38
#19	Search (#14 NOT #17)	934
Search #2	**Query**	**Items found**
#1	Search 23257892[uid]	1
#2	Search "Survivors"[Mesh] OR survivorship OR survivor	771137
#3	Search "Neoplasms"[Mesh]	2411985
#4	Search (("Aftercare"[Mesh]) OR "Continuity of Patient Care"[Mesh]) OR "Delivery of Health Care"[Mesh]	744808
#5	Search ((((("Patient Care Planning"[Mesh]) OR "Models, Nursing"[Mesh]) OR "Health Services/utilization"[Mesh]) OR "methods" [Subheading]) OR "standards" [Subheading]	2854158
#6	Search (#2 AND #3 and #4 AND #5)	1715
#7	Search (#2 AND #3 and #4 AND #5) Filters: Humans	1712
#8	Search (#2 AND #3 and #4 AND #5) Filters: Humans; Adult: 19+ years	1020
#9	Search (#2 AND #3 and #4 AND #5) Filters: Humans; English; Adult: 19+ years	975
#10	Search (#1 AND #9) Filters: Humans; English; Adult: 19+ years	0
#11	Search (#1 AND #9) Schema: all Filters: Humans; English; Adult: 19+ years	0
#12	Search (#1 AND #9)	0
#13	Search (#1 AND #9) Schema: all	0
#14	Search (("Survivors"[MAJR] AND "Neoplasms/therapy"[MAJR])) AND ("Aftercare"[Majr] AND "Delivery of Health Care"[Mesh])	30
#15	Search (#14 AND #1)	1
#16	Search (#14 NOT #9)	19

PubMed = 953

Cochrane Library = 13 = 7 unduplicated
EMBASE = 146 = 146 unduplicated
CINAHL = 23 = 21 unduplicated
Academic OneFile = 46 = 39 unduplicated
LexisNexis Academic = 10 = 10 unduplicated

Dissertations & Theses = 4 = 4 unduplicated
NIH RePORTer = 11 = 11 unduplicated
HSRProj (Health Services Research Projects in Progress) = 20 = 11 unduplicated
American Cancer Society = 4
Databases beyond PubMed = 277
Unduplicated additions = 253
Total unduplicated database = 1, 202

We will update the literature review by repeating the initial search concurrent with the peer review process. Any literature suggested by Peer Reviewers or public comment respondents will be investigated and, if appropriate, incorporated into the final review. We will scan the reference lists of systematic reviews that are pertinent but do not meet inclusion criteria to identify studies that should be considered for this review. We will evaluate each study identified through these "hand-search" processes against the a priori inclusion and exclusion criteria described in Table 1.

3. *Data Abstraction and Data Management.* We will develop forms for the initial inclusion/exclusion process at the title/abstract and full-text review stages. The forms will be used to screen titles, abstracts, and full reviews and to gather information about study characteristics and the PICOTS (**p**opulation, **i**ntervention, **c**omparator, **o**utcomes, **t**iming, and **s**etting) of each study.

   All titles and abstracts identified through searches will be independently reviewed for eligibility against our inclusion/exclusion criteria by two trained members of the research team. Studies marked for possible inclusion by either reviewer will undergo a full-text review. For studies without adequate information to determine inclusion or exclusion, we will retrieve the full text and then make the determination. All results will be tracked in an EndNote® database (Thomson Reuters, New York, NY).

   We will retrieve and review the full text of all articles included during the title/abstract review phase. Each full-text article will be independently reviewed by two trained members of the research team for inclusion or exclusion on the basis of the eligibility criteria described earlier. If both reviewers agree that a study does not meet the eligibility criteria, the study will be excluded. If the reviewers disagree, conflicts will be resolved by discussion and consensus or by consulting a third member of the review team. All results will be tracked in an EndNote database. We will record the reason that each excluded full-text publication did not satisfy the eligibility criteria so that we can later compile a comprehensive list of such studies.

   For studies that meet the inclusion criteria, we will abstract relevant information into summary tables. We will also design data abstraction forms to gather pertinent information from each article, including characteristics of study populations, interventions, comparators, outcomes, study designs, settings, and methods. Trained reviewers will extract the relevant data from each included article into the evidence tables. All data abstractions will be reviewed for completeness and accuracy by a second member of the team.

4. *Data Synthesis*. To be consistent with the purpose of the Technical Brief, we will not include an analytic synthesis such as a meta-analysis, but we will summarize the

evidence for each GQ in the summary tables. We will consider the models used, study design, analytic methods, and the similarities and differences of included patients according to sociodemographic factors (e.g., age) and classified type of cancer. The report will be organized by the GQs.

5. *Data Organization and Presentation.* The Evidence-based Practice Center (EPC) researchers shall discuss ways in which information will be summarized and presented in the Technical Brief.

D. Information Management. We will abstract data from each included study using a standardized template. Table 3 lists fields for data abstraction. Data from the published literature will be integrated with information from the gray literature and discussions with KIs. We anticipate that responses to GQs 1 and 2 will be informed primarily by information from discussions with KIs and secondarily by gray literature or nonsystematic published reviews. Some questions—particularly the question, "How do models of care vary based on setting, organizational structure, provider type (including in the context of transitions of care), payment considerations, and patient characteristics such as age, race, cancer type, stage of disease, other risk stratification issues?"—may also be informed by published literature or peer-reviewed evidence. In instances where empirical evidence may also inform the response, we will first provide a summary of the empirical evidence, followed by a summary of information from other sources. Responses to GQ 3 will be based primarily on peer-reviewed, published literature and may be combined with information from the gray literature. Responses to GQ 4 will be shaped primarily by information from KIs; we will interpret their feedback in light of our responses to GQs 1, 2, and 3.

Table 3. Proposed fields for data abstraction

Study Identifier	Reference Number, Author, Year
Study characteristics	• Study design • Inclusion/exclusion criteria • Sample size for eligibility, at recruitment, and at followup
Population characteristics	• Age, race/ethnicity, cancer type, stage of disease, other risk-stratification issues
Intervention characteristics	• Type and components (one or more of the four IOM components) of survivorship care model • Provider type (including in the context of transitions of care) • Payment considerations • Organizational structure • Concurrent or previous interventions
Comparator	• Type of comparator
Outcomes measured	• Intermediate patient health outcomes • Morbidity • Mortality • Quality of life • Satisfaction with care • Cost and resource utilization • Adverse events
Timing	• Length of survivorship care services

	• Timing of outcome measurement
Setting	• Setting of care delivery • Geographical location (country, rural/urban)

IOM = Institute of Medicine

E. Data Presentation. Our findings will be presented in the order of the GQs. We will qualitatively summarize findings from grey literature searches and interviews with KIs. For questions with empirical evidence or in-progress studies to inform the results, we will build on study-specific tables to generate cross-cutting tables describing the state of evidence on study characteristics (number and types of study designs addressing each survivorship model or component), intervention characteristics, and types of outcomes planned or presented for each survivorship model. Depending on the availability and appropriateness of the information that we find, we will explore graphical presentations of these data.

IV. References

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16. Harrop JP, Dean JA, Paskett ED. Cancer survivorship research: a review of the literature and summary of current NCI-designated cancer center projects. Cancer Epidemiol Biomarkers Prev 2011 Oct;20(10):2042-7. PMID: 21980012.

V. Definition of Terms

Cancer survivor: An individual who has completed the majority or all of their active treatment for cancer (i.e., treatment with curative intent).

Survivorship care: A health care service or combination of services for cancer survivors that has one or more of these four components as defined by the Institute of Medicine Committee on Cancer Survivorship in *From Cancer Patient to Cancer Survivor: Lost in Transition* (Washington, DC: The National Academies Press; 2005. p. 3):

- **Prevention** of recurrent cancer and new [primary] cancer and of other late effects; promotion of healthy behaviors and appropriate screening procedures
- **Surveillance** for cancer spread, cancer recurrence, or a second [primary] cancer; assessment of medical and psychosocial late effects
- **Intervention** for consequences of cancer and its treatment, for example: physical consequences such as medical problems or symptoms, including pain and fatigue; psychological distress experienced by cancer survivors and their caregivers; and social and spiritual concerns
- **Coordination** between specialists and primary care providers to ensure that all of the survivor's health needs are met through clear communication and implementation of survivorship care plans

Survivorship research: Cancer survivorship research encompasses the physical, psychosocial, and economic sequelae of cancer diagnosis and its treatment among both pediatric and adult survivors of cancer. It also includes within its domain issues related to health care delivery, access, and followup care, as they relate to survivors. Survivorship research focuses on the health and life of a person with a history of cancer beyond the acute diagnosis and treatment phase. It seeks to both prevent and control adverse cancer diagnosis and treatment-related outcomes such as late effects of treatment, second cancers, and poor quality of life, to provide a knowledge base regarding optimal followup care and surveillance of cancers, and to optimize health after cancer treatment. (Source: www.dccps.nci.nih.gov/ocs/definitions.html)

VI. Summary of Protocol Amendments

No amendments have been made to this current version of this protocol.

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient or policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are cross-checked against available literature and statements from other Key Informants. Information gained from KI interviews is identified as such in the report; they do not perform analysis of any kind nor contribute to the writing of the report. Also, they have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Key Informants, and those who present with potential conflicts may be retained. AHRQ and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

VIII. Peer Reviewers

Peer Reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers peer review comments on the preliminary draft in preparing the final draft of the report. Peer Reviewers do not participate in writing or editing the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published 3 months after the publication of the Evidence report.

Potential Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer Reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

IX. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest which cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

X. Role of the Funder

This project was funded under Contract No. HHSA 290-2012-00008-I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.