Pre-Test of Instruments of Psychosocial Care for the Treatment of Adults with PTSD
Office of Management and Budget Supporting Statement

Part A: Justification
October 29, 2013

Submitted by:

Office of the Assistant Secretary for Planning and Evaluation
Office of Disability, Aging and Long-Term Care Policy

U.S. Department of Health and Human Services

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A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) requests a clearance from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 to pre-test a survey that measures the quality of psychotherapy for adults with post-traumatic stress disorder (PTSD), defined in terms of the concordance with evidence-based strategies, in outpatient treatment settings. ASPE is undertaking this effort in partnership with the National Institute of Mental Health (NIMH), National Institutes of Health. ASPE and NIMH are components of the U.S. Department of Health and Human Services (HHS).

This work aligns with the mission and strategic planning priorities of ASPE and NIMH. ASPE supports HHS in its effort "to enhance the health and well-being of Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."[1] These advances include treatments for behavioral health conditions. In particular, "improving health care quality and patient safety" through wider dissemination of effective mental health treatment such as evidence-based psychotherapy is an HHS priority.[2] The mission of NIMH is to "transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure."[3] Effective treatment for PTSD and examination of the delivery of psychotherapy treatment and its concordance with evidence-based strategies align with NIMH's current strategic goal of "providing a knowledge base to move evidence-based interventions into practice."[4] This research project is also responsive to the president's executive order of August 2012, which directed HHS to "develop more effective PTSD treatment methodologies."[5]

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[1] U.S. Department of Health and Human Services, "Introduction," http://www.hhs.gov/secretary/about/introduction.html, accessed October 24, 2013.

[2] U.S. Department of Health and Human Services, "Goal 3: Advance the Health, Safety, and Well-Being of the American People," http://www.hhs.gov/secretary/about/goal3.html, accessed October 24, 2013.

[3] National Institute of Mental Health, "About NIMH," http://www.nimh.nih.gov/about/index.shtml, accessed October 24, 2013.

[4] National Institute of Mental Health, "Strategic Objective 3: Develop New and Better Interventions for Mental Disorders That Incorporate the Diverse Needs and Circumstances of People with Mental Illness," http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml#strategic-objective3, accessed October 24, 2013.

[5] White House, "Fact Sheet: President Obama Signs Executive Order to Improve Access to Mental Health Services for Veterans, Services Members, and Military Families," August 31, 2012, http://www.whitehouse.gov/the-press-office/2012/08/31/fact-sheet-president-obama-

According to the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) IV criteria, PTSD is an anxiety disorder[6] that some people develop following exposure to a traumatic event.[7] It commonly co-occurs with depression, substance abuse, traumatic brain injury, and metabolic conditions.[8, 9] Because other conditions (e.g., substance abuse) may be the impetus for a person to seek treatment, a PTSD diagnosis may come laden with stigma in certain populations. The illness may occur well after the traumatic incident or reoccur at different points during the life cycle. PTSD in the general population may be underreported. Current research puts the figure somewhere around 6.8 percent, with women estimated to have higher prevalence than men (10 percent for women versus 3.5 percent for men)[10] and veterans having a higher prevalence than the general population (11 percent to 20 percent for veterans of the current wars, and estimates of about 30 percent for all veterans of the Vietnam War).[11] The cost of care can be significant as well. Studies have found that individuals with PTSD have increased health care service utilization as measured by number of physical and mental health appointments and hospitalizations (Tuerk et al. 2012).[12] Moreover, one study found an association between veterans who screened positive for PTSD and self-reports of more days of work missed, poorer health, and lower quality of life overall than among veterans who did not screen positive for PTSD (Hoge et al. 2007).

In recent years however, increased national attention has led to an improvement in the types and effectiveness of treatments for individuals diagnosed with PTSD. Particularly promising is the number of psychotherapy treatment approaches—for example, cognitive behavioral therapy (CBT) and

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signs-executive-order-improve-access-mental-h, accessed October 24, 2013.

[6] The DSM V, released in May 2013, placed PTSD into a new class named trauma and stressor-related disorders.

[7] Not everyone who is exposed to a traumatic event develops PTSD.

[8] U.S. Department of Veteran Affairs, "Traumatic Brain Injury and PTSD," December 20, 2011, http://www.ptsd.va.gov/professional/pages/traumatic-brain-injury-ptsd.asp, accessed October 24, 2013.

[9] U.S. Department of Veteran Affairs, "PTSD and Physical Health," December 20, 2011, http://www.ptsd.va.gov/professional/pages/ptsd-physical-health.asp, accessed October 24, 2013.

[10] See National Comorbidity Survey, NCS-R Appendix Table 1, "Lifetime Prevalence of DSM-IV/WMH-CIDI Disorders by Sex and Cohort," 2005, http://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_Lifetime_Prevalence_Estimates.pdf; and National Comorbidity Survey, NCS-R Appendix Table 2, "Twelve-Month Prevalence of DSM-IV/WMH-CIDI Disorders by Sex and Cohort," 2005, http://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf, both accessed October 24, 2005.

[11] U.S. Department of Veteran Affairs, "How Common Is PTSD?," April 25, 2012, http://www.ptsd.va.gov/public/pages/how-common-is-ptsd.asp, accessed October 24, 2013.

[12] Complete citations for all references are provided in Attachment 13.

exposure therapy—that have demonstrated slightly to significantly better treatment outcomes, such as reduction of symptoms and improved mental health, for those diagnosed with PTSD.[13] Yet despite enormous expenditures and remarkable breakthroughs in treatment, there is a clear gap between what is known about effective treatments for individuals with PTSD and what clinicians actually implement. Quality-improvement initiatives that measure providers' use of evidence-based strategies and promote feedback to providers may enhance the adoption of evidence-based services and ultimately improve quality of care and consumer health outcomes.[14] Quality measures for the delivery of evidence-based therapies for PTSD do not currently exist and could be used to reduce this gap. ASPE, in partnership with NIMH, has undertaken a project to pre-test clinician and consumer surveys of the quality of therapies for adults with PTSD that are concordant with evidence-based therapeutic strategies.

By collecting pre-test data, this project directly serves ASPE's goal of developing an effectiveness-based measure that could be used to improve the quality of PTSD care. The project has more specific goals as well:

1) It seeks to pre-test three instrument prototypes, which involve parallel versions for use with different respondents—one for PTSD clinicians, one for individuals with PTSD seen by these clinicians, and one for supervisors of these clinicians—in a limited number of settings. The pre-test is designed to
    a. assess the development of data collection procedures;
    b. initially assess the instruments' reliability and determine if they produce consistent results regarding the delivery of evidence-based therapies;
    c. initially assess the instruments' validity and determine if they produce credible results regarding the delivery of evidence-based therapies;
    d. examine the factor structure of the instruments' items and determine if the instruments can be shortened; and
    e. assess the feasibility of the instruments' use with instrument respondents and relevant stakeholders.
2) The project also seeks to suggest revisions to the instrument based on the results from the pre-test, and to prepare a final report that details the methodological and resource requirements associated

[13] For a recent synthesis of the evidence on PTSD treatment, see Institute of Medicine (2012, chap. 7).

[14] ASPE prefers the term "consumer" to "patient" and will use this term throughout the text for individuals seeking treatment or being treated for PTSD.

with the instruments' use and delineates the need for additional testing with larger samples.

Because this is a pre-test, the information collected will not generalize to all behavioral health organizations or clinicians. ASPE, and ASPE's partner NIMH, will use the results of these analyses to determine what modifications to and additional testing of the surveys is necessary before the measures can be implemented for quality-improvement purposes. The products that will result from this project include a report that makes recommendations for revisions to the surveys and that delineates the need for additional testing. To achieve the two goals described above, the following data collections will be implemented:

1) Clinician's survey of the delivery of evidence-based psychotherapy
2) Clinician supervisor's survey of the delivery of evidence-based psychotherapy
3) Consumer's survey of the delivery of evidence-based psychotherapy
4) Site coordinator's checklist to obtain site-of-care characteristics
5) Site coordinator's sample section abstraction form used to identify persons being treated for PTSD and their associated PTSD clinician and clinician Supervisor.
6) Clinician and supervisor demographics questionnaire

This study is being conducted by ASPE through its contractor, Mathematica Policy Research (Mathematica), pursuant to ASPE's statutory authority through legal code in Section 301 of the Public Health Service Act [42 U.S.C. 241] (see Attachment 7).

Survey Item Development

Before survey item development began, Mathematica conducted an environmental scan of the PTSD literature. The goal of the scan was to develop a list of evidence-based practices for treatment of PTSD that are currently considered to have the strongest evidence base.[15] The majority of

[15] The contractor used three main websites to conduct the search: National Guideline Clearinghouse (www.ngc.gov), Guidelines International Network (www.g-i-n.net), and PubMed (http://www.ncbi.nlm.nih.gov/pubmed/). The search terms used included *psychology*, *psychiatry*, *adult and trauma*, *anxiety disorders*, and *stress*. The following seven guidelines were found to be relevant to PTSD:

- Australian Guidelines for the Treatment of Adults with Acute Stress Disorder and Posttraumatic Stress Disorder
- Bandelow, et al. World Federation of Societies of Biological Societies (WFSBP) Guidelines for Pharmacological Treatment of Anxiety, Obsessive-Compulsive and Post

reviews in the empirical literature rated CBT and variants of this treatment (such as exposure therapy and cognitive processing therapy) as the recommended treatment for PTSD. Results of the scan were then presented to a technical advisory group (TAG) convened by Mathematica (on February 29 and March 1, 2012). The TAG comprised leaders in the field of PTSD clinical research as well as a consumer representative. At that meeting, participants identified a number of gaps in the research and in efforts to develop quality measures, and also advanced possible approaches to closing these gaps. The TAG's conclusions and the empirical evidence combined to make one of the major gaps clear: although CBT and its variants are currently considered best practices for the treatment for PTSD, a measure of psychotherapy delivery to assess the use of strategies common to evidence-based treatments has not been developed yet. ASPE and NIMH concluded that without such a measure, there is no standardized way of ascertaining whether clinicians are providing the highest standard of care in treating adults diagnosed with PTSD. Given the findings, ASPE and NIMH decided to proceed with developing a survey that measures the delivery of care using CBT as the model.

The next step was developing a set of survey items that were robust in measuring the provision of key elements of CBT treatment of PTSD. These elements were distilled using a seminal method developed by Chorpita (2005, 2009) that explains how to empirically identify essential components of successful evidence-based psychological treatments. After this process was completed, a technical expert panel (TEP), consisting of experts in the treatment of PTSD and psychotherapy research, who were not members of the original TAG, was convened. The TEP reviewed results of the distillation process and made decisions about how to translate key treatment concepts (e.g., cognitive restructuring) into survey items that could be understood by a broad audience.

Using a core set of items derived through this empirical process and approved by the TEP, three separate surveys were created:

1) Clinician's survey of the delivery of evidence-based psychotherapy

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–Traumatic Stress Disorders—First Revision. The World Journal of Biological Psychiatry, 2008; 9(4): 248-312.

- Forbes, et al. A Guide to Guidelines for the Treatment of PTSD and Related Conditions. Journal of Traumatic Stress, 2010; 23(5): 537-552.
- Guideline Watch (March 2009): [APA] Practice Guideline for the Treatment of Patients with Acute Stress Disorder and Posttraumatic Stress Disorder
- National Institute for Clinical Excellence. The Management of PTSD in Adults and Children in Primary and Secondary Care, 2005.
- Second Edition of the International Society for Traumatic Stress Studies (ISTSS)
- VA/DoD Clinical Practice Guideline. Management of Post-Traumatic Stress, 2010.

2) Clinician supervisor's survey of the delivery of evidence-based psychotherapy
3) Consumer's survey of the delivery of evidence-based psychotherapy

Mathematica then conducted cognitive testing with nine practicing clinicians who made treatment of consumers with PTSD a main practice focus, or who self-identified as practicing CBT or a variant of CBT. The testing asked about the following: item comprehension: clarity of wording, definition, or presentation; reaction to certain items or examples (e.g., use of sexual trauma as an example); and feasibility of completing the survey in under 10 minutes. Testing was an iterative process where questions were amended based on feedback. Interviewees were provided a choice between two versions of a question or asked to endorse or reject the new wording. A member of the TEP who is a clinical supervisor and two of the clinicians who are also supervisors were asked to react to the same items from a supervisor's perspective.

Items on the consumer survey were meant to parallel items on the clinician and supervisor surveys. However, there were a few items that were dropped because project leadership, along with the TEP, agreed that the questions were too technical for a consumer survey. Six consumers with a diagnosis of PTSD participated in cognitive testing. The participants included both men (n = 3) and women (n = 3). Consumers, like clinicians, were asked about item comprehension, about clarity of wording, definition, or presentation, and about their reaction to certain items or examples (e.g., use of sexual trauma as an example). Unlike clinicians, consumers were also asked to react to a few terms like "psychotherapist" or "therapy" so that instructions could be appropriately worded. Testing of the consumer survey was also an iterative process where questions were modified based on feedback. Interviewees were provided a choice between two versions of a question or asked to endorse or reject the new wording. Final draft versions of the surveys are included in Attachment 1 (clinician survey), Attachment 2 (supervisor survey), and Attachment 3 (consumer survey).

Three additional tools also were developed to assist with sampling and data collection:

1) Site coordinator's checklist for site characteristics (see Attachment 4)
2) A data abstraction form used to identify and sample clinicians, sessions, supervisors, and consumers (see Attachment 5)
3) A clinician and supervisor demographic questionnaire to obtain basic demographic data about the clinicians and supervisors administering PTSD treatment (Attachment 6)

Under the proposed plan for information collection, ASPE's contractor will partner with six behavioral health organizations providing outpatient

therapy to adults with PTSD to pre-test the instruments. The information will be collected using web-based surveys of clinicians, consumers, and clinical supervisors. Information from the site characteristic checklist (Attachment 4) will be obtained through a preliminary telephone conversation with the site coordinator. This checklist was created so that Mathematica could identify sites with the capacity to participate in pre-testing the surveys. The site coordinator will also populate the electronic data abstraction form (Attachment 5), which will be used to select a sample of clinicians, clinical supervisors, and consumers to take the surveys. This form will be uploaded to key Mathematica project staff by the site coordinator through a secure file-transfer site. Clinicians and supervisors will complete the demographics questionnaire to provide important contextual information such as their clinical training background, the length of time in treating adults with PTSD, their client caseload (Attachment 6).

The web-based surveys will assess the delivery of psychotherapy for PTSD and include items from the perspective of the clinician (see Attachment 1), the clinical supervisor (see Attachment 2), and the consumer (see Attachment 3). Web-based surveys are an efficient method of obtaining information from respondents. The surveys are designed to take 5 to 10 minutes to complete and will yield information to inform a preliminary reliability and validity assessment.

Survey Participants. Within each behavioral health organization, four types of individuals will be involved in this data collection effort: site coordinators, clinicians, clinical supervisors, and consumers. Clinicians, supervisors, and consumers will complete a web-based survey about the same therapy session. This approach will allow a comparison of results for the same session across the multiple raters. Clinical supervisors will base their survey response on their direct observation of the therapy session (by one-way mirror or video or audio recording). Site coordinators will complete the site characteristic checklist (Attachment 4) over the phone with Mathematica and will also complete the data abstraction form (Attachment 5).

A2. Purpose and Use of Information Collection

Pre-testing is an essential component in developing any useful, reliable, and valid instrument. The primary purpose of this effort is to determine feasibility of data collection, develop preliminary procedures for data collection, and provide initial assessment of reliability and validity of all the surveys. As this is a pre-test study, the purpose is not to demonstrate efficacy or effectiveness of the instruments. Rather, knowledge gained from this pre-test test will help identify needed modifications to the instruments and will determine whether broader testing at a larger, more diverse set of

sites is merited. Since only six sites are involved in the pre-testing, ASPE does not claim that outcomes will be generalizable; they are rather illustrative of the kinds of data that might be generated by the surveys.

A3. Use of Improved Information Technology and Burden Reduction

To reduce respondent burden, the clinician's survey, clinician supervisor's survey, and consumer's survey will be administered using web-based data collection methodologies. Surveys will be completed online (by respondents) using a secure web-based program that can be accessed from any computer with an Internet connection. The data collection methodologies will be based upon those documented in the survey research literature, which ASPE's contractor has used for a number of years. All information collected will meet federal requirements regarding security and personal identifiable information, in addition to any Health Insurance Portability and Accountability ACT (HIPAA) regulations.

A4. Efforts to Identify Duplication and Use of Similar Information

To determine if any instruments (tools or quality measures) already in existence could be used to measure the concordance of PTSD treatment with evidence-based approaches, ASPE's contractor conducted searches of peer-reviewed published literature, unpublished literature and reports, and databases of existing quality-improvement measures; it also consulted with staff from ASPE and NIMH and with PTSD experts. Given that no such instruments were identified, this project will not duplicate any efforts to develop a quality-improvement measure in this area.

A5. Impact on Small Businesses or Other Small Entities

Of the six sites being recruited for the pre-test, one could be a considered a small business (i.e., community mental health organization). In an effort to minimize the impact of participating in this data collection effort in general, we have designed the survey to be completed in 10 minutes or less, and have requested only the minimum information needed. To further reduce burden, we will prioritize the participation of larger behavioral health organizations and those in which clinical supervisors currently evaluate clinicians' delivery of evidence-based therapies. This approach will ensure that the proposed data collection aligns with organizations' standard work practices. Furthermore, by distributing data collection across multiple behavioral health organizations, most of which would not be considered small, we minimize the burden to any one organization.

A6. Consequences of Collecting the Information Less Frequently

Pre-testing is an essential component of developing a useful, reliable, and valid instrument that can be used to measure the delivery of evidence-based psychotherapy treatment for PTSD. The consequence of not collecting these data through the surveys described above is that ASPE will not be able to develop a measure of evidence-based PTSD treatment, nor advance the goals of the president's executive order calling for the advancement of research on PTSD treatment methods.[16]

The current data collection is scheduled to occur only once, over a six-month period from summer 2014 through winter 2014. Over this time period, each clinician will complete the survey three times and will spend a maximum of 30 minutes on this data collection effort. During this same time period, individual clinical supervisors within the behavioral health organizations will complete the survey 18 times and will spend a maximum of 180 minutes on this data collection effort. Because we plan to recruit behavioral health organizations that provide clinical supervision as part of routine practice, we anticipate that the supervisors' participation in this effort will have a limited impact on their time. Consumers receiving treatment in the participating behavioral health organizations will complete the survey once during their treatment.

Because it is unclear whether consumers will be able to identify and recognize the components of therapy delivered by the clinician and because consumers, clinicians, and clinical supervisors may have different assessments of the delivery of therapeutic elements, it is critical that all three respondents (clinicians, clinical supervisors, and consumers) complete the survey on the same therapy session.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with 5 CFR 1320.5. There are no special circumstances for collecting this information.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Federal Register Notice

[16]White House, "Fact Sheet: President Obama Signs Executive Order to Improve Access to Mental Health Services for Veterans, Service Members, and Military Families," August 31, 2012, http://www.whitehouse.gov/the-press-office/2012/08/31/fact-sheet-president-obama-signs-executive-order-improve-access-mental-h, accessed October 24, 2013.

A 60-day notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on Nov. 27, 2013; a copy is provided as Attachment 8.

Outside Consultations

On an ongoing basis, ASPE, NIMH, and Mathematica consult with individuals regarding the development and pre-testing of the instruments to measure the delivery of evidence-based psychotherapy for PTSD. Among others, they have consulted with Dr. Ginny Strand of Fordham University, Jeannie Campbell and Cheryl Sharp of the National Council of Community Behavioral Healthcare, and Elizabeth Ricksecker of the Centers for Medicare & Medicaid Services/Center for Clinical Standards and Quality. These individuals provided input on the project's methodological approach, the implementation of trauma-informed care in community settings, potential pre-test testing partners, and the VA's approach to implementing evidence-based PTSD care. Dr. Joel Sherrill at NIMH is also regularly consulted.

Mathematica also consults with a five-member TEP made up of experts in the development and implementation of PTSD treatments, study design, mental health research, and clinical care of individuals with PTSD. The TEP met as a group, via conference call, in November 2012 and March 2013, to provide input on specific questions related to the items to be included in the surveys and on plans to pre-test the surveys. Individual TEP members have provided additional feedback via email and phone calls and continue to be available for consultation. Table A.1 lists contact information for the members as well as the years in which each serves on the TEP.

Table A.1. Technical Expert Panel Members

Name	Affiliation	Years of TEP Participation
Kathleen Chard, Ph.D.	Cincinnati VA Medical Center	2013–2014
Edna Foa, Ph.D.[a]	University of Pennsylvania	2012–2014
Patricia Resick, Ph.D., ABPP[b]	National Center for the Study of PTSD, U.S. Department of Veteran Affairs	2012–2014
Barbara Rothbaum, Ph.D., ABPP	Emory University School of Medicine	2012–2014
Lori Zoellner, Ph.D.	University of Washington	2012–2014

ABBP = American Board of Behavioral Psychology.

[a]Developer of prolonged exposure CBT; see Foa et al. (2007).

[b]Developer of cognitive processing therapy; see Resick and Schnicke (1996).

A9. Explanation of Any Payment or Gift to Respondents

Mathematica will enter into contractual agreements with behavioral health organizations participating in the data collection effort. The six pre-test sites will each be paid for their work as independent data collection agents.

Individual clinicians and clinical supervisors will not be compensated for their participation, but consumers will receive a $20.00 gift card (from Target, WalMart, Visa, etc.) for completing the informed consent and the survey. The project team consulted with internal experts to determine that this payment would be sufficient to motivate (but not coerce) individuals to take part in the project. Without such payments, it is much less likely that consumers would be willing to participate.

A10. Assurance of Confidentiality Provided to Respondents

As health care providers, all sites are bound by HIPAA regulations, and staff are trained in how to protect the confidentiality of their clients. Information collected (and transmitted to Mathematica) through the data abstraction form (Attachment 5) will comply with all aspects of the privacy act. Clinicians and clinical supervisors will be given this assurance when the behavioral health organization enters into a contractual agreement with Mathematica to participate in pre-testing the surveys. Consumers will receive this assurance when they are invited to participate and again when they log onto the website to provide informed consent and to complete the survey (see Attachment 9). All participants will further receive assurance that the information being gathered is for quality-improvement purposes. Respondents will be told that the information they provide will be shared with ASPE and NIMH in an aggregate form; that it may be presented in briefings, reports, or papers; and that no personal identifying information will be attached to any information presented or described.

Safeguarding Data

Mathematica has established data security plans for the handling of all data collection efforts. Its plans meet the requirements of U.S. federal government agencies and are continually reviewed for compliance with new government requirements and data collection needs. Such security is based on (1) an exacting company policy promulgated by the highest corporate officers in consultation with systems staff and outside consultants, (2) a secure systems infrastructure that is continually monitored and evaluated with respect to security risks, and (3) secure work practices of an informed staff that take all necessary precautions when dealing with confidential data.

The names of potential participants provided to Mathematica to generate the survey sample will be linked to survey responses only by means of a unique, nonidentifying numeric code; this approach protects privacy but also makes it possible to see which clinicians, clinical supervisors, and consumers were involved in the same therapy session, as well as to monitor survey completion and provide incentive payments. Data will be encrypted prior to transmittal, and all information will be de-identified prior to conducting any analyses.

All data will be stored on a secured password-protected server accessible only to project staff and on a need-to-know basis. When the project is completed, the project staff will securely destroy all electronic data by using Eraser, a file deletion utility that overwrites data at least three times, or equivalent software. Project staff will formally attest to the fact that the data have been destroyed.

A11. Justification for Sensitive Questions

Clinicians and clinical supervisors are not asked any questions of a sensitive nature. The questions asked of consumers are not sensitive in nature. The consumer survey asks about the clinician's delivery of therapeutic elements (e.g., "Did your therapist assign homework?" and "Did your therapist help you understand how your thoughts and feelings are related?"). It does not ask for any information about the topics discussed in the therapy session.

A12. Estimates of Annualized Hours and Costs

Table A.2 shows the estimated annualized burden-hours for respondents' participation in the surveys. The demographics questionnaires will take clinicians and clinical supervisors 5 minutes to complete. The web-based surveys will take no more than 10 minutes to complete. It is estimated that the total burden-hours to collect responses is 21 hours for clinicians and 19 hours for clinical supervisors. The total burden-hours for consumers is 18 hours The total burden for the site coordinators is 576 hours. This includes time for the initial 1-hour meeting to fill out the site coordinator checklist (Attachment 4), the coordinator's completion of the data abstraction form (Attachment 5), the initial 1-hour training on data collection procedures, weekly "check in" meetings with Mathematica to discuss and address any data collection challenges, and coordination of survey completion for each respondent type. The total burden for this quality measure development project is 634 hours.

Table A.3 shows that the total estimated annualized cost of pre-testing the measures is $13,532. The total estimated cost is computed from the total annual burden-hours and an average hourly wage for the respondent

Table A.2. Estimated Annualized Burden-Hours

Respondent Type	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Response	Total Burden-Hours
Clinician (demographics questionnaire)	36	1	36	5/60	3
Clinician Supervisor (demographics questionnaire	6	1	6	5/60	1
Clinician (clinician survey)	36	3	108	10/60	18
Clinician Supervisor	6	18	108	10/60	18
Consumer	108	1	108	10/60	18
Site Coordinator	6	1	6	96	576
Total	192	24	372		634

Table A.3. Estimated Annualized Cost Burden

Respondent Type	Total Burden-Hours	Average Hourly Wage[a]	Total Cost Burden
Clinician Demographics Questionnaire Total	3		
Psychiatrist	1	$85.35	$141
Clinical psychologist	1	$34.72	
Social worker	1	$20.84	
Clinician Survey Total	18		
Psychiatrist	2	$85.35	$598
Clinical psychologist	7	$34.72	
Social worker	8	$20.84	
Clinical Supervisor Demographics Questionnaire	1	$34.72	$35
Clinical Supervisor Survey	18	$34.72	$625
Consumer	180	$16.27	$130
Site Coordinator	576	$20.84	$12,003
Total		n.a.	$13,532

[a]Average hourly wages for psychiatrists, clinical psychologists, and social workers are from Bureau of Labor Statistics, "National Compensation Survey: Occupational Wages in the United States May 2012," [http://www.bls.gov/oes/current/oes_nat.htm]. Clinical supervisors are clinical psychologists. Average hourly wages for consumers are based on reported income in research studies for adults with PTSD; see for example Campbell et al. 2007; Taft et al. 2008; Hanley et al. 2013; and Matlow and DePrince 2013.

n.a. = not applicable.

A13. Estimates of Other Total Annual Costs

No capital costs are involved in this data collection.

A14. Annualized Cost to Federal Government

This quality measure development project takes place over a three-year period. The total cost of the project to the government is $572,156 which includes the amount awarded via contract to ASPE's contractor and ASPE staff time/resources. The total cost was based on the budget developed by Mathematica, which calculated wages and hours for all staff, telephone charges, and overhead costs per contract year along with the government staff costs. Dividing the total funded amount by three years gives an annualized contract cost of $190,719 per year.

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

Pending OMB clearance, ASPE expects data collection to begin in summer 2014 and to continue through winter 2014. ASPE's contractor will begin to prepare materials for disseminating the results of the data collection in late 2014. Table A.4 presents the anticipated data collection and reporting schedule.

Table A.4. Project Time Line

Task	Schedule
Recruit data collection sites	One month after OMB clearance
Collect data from web-based survey	Two months after OMB clearance
Analyze data	Six months after beginning data collection
Prepare and submit draft report	One month after completion of data analyses
Prepare and deliver briefing	Three weeks after delivery of draft report
Prepare and submit final report	Three weeks after delivery of briefing

Before data analysis begins, Mathematica will produce a cleaned data file and data dictionary for the analyses. The analyses will involve generation of tables showing univariate and bivariate distributions for each survey item by key variables, such as respondent type. For example, a table could show the percentage of clinicians, clinical supervisors, and consumers who indicated that the clinician "discussed the client's treatment expectations." In presenting the results of the analyses, the limitations of this data collection effort will be acknowledged.

To inform survey revisions and future testing needs, multiple analyses will be conducted to assess preliminary psychometric properties of the measures:

- Preliminary reliability analyses will include a Kappa test to assess inter-rater agreement.
- Preliminary validity analyses will include a calculation of the surveys' sensitivity and specificity.
- An exploratory factor analysis will examine the constructs underlying the measures and explore whether any survey items should be considered for removal.

To inform approaches to scoring the measure, exploratory analyses will examine the percentage of clinicians who would "pass" the measure at various thresholds.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

ASPE does not seek this exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Clinician's survey of the delivery of evidence-based psychotherapy
2. Clinician supervisor's survey of the delivery of evidence-based psychotherapy
3. Consumer's survey of the delivery of evidence-based psychotherapy
4. Site coordinator's checklist to obtain site-of-care characteristics
5. Site coordinator's sample section abstraction form used to identify persons being treated for PTSD and their associated ptsd clinician and clinician supervisor
6. Clinician Demographics Questionnaire
7. Section 301 of the Public Health Service Act [42 U.S.C. 241]
8. 60-Day federal register notice
9. Project background/invitation to participate, and consumer participation consent forms
10. Site recruitment document
11. Project description
12. Site coordinator reminder to clinicians
13. Supporting Statement A references
14. Supporting Statement B references