

## Evidence-based Practice Center

### Project Title: Disparities within Serious Mental Illness

#### I. Background and Objectives for the Technical Brief

The goal of this Technical Brief is to describe the evidence of the effectiveness of interventions to reduce disparities among patients with serious mental illness (SMI). The topic emerged from a priority listing developed through an Agency for Healthcare Research and Quality (AHRQ) Issues Exploration Forum that the RTI International-University of North Carolina Evidence-based Practice Center (EPC) conducted early in EPC-IV.<sup>1</sup> We define disparities as differences or gaps in care experienced by one population group compared with another; in this case, between subgroups of patients with SMI, such as those differing by racial, ethnic, economic (including homelessness), and geographic characteristics (e.g., urban versus rural), and disparities experienced by lesbian, gay, bisexual, transgender (LGBT) individuals or those who have difficulty communicating in the local primary language.

Care can refer to access to accurate diagnosis, health care services, and treatment; quality of health care; and response to treatment. These differences or gaps in care between groups represent a lack of efficiency within the health care system and can result in excess economic burden on the health care system as a whole.<sup>2</sup>

SMI commonly refers to a diagnosis of psychotic disorders, bipolar disorder, and either major depression with psychotic symptoms or treatment-resistant depression (although SMI can include anxiety disorders, eating disorders, and personality disorders, if the degree of functional impairment is severe).<sup>3,4</sup> SMIs are long-term illnesses involving substantial functional impairment over multiple symptom domains. These impairments often lead to an inability to maintain gainful employment, poor social support, repeated psychiatric hospitalizations, homelessness, incarceration, and coexisting substance use disorders.

Disparities can occur at multiple points along the health care continuum—in access to accurate diagnosis; in access to care generally, as well as specific health care resources; in the receipt of appropriate standard-of-care treatment; and in adequate monitoring and followup.<sup>5</sup> Considering how to effectively reduce these disparities at each step is crucial for optimizing care for patients with SMI, who often have complex and chronic treatment needs.

Several key issues highlight the importance of this topic. First, the prevalence of SMI and morbidity from these illnesses in the United States is striking. Rates of SMI for adults range from 4 to 6 percent; affecting more than 11 million adults.<sup>6,7</sup> Second, SMI is frequently untreated or undertreated. Many people with an SMI receive no treatment. Among adults with an SMI in 2008, less than 60 percent had used mental health services in the previous year, and only 40 percent had used any outpatient health care services.<sup>8</sup> The American Psychological Association highlights the fact that lack of access to mental health care is even more pronounced in various racial groups; disparities in quality of care (i.e., access to comparable care or disparities in the treatment received at the same facilities or both) have been found to be related to racial, ethnic, geographic, and socioeconomic differences.<sup>9</sup>

While disparities in access to needed care exist between patient populations with and without SMI, the focus of this Technical Brief is limited to disparities between groups within the SMI population. For example, among Medicaid beneficiaries with schizophrenia, the quality of mental health care has been found to differ among whites, blacks, and Latinos: a measure of quality of care, incorporating indicators of pharmacological, psychosocial, and health services utilization, was lowest for blacks in all states and was lower for Latinos than whites in three of the four states sampled.<sup>10</sup> Racial disparities in the use of atypical antipsychotics by veterans with schizophrenia have also been identified.<sup>11</sup> Gender differences in response to treatment among individuals with co-occurring substance abuse and mental health disorders have also been reported.<sup>12</sup> Individuals who lived in rural geographic areas had higher suicide death rates than those who resided in large fringe metropolitan areas (suburbs) from 2008 to 2011, based on a 2013 AHRQ National Health Care Disparities Report.<sup>13</sup> Research related to mental health care among LGBT people is limited, but important because this population experiences higher rates of mood and anxiety disorders and suicidal ideation and behavior.<sup>14,15</sup>

This nomination stems from two important perceptions by clinicians, patients, and families about SMI. Firstly, that within the SMI population, disparities exist in relation to (a) access to accurate diagnostic evaluation; (b) access to health care, including health care coverage; (c) quality of health care received; and (d) adherence and response to treatment or other health outcomes. Secondly, interventions exist to address these disparities within the SMI population, but little is known about their effectiveness (or comparative effectiveness). Nominators are seeking to identify solutions to promote equal access to treatment and quality care for all SMI patients.

## II. Guiding Questions (GQs)

1. From available evidence and input from Key Informants (KIs): Describe interventions (types or modalities) to reduce disparities among SMI subgroups. Interventions may address one or more of the following concerns within an SMI subgroup: (a) access to accurate diagnostic evaluation; (b) access to health care, including health care coverage; (c) improving quality of health care; and (d) improving adherence to treatment, response to treatment, or other health outcomes.
  - a. What are the goals of the interventions?
  - b. What are the components of the interventions?
  - c. What are the outcomes of the interventions?
  - d. What disparity subgroups are the focus of the interventions?
  - e. What are other key characteristics of the disparity subgroups who are eligible for each of the interventions (e.g., age; type, stage, or severity of the SMI condition; or other risk-stratification issues)?
  - f. What is the level of staffing and qualifications of staff required (including background, training, and/or necessary certification)?
  - g. What are the potential advantages of this type of intervention when compared with other types of interventions or with usual care?
  - h. What are the potential disadvantages of these types of interventions, including safety issues and harms?

2. From available evidence and input from KIs: Describe the context for each intervention (type or modality) identified in GQ1 to reduce disparities among SMI subgroups. Intervention may address one or more of the following concerns: (a) access to accurate diagnostic evaluation; (b) access to health care, including health care coverage; (c) improving quality of health care; and (d) improving response to treatment, adherence to treatment, or other health outcomes.
  - a. What is the setting for the intervention; in particular, what is the structure, components, and/or characteristics of the organization(s) providing the intervention?
  - b. What other responsibilities do the health professionals (including clinicians) participating in the intervention have for the medical and mental health care of patients with SMI, including transitions of patients from inpatient to outpatient care and vice versa?
  - c. What other resources (e.g., health information technology) are needed to provide the intervention?
  - d. Does successful implementation of this intervention require changes/cooperation/integration by other service providers?
3. From available evidence: Describe the current evidence about the effectiveness (or comparative effectiveness) of interventions that have been implemented to reduce disparities among SMI subgroups. Interventions may address one or more of the following concerns: (a) access to accurate diagnostic evaluation; (b) access to health care, including health care coverage; (c) improving quality of health care; and (d) improving adherence to treatment, response to treatment, or other health outcomes. Data on a specific intervention will optimally include:
  - a. Patient inclusion criteria
  - b. Type of intervention
  - c. Intervention design and size
  - d. Comparator intervention(s) used in comparative effectiveness evaluations
  - e. Length of followup
  - f. Outcomes
  - g. Types of health care professionals providing services in the intervention or targeted by the intervention
  - h. Concurrent and prior treatment
  - i. Setting of the intervention
  - j. Costs and resource used in providing the intervention
  - k. Payment considerations (such as availability of insurance coverage)
4. From available evidence and input from KIs, identify gaps in knowledge and future research needs:
  - a. Are any interventions to address disparities among SMI subgroups planned by researchers, clinicians, patient advocacy groups, or others but not yet implemented?

- b. In current interventions, are the correct outcomes being measured? Are relevant outcomes being measured with appropriate instruments and data?
- c. What gaps exist in the evidence base for best practices or interventions for addressing disparities in SMI?
- d. What are possible areas of future research?
- e. What are potential long-term (10-year +) developments in this field?

### III. Methods

1. Data Collection: Information to address our GQs will come from three sources: KIs, gray literature searches, and published literature searches.

#### A. Discussions With Key Informants

KIs are particularly vital to shaping this Technical Brief because a myriad of conceptual frameworks might guide the application of interventions to reduce disparities among SMI subgroups. As such, it will be challenging to distinguish commonalities in how disparities and SMI are defined across studies.

We will conduct interviews with KIs in two phases. The first phase will include a group interview to aid in further conceptualizing the relevant definitions of SMI, including the range and types of diagnoses and which specific “disparities” should be of focus. Though all SMIs and disparities are important, the KIs will provide a more focused scope for our search strategy and help identify key research gaps for interventions that are aimed at reducing disparities within SMI. The second phase will include additional group, and when necessary individual, interviews with KIs focused on our GQs.

Specifically, our responses to GQs 1 (description and definition of interventions to reduce disparities within SMI), 2 (context in which interventions are used to reduce disparities within SMI), and 4 (key remaining issues regarding interventions to reduce disparities within SMI) will be informed by KI discussions. Subquestions under GQs 1, 2, and 4 serve as prompts to discuss issues further: we may follow new avenues of discussion should conversations with KIs reveal new insights that require further exploration. Also, we do not anticipate that all KIs can or should answer all GQs. We anticipate asking KIs questions relevant to their specific expertise and exploring general topics as time permits. For GQs 1, 2, and 4, we will review the literature in parallel with KI interviews and explore points of commonality or departure between KI insights and the published literature in our analysis. Our review of the literature will be targeted and will rely on the best and most recent evidence available.

For GQ 3, we will conduct a comprehensive and systematic search of the peer-reviewed and gray literature and present all available and eligible evidence. KI insights will help us identify ongoing or planned research.

**Identifying Experts Without Conflicts of Interest (COIs).** We will determine possible COIs for review team members and stakeholders at the start of the project and will consult with AHRQ about disclosure or removal from the project for those individuals with clear financial or intellectual COIs. These specific steps may be

insufficient, however, for ensuring freedom from bias. Other requirements include ensuring balance in perspectives and interests for stakeholder groups and our core team. Our aim is to provide AHRQ with a Technical Brief that is as objective and unbiased as possible.

**Engaging Relevant Stakeholder Groups.** Stakeholder and partner engagement ensures usability and applicability of EPC products and, therefore, is critical to AHRQ's mission. When engaging stakeholders, we will aim to ensure a balance of viewpoints. We will engage KIs via teleconference, with targeted email communication as needed. We will provide materials for review 1 week before calls and will send reminder emails to KIs 2 to 3 days before the scheduled teleconference. We generally have specific questions for stakeholder input, but we will also provide time on calls for suggestions about our GQs. Further, we will obtain input from diverse stakeholders through peer review and public comment.

In consultation with AHRQ, we will identify the distinct perspectives that are essential for informing a well-rounded and balanced Technical Brief about disparities in SMI. Specifically, we will seek to recruit the following as KIs: minority health services and health disparities researchers, community care coordinators, mental health providers, representatives of professional societies, policymakers, and patient advocacy groups.

To facilitate broad participation, we will use staff with substantial experience in moderating calls, follow semistructured guides with built-in places for various stakeholders to provide input, call on silent individuals to elicit their views, redirect conversations as needed, and offer opportunities for feedback through other media (e.g., via email). 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.

## **B. Gray Literature Search**

We will use the gray literature to identify information beyond the published literature on interventions that address disparities in SMI. Sources for the gray literature include the following:

- **OpenSIGLE:** Operated by GreyNet, the OpenSIGLE Repository preserves and makes openly accessible research results originating in the International Conference Series on Grey Literature. GreyNet together with the Institute for Scientific and Technical Information-National Center for Scientific Research designed the format for a metadata record, which encompasses standardized PDF attachments for full-text conference preprints, PowerPoint presentations, abstracts, and biographical notes. All 11 volumes (1993–2009) of the Grey Literature Conference Proceedings are available in the OpenSIGLE Repository.
- **ClinicalTrials.gov:** ClinicalTrials.gov offers up-to-date information for locating federally and privately supported clinical trials for a wide range of diseases and conditions. The site contains approximately 12,400 clinical

studies sponsored by the National Institutes of Health, other federal agencies, and private industry. Studies listed in the database are conducted in all 50 states and in more than 100 countries.

- **Academic Search Complete:** This source provides information from a wide range of academic areas, including business, social sciences, humanities, general academic, general science, education, and multicultural topics. This multidisciplinary database features full text for more than 4,000 journals with many dating back to 1975, abstracts and indexing for more than 8,200 scholarly journals, and coverage of selected newspapers and other news sources.
- **NIH RePORTER:** 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.

We will also search Web sites of the National Guidelines Clearinghouse (NGC), the National Quality Measures Clearinghouse (NQMC), The Joint Commission, and other relevant organizations.

### **C. Published Literature Search**

We will systematically search the published literature for studies to address our GQs.

**Planned Databases.** We propose to conduct searches in PubMed (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, and the Cochrane Library and to perform gray literature searches (see above).

**Draft Search Strategy.** An experienced research librarian developed our draft search strategy during our refinement of this topic (Table 1). In a second round of searches, we will look for more studies in PubMed, CINAHL, PsycINFO, and the Cochrane Library. We will review the reference lists of identified papers and reviews to identify additional relevant papers. We will update the literature review by repeating the initial search concurrent with the peer review process. In addition, we will examine any literature suggested by KIs, Peer Reviewers, or public commenters and, if appropriate, incorporate it into the final work.

**Proposed Eligibility Criteria.** All identified citations will be imported into an EndNote database. Table 2 describes our proposed eligibility criteria. Two trained members of the research team will independently review all abstracts for eligibility based on the pre-established inclusion/exclusion criteria. Studies marked for possible inclusion by either reviewer will undergo a full-text review. Any study with inadequate information in the abstract will also undergo full-text review.

**Table 1. Draft search strategy**

Search	Query	Items found
#1	Search 18085577[uid]	1
#2	Search "Quality Assurance, Health Care"[MAJR]	118505
#3	Search "Quality Assurance, Health Care"[MeSH]	261245
#4	Search ("Mood Disorders"[Mesh] OR "Schizophrenia and Disorders with Psychotic Features"[Mesh] OR Depression[Mesh] OR (("Depressive Disorder, Major"[Mesh]) OR "Anxiety Disorders"[Mesh]) OR "Eating Disorders"[Mesh] OR "Personality Disorders"[Mesh] OR ((severe OR serious OR persistent) mental illness[Text Word]))	381974
#5	Search ((((((("Cultural Competency"[Mesh]) OR ("Healthcare Disparities"[Mesh] OR "Health Status Disparities"[Mesh] ))) OR ((((((("Minority Groups"[Mesh]) OR "Sexism"[Mesh]) OR ("Discrimination (Psychology)"[Mesh] OR "Social Discrimination"[Mesh] OR "Ageism"[Mesh] OR "Racism"[Mesh] )) OR "Rural Population"[Mesh]) OR ("Socioeconomic Factors"[Mesh] OR "Social Class"[Mesh] )) OR "Sexual Behavior"[Mesh]))) OR (((("Homeless Persons"[Mesh]) OR "African Americans"[Mesh])) OR ((("Homosexuality"[Mesh]) OR "Transgendered Persons"[Mesh]))	511302
#6	Search (#4 AND #5)	26603
#7	Search (#6 AND #3)	232
#8	Search (#6 AND #2)	51
#10	Search "Total Quality Management"[Mesh] OR "Quality Assurance, Health Care"[Mesh] OR "Health Care Quality, Access, and Evaluation"[Mesh] OR "Quality of Health Care"[Mesh]	5511478
#11	Search (#6 AND #10)	20210
#12	Search "Intervention Studies"[Mesh] OR "Crisis Intervention"[Mesh] OR intervention	380410
#13	Search (#11 AND #12)	1530
#16	Search (#11 AND #12) Filters: Humans; English; Adult: 19+ years	1163
#17	Search (#11 AND #12) Filters: Systematic Reviews; Humans; English; Adult: 19+ years	28
#19	Search (#11 AND #12) Filters: Clinical Trial; Randomized Controlled Trial; Humans; English; Adult: 19+ years	375

We will retrieve and review the full text of all articles included during the title/abstract review phase. Two trained members of the research team will independently review each full-text article for inclusion or exclusion on the basis of the eligibility criteria (Table 2). Disagreements about inclusion will be resolved by discussion or consensus with review by the full research team as needed.

All results will be tracked in the 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 in the final work.

**Table 2. Proposed eligibility criteria for literature regarding disparities within SMI**

Criterion	Inclusion	Exclusion
Population	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ <math>\geq 18</math> years with SMI<sup>a</sup> currently or at any time during the past year</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>▪ Part of a subgroup identified as being at risk of experiencing a mental health care disparity based on race, ethnicity, economic status (including homelessness), geographic location (e.g., urban versus rural), being LGBT, or difficulty communicating in the local primary language (e.g., English as a second language)</li> </ul>	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ <math>&lt;18</math> years</li> <li>▪ Primary diagnosis of substance abuse, dementia, or mental retardation without SMI</li> </ul>
Intervention	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ Interventions intended to reduce disparities among subgroups of individuals with SMI, including disparities in (a) access to accurate diagnostic evaluation, (b) access to health care, including health care coverage, (c) quality of health care, and/or (d) adherence to treatment, response to treatment, or health outcomes</li> </ul>	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ Approaches that do not attempt to reduce these disparities</li> </ul>
Comparator	<p>GQs 1, 2, and 4</p> <ul style="list-style-type: none"> <li>▪ No limitations</li> </ul> <p>GQ 3</p> <ul style="list-style-type: none"> <li>▪ Another intervention to reduce the same disparity</li> <li>▪ Usual care/active control</li> <li>▪ Waitlist</li> <li>▪ No comparator for single group pre-post studies</li> </ul>	<p>GQs 1, 2, and 4</p> <ul style="list-style-type: none"> <li>▪ Not applicable</li> </ul> <p>GQ 3</p> <ul style="list-style-type: none"> <li>▪ Studies with no comparator group except for single group pre-post studies</li> </ul>
Outcomes	<p>GQs 1, 2, and 4</p> <ul style="list-style-type: none"> <li>▪ No limitations</li> </ul> <p>GQ 3</p> <ul style="list-style-type: none"> <li>▪ Benefits, including improvements in disparity subgroups in (a) access to accurate diagnostic evaluation; (b) access to health care, including health care coverage; (c) quality of health care; and (d) adherence to treatment, response to treatment, or other health outcomes<sup>b</sup></li> <li>▪ Harms or adverse effects of the using these interventions</li> </ul>	<p>GQs 1, 2, and 4</p> <ul style="list-style-type: none"> <li>▪ Not applicable</li> </ul> <p>GQ 3</p> <ul style="list-style-type: none"> <li>▪ Outcomes not attributable to the interventions of interest</li> </ul>
Time frames	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ None</li> </ul>	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ None</li> </ul>
Setting	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ Inpatient or outpatient, primary care or mental health (specialty) care</li> </ul>	<p>All GQs</p> <ul style="list-style-type: none"> <li>▪ None</li> </ul>

**Table 2. Proposed eligibility criteria for literature regarding disparities within SMI**

Criterion	Inclusion	Exclusion
Study design	GQs 1, 2, and 4 <ul style="list-style-type: none"> <li>▪ No limitations</li> </ul> GQ 3 <ul style="list-style-type: none"> <li>▪ Systematic reviews</li> <li>▪ Randomized controlled trials</li> <li>▪ Nonrandomized controlled trials</li> <li>▪ Prospective and retrospective cohort studies</li> <li>▪ Case-control studies</li> <li>▪ Single-group pre-post studies</li> </ul>	GQs 1, 2, and 4 <ul style="list-style-type: none"> <li>▪ Not applicable</li> </ul> GQ 3 <ul style="list-style-type: none"> <li>▪ Case reports</li> <li>▪ Case series</li> <li>▪ Cross-sectional studies</li> <li>▪ Opinions</li> <li>▪ Commentaries</li> <li>▪ Nonsystematic reviews</li> <li>▪ Letters to the editor with no primary data</li> </ul>
Other	All GQs <ul style="list-style-type: none"> <li>▪ English language</li> <li>▪ Published 1980<sup>c</sup> and later</li> </ul>	All GQs <ul style="list-style-type: none"> <li>▪ Non-English language</li> <li>▪ Published prior to 1990</li> </ul>

GQ = guiding question; LGBT = lesbian, gay, bisexual, transgender; SMI = serious mental illness.

<sup>a</sup> SMI defined as (1) schizophrenia or schizoaffective disorder (or other related primary psychotic disorder); (2) bipolar disorder; (3) current major depression; (4) anxiety disorders; (5) eating disorders; or (6) personality disorders, per DSM-IV (*Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> Edition) or their ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) equivalent (and subsequent revisions). Requires functional impairment that substantially interferes with or limits one or more major life activities.

<sup>b</sup> Other health care outcomes can include but are not limited to: housing stability; social support; remission of disorder; physical health outcomes; quality of life; clinical engagement; satisfaction with care; symptom relapse; criminal justice encounters; suicidality and other self-injurious behaviors; homicide and other aggressive behaviors.

<sup>c</sup> Given that contemporary resources, finances, and approaches to treatment have changed substantially in the last 35 years or so, we systematically searched the published literature from January 1, 1980, to the present.

## 2. Data Organization and Presentation:

### A. Information Management

Information collected to inform disparities in SMI includes information gleaned from discussions with KIs, comprehensive searches of the peer-reviewed literature, and targeted searches of the gray literature.

**Data Abstraction:** We will abstract data from each included study, using a standardized template organized to address the GQs. One member of the review team will collect the data, and a second team member will review it for accuracy and completeness. The following information will be obtained from each study, where applicable: author, year of publication, source of study funding, study design characteristics, study population (including study inclusion and exclusion criteria), interventions to reduce disparities, duration of patient followup, outcomes assessed (specific measures used, as well as timing of assessment), and other pertinent information.

Two researchers will independently review each of the KI interview summaries, provided by DESA, Inc., in preparation for a potential qualitative analysis. If there are

a large number of individual KI interviews, we will use NVivo qualitative software for the analysis.

**Integration of Information:** Data from the published literature will be integrated with information from the gray literature and KI discussions. We anticipate that GQs 1 and 2 will be informed primarily by information from KI discussions and secondarily by gray literature or nonsystematic published reviews. Parts of these questions may also be informed by published literature or peer-reviewed evidence, particularly the following:

- What are the components, outcomes, and potential safety issues and harms of interventions?
- What is the level of staffing and qualifications of staff required for the interventions?

In instances where evidence from empirical studies informs 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 through 3.

**Conceptual Framework: A conceptual framework will be developed mapping to the PICOTS criteria (i.e., population, interventions, comparators, outcomes, timing and setting).**

## **B. Data Presentation**

Our findings will be presented in the order of the GQs. We will qualitatively summarize findings from gray literature searches and KI interviews. For questions with empirical evidence or in-progress studies to inform the results, we will present study-specific tables and use these to create cross-cutting tables describing the state of evidence in relation to study characteristics (number and types of study designs addressing interventions to reduce disparities within serious mental illness), and types of outcomes. We will explore ways to present data graphically based on the availability and appropriateness of the information that we find.

## **IV. References**

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14. Institute of Medicine (US) Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding.* Washington, DC: National Academy of Sciences; 2011.
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## V. Definition of Terms

**Serious Mental Illness (SMI):** Based on our previous work , we are defining SMI as (1) schizophrenia or schizoaffective disorder (or other related primary psychotic disorder); (2) bipolar disorder; (3) current major depression; (4) anxiety disorders; (5) eating disorders; or (6) personality disorders, per DSM-IV (*Diagnostic and Statistical Manual of Mental Disorders*, 4th Edition) or their ICD-9-CM (International Classification of Diseases, Ninth Revision,

Clinical Modification) equivalent (and subsequent revisions) that includes functional impairment that substantially interferes with or limits one or more major life activities.

## **VI. Summary of Protocol Amendments**

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

## **VII. Key Informants**

Within the Technical Brief process, KIs 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 crosschecked against available literature and statements from other KIs. Information gained from KI interviews is identified as such in the report. KIs do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

KIs 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 KIs, and those who present with potential conflicts may be retained. The Task Order Officer 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 methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of 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 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 that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators.

## **X. Role of the Funder**

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