HPTN
HIV Prevention
Trials Network

Posttraumatic Stress Disorder (PTSD) Measures Recommendations

HPTN Socio-Behavioral and Structural Working Group

Introduction

The HIV Prevention Trials Network (HPTN) maintains network-wide Scientific Committees and Working Groups to inform the network's ongoing and proposed work in HIV prevention. In the case of the Socio-Behavioral and Structural Working Group (SBSWG), team members focus on identifying key socio-behavioral and structural priorities, questions and methodologies, including recommendations for network-wide use of key measures to capture important socio-behavioral constructs that are commonly evaluated in HPTN studies. The Mental Health Subgroup (MHS) of the SBSWG was formed to aid the larger working group in developing responses to network-wide measurement issues around mental health. With this document, the SBSWG MHS set out to provide recommendations for network-wide use of Posttraumatic Stress Disorder (PTSD) measures in HPTN studies.

Mental Health Assessments in HIV Prevention Trials

Although most HPTN studies utilize some kind of mental health (MH) assessment, many studies include measures of MH without a specific analysis plan and/or use varying measures. Thus, the HPTN could benefit from network-wide guidance on what measures to use for the different MH challenges (potentially) experienced by participants who enroll in HIV prevention trials within the network.

MH challenges both negatively affect the quality of life of study participants and can also impact the success of a prevention trial due to, for example, negatively affecting uptake of biomedical or behavioral interventions, adherence to prevention products, attendance at study visits, and study retention. MH assessments aid investigators and sites in providing an ethical response for individuals in need of MH services and help raise awareness and appropriate action if high rates of MH problems are found. Of note, it is also important to include people with lived experience of mental illness in HIV prevention trials, so that we have a representative population, given the high prevalence of mental illnesses globally. Further, because MH symptoms are associated with reduced use of HIV prevention and treatment products, MH assessments may help investigators better understand lack of uptake or non-adherence. For this and other reasons, assessment of MH can help investigators interpret study results.

Overall Considerations for Recommended Measures for PTSD

PTSD is a frequent and impairing mental health condition that occurs in the context of HIV prevention and treatment. PTSD occurs when an individual has a prolonged reaction to a trauma, such as going through or witnessing a life-threatening event (National Center for PTSD: https://www.ptsd.va.gov/PTSD/understand/what/index.asp).

There are many measures of PTSD and cross-cultural validation has not yet been established for all measures, given the changes in criteria for PTSD from the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM IV) to the current version, DSM 5. The DSM 5 was released in 2013, which

necessitated the development and validation of new PTSD screening assessments; at this point, many of these new screening assessments have not yet been validated in many languages and/or cultures. Partially in an effort to harmonize measures across DAIDS Networks and the International epidemiology Databases to Evaluate AIDS (IeDEA) Network, the SBSWG MHS recommends two measures for measuring PTSD in HPTN trials: **1) the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5); and 2) the PTSD Checklist for DSM-5 (PCL-5).***

Asking about stressful events, whether labeled trauma or not, can trigger reactions for participants and further exploration of these events may exacerbate these reactions. Staff may not feel they have the training to address related mental health concerns of participants. However, with proper training and site standard operating procedures in place, staff would provide referrals for participants to mental health care and other resources available, which are anticipated to be beneficial for participants. Of note, some people will have responses to traumatic stressors which might not meet the formal PTSD diagnosis, but those responses still impact their use of HIV prevention and treatment modalities. In assessing PTSD symptoms, there should be an understanding as to whether individuals consider certain events (e.g., intimate partner violence or IPV) to be traumatic events, depending on frequency, culture, and life situation.

Additionally, if the interview is completed in person, there will be other considerations, such as potential secondary traumatic stress (STS) for staff and consideration of the resources that will be available for staff, if the need arises.

Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)

The PC-PTSD-5 (https://www.ptsd.va.gov/professional/assessment/screens/pc-ptsd.asp; https://www.ptsd.va.gov/professional/assessment/documents/pc-ptsd5-screen.pdf) is a screener designed for use in primary care settings and is comprised of 5 questions. If no symptoms of trauma were experienced throughout an individual's lifetime, they complete the screener with a score of 0. If they have experienced symptoms over the past month, they move on to the other questions in the screener, which screens for probable PTSD (i.e., requires further screening). This screener does not give severity rating but instead offers a "likely PTSD" outcome. The developers added a 5th question to assess guilt, in response to the new diagnostic criteria found in DSM 5. The cut-point for an individual to likely be diagnosed with PTSD is usually a score of 4, but that is flexible, given the population and resources. In some trials, researchers use this screening tool and then administer the 20-item PCL next (see following section), if there is evidence of trauma on this initial screen. The PC-PTSD-5 has been validated in Korean, Chinese, Vietnamese, and potentially other languages.

PTSD Checklist for DSM-5 (PCL-5)

The PCL-5 (https://www.ptsd.va.gov/professional/assessment/adult-sr/ptsd-checklist.asp) is a straightforward 20-item self-report measure that assesses PTSD symptoms according to the DSM 5, is in the public domain, and may be the most widely used PTSD screener within the U.S. Respondents indicate, on a scale of 0-4 (5-point Likert scale: "not at all" to "extremely"), how often they experienced each of the 20 symptoms. PCL-5 scores are not compatible with the PCL for DSM IV scores. Typically, the

scores of the 20 items are summed for a total symptom severity score, although there are alternative ways to score the PCL-5.

The PCL-5 has been validated in the U.S., with additional validation studies in women in Greece, in Dutch, Chinese, Brazil, Portuguese, Kurdish and Arab displaced populations, Bangla, Zimbabwe (population with high HIV prevalence), German, French, and Japanese. It is also the PTSD screener used by the IeDEA Sentinel Research Network. The PCL-5 is found in many formats, including a version *without* a Criterion A component, which formally identifies an event as trauma. We recommend using this version of the PCL-5 (without Criterion A), since some individuals may not perceive or label an event as "trauma", but may still experience PTSD symptoms.

Conclusions

For HPTN trials, the SBSWG MHS recommends use of the PC-PTSD-5 and/or the PCL-5, as described. The biggest difference between the two measures is number of items (5 items vs. 20 items, respectively) and, therefore, length of time to complete the assessment. Both screeners ask about symptoms over the past month, although a past week version of the PCL-5 is also available. The PC-PTSD-5 is sometimes followed by the PCL-5 to gather more information.

The aforementioned are widely recommended measures across broad populations, age groups, geographies; however, depending on the objectives of the study and specifics of the population, there are other measures that could add more information.

Footnote

**Although the CAPS-5 (https://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp) is considered the "gold standard" for PTSD screeners, it is meant to be clinician-administered (para-professionals may administer it, but it requires more clinical judgement than the two screeners we recommend) and it usually takes 45-60 minutes to administer. Due to logistics and variability of administration in a clinical trial setting, often in low- and middle-income countries (LMICs) with few clinicians available and constraints on time, we focus on the PC-PTSD-5 and the PCL-5 in these PTSD Measures Working Recommendations. Researchers should consider differences in use regarding goals for their study - if the intervention is specific to trauma and this is the primary intervention in a trial, the CAPS-5 may be more appropriate.*

This document was drafted in collaboration with the following HPTN Socio-behavioral and Structural Working Group Mental Health Subgroup members (in alphabetical order):

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