

Conditions (List), and research regarding certain health conditions related to the September 11, 2001, terrorist attacks.

Title XXXIII of the PHS Act established the WTC Health Program within the Department of Health and Human Services. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

The Administrator is responsible for the administration of the WTCHP–STAC. CDC and NIOSH provide funding, staffing, and administrative support services for the WTCHP–STAC. The WTCHP–STAC’s charter was reissued on May 12, 2021, and will expire on May 12, 2023. In accordance with 42 U.S.C. 300mm–22(a)(6)(G)(i)(II), the Administrator must ask the WTCHP–STAC to review and evaluate any substantive amendment to any existing WTC Health Program policy or procedure.

Matters To Be Considered: The agenda will include presentations on the state of the WTC Health Program, the Program’s research activities, and uterine cancer coverage. There will be a presentation and discussion about substantive amendments to the existing *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions*. The amendments are intended to clarify the evaluation criteria used to assess the likelihood of a causal association between 9/11-related exposures and a health condition in the 9/11-exposed population. The revision also clarifies the nature of the rationale that provides the basis for the WTCHP–STAC recommendations.

The amended draft *Policy and Procedures for Adding Non-Cancer Health Conditions to the List of WTC-Related Health Conditions* as well as the agenda for this meeting are available on the WTC Health Program website at https://www.cdc.gov/wtc/stac_meeting.html. Agenda items are subject to change as priorities dictate.

Public Participation

Interested parties may participate by submitting written views, opinions,

recommendations, and data. You may submit comments on any topic related to the matters to be discussed by the Committee. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comments by email.

Oral Public Comment: The public is welcome to participate, via Zoom, during the public comment period on February 9, 2023, from 1:30 p.m. to 2:00 p.m. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first-come-first-served basis.

Procedure for Oral Public Comment: Members of the public who wish to address the WTCHP–STAC during the oral public comment session at the February 9, 2023, WTCHP–STAC meeting must sign up to speak by providing their name to Ms. Mia Wallace, Committee Management Specialist, via email at MWallace@cdc.gov, by February 3, 2023. Zoom instructions and participation details will follow.

Written Public Comment: Written comments will also be accepted per the instructions provided in the Addresses section above. Written public comments received prior to the meeting will be part of the official record of the meeting. The docket will close on February 9, 2023.

Policy on Redaction of Committee Meeting Transcripts (Public Comment): Transcripts will be prepared and posted to <https://www.regulations.gov> within 60 days after the meeting. If individuals making a comment give their name, no attempt will be made to redact the name. NIOSH will take reasonable steps to ensure that individuals making public comments are aware that their comments (including their names, if provided) will appear in a transcript of the meeting posted on a public website.

Such reasonable steps include a statement read at the start of the meeting stating that transcripts will be posted, and names of speakers will not be redacted. If individuals in making a statement reveal personal information (e.g., medical information) about themselves, that information will not usually be redacted. The CDC Freedom of Information Act coordinator will, however, review such revelations in accordance with the Freedom of Information Act and, if deemed appropriate, will redact such information. Disclosures of information concerning third party medical information will be redacted.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0053]

The Systematic Review Report for Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS); Notice of Availability

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the availability of the final systematic review report titled “Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS).” The report is accompanied by a summary of public comments.

DATES: The final document is available January 18, 2023.

ADDRESSES: The document may be found in the docket at www.regulations.gov, Docket No. CDC-2021-0053 in the Supporting Materials tab and at <https://www.cdc.gov/me-cfs/programs/evidence-review.html>.

FOR FURTHER INFORMATION CONTACT: Anindita Issa, MD, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H24-12, Atlanta, Georgia 30329; Telephone: 404-718-3959; Email: cfs@cdc.gov.

SUPPLEMENTARY INFORMATION: In 2022, the systematic review titled “Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)” conducted by the Pacific Northwest Evidence-Based Practice Center at Oregon Health and Science University, concluded that there is limited evidence on effective treatments for ME/CFS. The review updates a 2014 Agency for Healthcare Research and Quality (AHRQ)-funded review and its 2016 addendum. It also expands upon the prior AHRQ review by including children as well as adults, evaluating harms as well as benefits of diagnosis, and evaluating effects of treatment on depression, anxiety, sleep quality, pain, and other symptoms associated with ME/CFS in addition to fatigue, function, and quality of life. The report evaluates the quality of the scientific literature and does not make recommendations or guidelines. While improving clinical care remains a critical issue, the lack of sufficient evidence from the review resulted in the decision for CDC not to proceed with developing clinical management guidelines.

On May 17, 2021, CDC published a notice in the **Federal Register** (87 FR 26733) requesting public comment on the draft report of the systematic review for ME/CFS. One hundred and thirty-five commenters provided feedback including those from academia, professional organizations, advocacy groups, and the public. Some of the comments received were from organizations that represented patient advocacy groups. CDC highly values insights gained from these public comments and especially thanks patients living with ME/CFS, who shared their personal experiences in this public forum.

Comments were centered around several themes. All comments were carefully reviewed and considered by CDC. Themes from the comments included (1) concerns with cognitive behavioral therapy and graded exercise therapy; (2) personal testimonials; (3)

inclusion of studies with high risk of bias; (4) exclusion of certain studies on harms evidence; (5) concerns with case definitions and impact on the systematic review; (6) interpretation of results; (7) CDC programmatic concerns and recommendations; and (8) recommended references.

Comments: Concerns with cognitive behavioral therapy (CBT) and graded exercise therapy (GET): Commenters expressed concern with inclusion of the CBT and GET in the systematic review, including personal testimony of harms experienced after attempting treatment with CBT or GET, and critiques of the proposed mechanism (or lack of) of CBT or GET.

Response: CDC acknowledges the concerns that commenters have about the inclusion of CBT and GET in this systematic review. The authors of this systematic review report were aware of the criticisms of CBT and GET as treatments for ME/CFS. The studies for CBT and GET were included in the report because they met the inclusion and exclusion criteria of this systematic review protocol, and the limitations of the evidence on these therapies were described in the report as well. The purpose of this systematic review was to provide a summary of available published literature, including limitations. This systematic review does not make treatment recommendations, and therefore, does not recommend GET or CBT.

Comments: Personal testimonials: These testimonials spoke to the sincere frustration and desperation experienced by many patients with ME/CFS, including difficulty finding providers familiar with ME/CFS, struggles during and after attempted treatment with GET or CBT, and the impact of ME/CFS on their daily lives.

Response: CDC appreciates the patients living with ME/CFS to share their stories and acknowledges the struggles that they face on a daily basis. CDC highly values insights gained from these public comments. Some patients felt that this systematic review was recommending treatment with GET or CBT. However, the purpose of this systematic review was to provide a summary of available published literature, including limitations. This systematic review does not make treatment recommendations, and therefore, does not recommend GET or CBT.

Comments: Inclusion of studies with high risk of bias: Commenters expressing concern that unblinded trials and studies reporting participant-reported outcomes should have been rated high risk of bias or should be

downgraded unless there were other methodological limitations.

Response: CDC recognizes commenters' concerns about such studies. For interventions where blinding is not possible, we followed the standard approach used in many other systematic evidence reviews and downgraded for open-label design, but did not necessarily downgrade to high risk of bias unless there were other methodological limitations.

Comments: Exclusion of certain studies on harms evidence: Commenters suggest that the review missed potentially relevant evidence on harms by excluding observational studies and patient surveys.

Response: CDC understands commenters' concern about exclusion of these studies. We will take them into consideration for future systematic reviews. This review focused on randomized controlled trials (RCT) for evaluation of benefits and harms of treatments because observational studies and non-RCTs are susceptible to bias and confounding, particularly for more subjective outcomes like those evaluated in this report.

Comments: Concerns with case definitions and impact on the systematic review: Some commenters suggested the removal of studies that used older case definitions for the inclusion of this review.

Response: CDC respects the reasons for commenters' concerns with the case definitions used in the report, as many case definitions have emerged over the past several decades. To address the issue of the multitude of case definitions, regrouped analyses were performed for various case definitions.

Comments: Interpretation of results: Commenters questioned the use and interpretation of meta-analysis in the systematic review, due to high heterogeneity, low strength of evidence, and high risk of bias studies.

Response: CDC appreciates commenters' concerns with meta-analysis methodology. In the revision we incorporated some of these comments and added more details to address these concerns. Essentially, the meta-analysis results were restructured for visualization and to facilitate the interpretation of results, thus overcoming this challenge and allowing for useful information to be reviewed.

Comments: CDC programmatic concerns and recommendations: Commenters included requests or recommendations to the CDC ME/CFS program regarding future research and/or guidelines.

Response: CDC appreciates the comments for improving the CDC ME/

CFS program and will address them with leadership during program planning activities.

Comments: Recommended references: Commenters suggested additional information available on websites and in scientific publications.

Response: CDC recognizes the importance of reviewing these suggested references. Each suggested reference was assessed for this current review with pre-established inclusion/exclusion criteria. For future systematic reviews CDC may consider different criteria, which may allow for taking the suggested references into further consideration.

Based on public comments, CDC revised the final report to include (1) information about the decision not to proceed with developing clinical management guidelines; (2) regrouping of plots for the meta-analysis by case definition to facilitate the interpretation of results by various case definitions; (3) regrouping limitations into two major categories (study and clinical trial limitations and limitation in methods used to conduct the review); and (4) adding a description about the importance of collecting common data elements via standardized instruments or other assessment tools. The final report and a thematic summary of responses to public comments can be found in the Supporting Materials tab of the docket and at <https://www.cdc.gov/me-cfs/programs/evidence-review.html>. Although ultimately, at this time, CDC did not find sufficient evidence from the review to proceed with the development of clinical management guidelines for ME/CFS, the review was instrumental in spotlighting the research gaps in the currently available literature, and consequently, possible improvements for future clinical trial design and ways to leverage funding resources for clinical trials.

Dated: January 11, 2023.

Tiffany Brown,

Acting Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-221J]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for

Disease Control and Prevention (CDC) has submitted the information collection request titled "Evaluation of safe spaces in CDC-directly funded community-based organizations (CBOs)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 30, 2022, to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570.

Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Evaluation of Safe Spaces in CDC-directly funded Community-based Organizations (CBOs)—New—National Centers for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC-funded HIV prevention program for young men of Color who have sex with men (YMSM) and young transgender persons (YTG) of Color employs an innovative strategy to address the social determinants of health (e.g., housing, employment) that contribute to health inequities and impact HIV outcomes: safe spaces. Safe spaces are culturally, linguistically, and age-appropriate physical spaces for engaging people who are at increased risk for HIV and providing HIV prevention and care activities. Under this program, funded community-based organizations (CBOs) must address at least two social determinants of health within their safe spaces. CBOs will employ a community-driven approach and work with people who are at increased risk for HIV to select social determinants of health with the most potential to reduce barriers to accessing HIV prevention and care services and promote health equity.

The purpose of this data collection is to assess the implementation of safe spaces, participant perceptions about the role of space spaces in addressing social determinants of health and promoting HIV prevention and care, and the association between safe space implementation and HIV process and outcome indicators. The primary objectives of this data collection are to obtain data to: (a) describe the implementation of safe spaces; (b) to describe the impact on participants served; and (c) identify successful models for safe spaces to inform other CBOs and CDC.

By describing safe spaces and their impact on HIV-related outcomes, this data collection provides an important data source for evaluating a public health strategy aimed at reducing new infections, increasing HIV testing, and prioritizing populations at high risk for acquiring HIV.

CDC requests approval for a two-year information collection. Data are collected through surveys with participants of the safe spaces and phone-based interviews conducted with safe space staff. Persons attending the safe spaces are young men who have sex with men and young transgender persons of Color over the age of 18. A