

## PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
	<ul style="list-style-type: none"> <li>○ Diagnosis of PANS/PANDAS.</li> <li>○ OCD in first degree relatives.</li> <li>○ Level of family accommodation.</li> <li>○ Co-occurring disorders (e.g., major depressive disorder, anxiety disorders, attention-deficit hyperactivity disorder, conduct disorders, autism spectrum disorder, and Tourette syndrome, other tic disorders).</li> <li>○ Diagnosis during COVID-19 pandemic (as defined by study authors).</li> <li>○ Primary versus specialist care.</li> </ul> <ul style="list-style-type: none"> <li>● Respondent type.</li> </ul> <p><i>Exclude:</i></p> <ul style="list-style-type: none"> <li>● Neuroimaging, e.g., functional MRI.</li> </ul>	<ul style="list-style-type: none"> <li>○ Diagnosis of PANS/PANDAS.</li> <li>○ OCD in first degree relatives.</li> <li>○ Level of family accommodation.</li> <li>○ Co-occurring disorders (e.g., major depressive disorder, anxiety disorders, attention-deficit hyperactivity disorder, conduct disorders, autism spectrum disorder, and Tourette syndrome, other tic disorders).</li> <li>○ Diagnosis during COVID-19 pandemic (as defined by study authors).</li> <li>○ Duration of symptoms prior to treatment.</li> <li>○ Symptom severity.</li> <li>○ In-session exposure and response prevention.</li> <li>○ Medication dose.</li> <li>○ Care settings and care intensities. <ul style="list-style-type: none"> <li>■ Traditional outpatient.</li> <li>■ Intensive outpatient. <ul style="list-style-type: none"> <li>● Day programs (e.g., partial hospitalization).</li> <li>● Residential.</li> </ul> </li> <li>■ Inpatient.</li> <li>■ Other care settings, including school-based settings.</li> <li>■ Telehealth (vs. in-person).</li> <li>■ Primary versus specialist care.</li> </ul> </li> </ul>
Design .....	<p>Cohort or cross-sectional studies:</p> <ul style="list-style-type: none"> <li>● comparing an index test(s) to a reference standard.</li> <li>● comparing an index test(s) in two or more subgroups of interest.</li> <li>● comparing two or more diagnostic strategies.</li> </ul> <p>Randomized controlled trials.</p> <p>Nonrandomized comparative studies:</p> <ul style="list-style-type: none"> <li>● prospective or retrospective with appropriate adjustment for confounding.</li> </ul> <p>Systematic reviews (for reference lists only).</p> <p><i>Exclude:</i></p> <ul style="list-style-type: none"> <li>● Prevalence studies.</li> <li>● Qualitative studies.</li> <li>● Case reports and case series.</li> <li>● Unpublished studies, including conference abstracts (but include studies with reported results in the <i>ClinicalTrials.gov</i> database).</li> </ul>	<p>Comparative trials:</p> <ul style="list-style-type: none"> <li>● Randomized controlled trials.</li> <li>● Nonrandomized comparative studies. <ul style="list-style-type: none"> <li>○ prospective or retrospective with appropriate adjustment for confounding.</li> </ul> </li> </ul> <p>Single arm studies, N ≥ 50:</p> <ul style="list-style-type: none"> <li>● with multivariable analyses of potential effect modifiers/subgroups of interest.</li> </ul> <p>Systematic reviews (for reference lists only).</p> <p><i>Exclude:</i></p> <ul style="list-style-type: none"> <li>● Cross-sectional studies (no longitudinal follow-up).</li> <li>● Qualitative studies.</li> <li>● Case reports and case series.</li> <li>● Unpublished studies, including conference abstracts (but include studies with reported results in the <i>ClinicalTrials.gov</i> database).</li> </ul>
Timing .....	Any.	Any.
Setting .....	Any, including administration of test(s) in-person or via telehealth.	Any.

\* Prioritized outcome.

Dated: August 21, 2023.

**Marquita Cullom,**  
Associate Director.

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES****Centers for Disease Control and  
Prevention****Clinical Laboratory Improvement  
Advisory Committee****AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).**ACTION:** Notice of meeting.**SUMMARY:** In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC). This is a hybrid meeting, accessible both in

person and virtually. It is open to the public, limited only by the in-person space available. The public is also welcome to view the meeting by joining the audio conference (information below). Time will be available for public comment, and the public is also welcome to submit written comments in advance of the meeting (see the public participation section below).

**DATES:** The meeting will be held on November 8, 2023, from 8:30 a.m. to 5:30 p.m., EST, and November 9, 2023, from 8:30 a.m. to 12 p.m., EST.**ADDRESSES:** Centers for Disease Control and Prevention, 2400 Century Parkway NE, Room 1020/1023, Atlanta, Georgia 30345. The conference room will have seating for approximately 60 people.**Meeting Information:** All people attending the CLIAC meeting in person are required to register online for the meeting at least five business days in advance for U.S. citizens and at least 20 business days in advance for international registrants. Register at: [https://www.cdc.gov/cliac/upcoming-](https://www.cdc.gov/cliac/upcoming-meeting.html)

[meeting.html](https://www.cdc.gov/cliac/upcoming-meeting.html). Register by scrolling down and clicking the “Register for this Meeting” button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than November 1, 2023, for U.S. registrants and October 11, 2023, for international registrants. The confirmed meeting times, agenda items, and meeting materials, including instructions for accessing the live meeting broadcast, will be available on the CLIAC website at <https://www.cdc.gov/cliac/upcoming-meeting.html>.

**FOR FURTHER INFORMATION CONTACT:** Heather Stang, MS, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Office of Laboratory Science and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4027. Telephone: (404) 498-2769; Email: [HStang@cdc.gov](mailto:HStang@cdc.gov).**SUPPLEMENTARY INFORMATION:**

**Purpose:** The Clinical Laboratory Improvement Advisory Committee (CLIAC) is charged with providing scientific and technical advice and guidance to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention (CDC); the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare & Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve quality, safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

**Matters To Be Considered:** The agenda will include agency updates from CDC, CMS, and FDA. Presentations and CLIAC discussions will focus on the final report from the CLIA Regulations Assessment Workgroup, efforts to address the CLIA top 10 laboratory deficiencies, standardization of test result communication, and the role of the laboratory in antibiotic stewardship. Agenda items are subject to change as priorities dictate.

### Public Participation

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items.

**Oral Public Comment:** Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov) or notify the contact person above (see **FOR FURTHER INFORMATION CONTACT**) at least five business days prior to the meeting date.

**Written Public Comment:** CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments should be submitted by email to [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov) or to the contact person above. All written comments will be included in the meeting minutes posted on the CLIAC website.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, 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

#### Solicitation of Nominations for Appointment to the Lead Exposure and Prevention Advisory Committee

**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), within the Department of Health and Human Services (HHS), is soliciting nominations for membership on the Lead Exposure and Prevention Advisory Committee (LEPAC). The LEPAC is composed of 15 members that are Federal and non-Federal experts in fields associated with lead screening, the prevention of lead exposure, and services for individuals and communities affected by lead exposure.

**DATES:** Nominations for membership on the LEPAC must be received no later than September 30, 2023. Packages received after this time will not be considered for the current membership cycle.

**ADDRESSES:** All nominations should be emailed to [LEPAC@cdc.gov](mailto:LEPAC@cdc.gov).

**FOR FURTHER INFORMATION CONTACT:** Paul Allwood, Ph.D., M.P.H., Designated Federal Officer, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, Atlanta, Georgia 30341. Telephone: 770-488-6774; Email: [PAllwood@cdc.gov](mailto:PAllwood@cdc.gov).

#### SUPPLEMENTARY INFORMATION:

Nominations are being sought for individuals with expertise in the fields of epidemiology, toxicology, mental health, pediatrics, early childhood education, special education, diet and nutrition, and environmental health. Members may be invited to serve for three-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of Lead Exposure and Prevention Advisory Committee (LEPAC) objectives.

The members of this Committee are selected by the Secretary of the Department of Health and Human Services (HHS). The committee's objective is to advise the Secretary, HHS and the Director, Centers for Disease Control and Prevention (CDC)/ Administrator, Agency for Toxic Substances and Disease Registry on a range of activities to include: (1) review of Federal programs and services available to individuals and communities exposed to lead; (2) review of the current research on lead exposure to identify additional research needs; (3) review of and identification of best practices, or the need for best practices regarding lead screening and the prevention of lead exposure; (4) identification of effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Public Law 114-322 section 2203(b) (42 U.S.C. 300j-27); and (5) undertaking of any other review or activities that the Secretary determines to be appropriate.

Annually as determined necessary by the Secretary or as required by Congress, the committee shall submit a report to include: (1) an evaluation of the effectiveness of the Federal programs and services available to individuals and communities exposed to lead; (2) an evaluation of additional lead exposure research needs; (3) an assessment of any effective screening methods or best practices used or developed to prevent or screen for lead exposure; (4) input and recommendations for improved access to effective services relating to health care, education, or nutrition for