DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) announces a Special Emphasis Panel (SEP) meeting on ''Consumer Assessment of Healthcare Providers and Systems (CAHPS) VI (U18)''. This SEP meeting will be closed to the public.

DATES: July 22, 2022.

ADDRESSES: Agency for Healthcare Research and Quality, (Video Assisted Review), 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Jenny Griffith, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, Agency for Healthcare Research and Quality, (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 427–1557.

SUPPLEMENTARY INFORMATION: A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by AHRQ, and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

The SEP meeting referenced above will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2, section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). Grant applications for ''Consumer Assessment of Healthcare Providers and Systems (CAHPS) VI (U18)'' are to be reviewed and discussed at this meeting. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Agenda items for this meeting are subject to change as priorities dictate.

Dated: July 11, 2022.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on ADHD Diagnosis and Treatment in Children and Adolescents

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *ADHD Diagnosis and Treatment in Children and Adolescents,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before August 15, 2022.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Center (EPC) Program to complete a review of the evidence for *ADHD Diagnosis and Treatment in Children and Adolescents.* AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on ADHD Diagnosis and Treatment in Children and Adolescents, including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/attention-deficit-hyperactivity-disorder/protocol.*

This is to notify the public that the EPC Program would find the following information on ADHD Diagnosis and Treatment in Children and Adolescents helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov* along with the *ClinicalTrials.gov* trial number.
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ1: For the diagnosis of ADHD:

- What is the comparative diagnostic accuracy of approaches that can be used in the primary care practice setting or by specialists to diagnose ADHD among individuals younger than 7 years of age?
- What is the comparative diagnostic accuracy of EEG, imaging, or approaches assessing executive function that can be used in the primary care practice setting or by specialists to diagnose ADHD among individuals aged 7 through 17?
- For both populations, how does the comparative diagnostic accuracy of these approaches vary by clinical setting, including primary care or specialty clinic, or patient subgroup, including age, sex, or other risk factors associated with ADHD?
- What are the adverse effects associated with being labeled correctly or incorrectly as having ADHD?

KQ2: What are the comparative safety and effectiveness of pharmacologic and/or nonpharmacologic treatments of ADHD in improving outcomes associated with ADHD?

- How do these outcomes vary by presentation (inattentive, hyperactive/impulsive, and combined) or other comorbid conditions?
- What is the risk of diversion of pharmacologic treatment?

KQ 3: What are the comparative safety and effectiveness of different empirical monitoring strategies to evaluate the effectiveness of treatment in improving ADHD symptoms or other long-term outcomes?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

PICOTS element	Inclusion criteria	Exclusion criteria
Population	*KQ 1* (diagnosis): Individuals birth through 17 years of age without the diagnosis of ADHD. *KQ 2* (treatment): Individuals birth through 17 years of age with a diagnosis of ADHD. *KQ 3* (monitoring): Individuals birth through 17 years of age who have previously begun treatment for ADHD.	*KQ 1, KQ 2:* Individuals 18 years of age or older unless findings are reported separately for individuals 18 years and under, or if the mean patient age plus the standard deviation is not greater than 21 years of age. *KQ 3:* For long-term studies, the age of the individuals may be greater than 17, but these studies are only considered for inclusion if the age at enrollment in the study was 18 years or younger, and administrative claims data used for diagnosis of ADHD.
Interventions	*KQ 1* (diagnosis): Any standard ADHD diagnostic strategy, including clinician interview, standardized instrument (*e.g.,* Vanderbilt scales, Conner scales, SNAP–IV rating score), neuropsychological test measures (*e.g.,* working memory, processing speed, continuous performance tasks) for individuals under 7 years of age. The use of EEG-based systems, imaging, or assessment of executive function for the diagnosis of ADHD in individuals through 17 years. *KQ 2* (treatment): Any pharmacologic or nonpharmacologic treatment of ADHD, alone or in combination: • Pharmacologic treatments considered are brand name and generic formulations of FDA-approved stimulants (methylphenidate, amphetamine) and nonstimulants (norepinephrine reuptake inhibitors, alpha agonists) and other suggested treatments, including methylphenidate, dexmethylphenidate, dextroamphetamine, lisdexamfetamine, mixed amphetamine salts, amphetamine, tricyclic antidepressants, desipramine, nortriptyline, selective norepinephrine reuptake inhibitors, atomoxetine, alpha-2 agonists, clonidine, guanfacine, dopamine reuptake inhibitors, modafinil, armodafinil, norepinephrine-dopamine reuptake inhibitors, bupropion, serotonin-norepinephrine reuptake inhibitors, duloxetine, serotonin-norepinephrine-dopamine reuptake inhibitors, venlafaxine, monoamine oxidase type B inhibitors, selegiline, N-methyl-D-aspartate receptor antagonists, amantadine, memantine.	*KQ 1:* Validation studies or diagnosis conducted using a non-validated instrument. *KQ 2:* Studies comparing pharmacologic agents approved by the FDA for the treatment of ADHD that have enrollment of fewer than 100 patients with ADHD, or less than 6 months of follow-up.

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

PICOTS element	Inclusion criteria	Exclusion criteria
	• Nonpharmacologic therapies considered include psychosocial interventions, behavioral interventions, cognitive behavioral therapy, digital gamified cognitive therapies, EndeavorRx, play therapy, play-based interventions, mindfulness-based therapies, school interventions, cognitive training therapies, biofeedback or neurofeedback, parent behavior training, dietary supplements (*e.g.,* omega-3 fatty acids, vitamins, herbal supplements, probiotics), homeopathy, acupuncture, elimination diets, vision training, exercise, chiropractic treatment, peer interventions, and Monarch external trigeminal nerve stimulation (eTNS) system. *KQ 3* (monitoring): Follow-up visits in primary care using various methods and frequencies (monthly to annually) for monitoring, independent of treatment, including the selection of scales/validated tools for monitoring of ADHD severity and treatment response along with forms of remote monitoring or telehealth strategies.	
Comparators	*KQ 1* (diagnosis): Confirmation of diagnosis by a specialist (gold standard), such as a psychologist, psychiatrist or other care provider using a well-validated and reliable process of confirming the diagnosis of ADHD according to the DSM–5. *KQ 2* (treatment): Specific treatments compared with other treatments as described above or to no treatment. *KQ 3* (monitoring): Follow-up compared with differing frequencies of follow-up or different settings of follow-up for monitoring strategies; no restrictions for long-term outcomes.	*KQ 1:* Comparison to diagnosis with a non-validated instrument. *KQ 2:* Comparisons to other patient groups rather than treatments.
Outcomes	*KQ 1* (diagnosis): • Accuracy of diagnostic strategy, as measured by: diagnostic concordance of primary care provider with specialist, inter-rater reliability, internal consistency, test-retest, sensitivity, specificity, area under the curve, positive predictive value, negative predictive value, false positives, false negatives. • Risk of misdiagnosis, missed condition that can appear as ADHD Labeling is any measure of stigma following diagnosis comparing those with and without ADHD. • Costs. *KQ 2* (treatment): • Intermediate outcomes: ○ Changes on standardized symptom scores, including narrow-band focused instruments (Vanderbilt rating scales, ADHD Rating Scales such as the Strength and Weaknesses of Attention-Deficit/Hyperactivity Disorder Symptoms [SWAN]) and broad-band scales (Child Behavior Checklist and Teacher Report Form, Behavior Assessment System for Children, Conners' Rating Scales-Revised, Conners' 3 Parent, Conners' 3 Teacher). ○ Progress toward patient-identified goals. ○ Executive functioning measure changes. ○ Functional impairment (assessed using the Clinical Global Impressions [CGI] scale of the Impairment Rating Scale [IRS]). ○ Acceptability of treatment. • Final outcomes: ○ Academic performance (Academic Performance Rating Scale Academic Competency Evaluation Scale (ACES), school grades, grade retention/not being promoted, Vanderbilt Teacher Form Academic Performance Subscale, standardized achievement tests (WIAT, WJ, WRAT).	

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

PICOTS element	Inclusion criteria	Exclusion criteria
	○ Workforce participation, quality of peer relationships, divorce/relationship status, motor vehicle collisions or other accidents, motor vehicle violations, risk-taking behaviors, incarceration or other interactions with the legal system (juvenile detention, probation, court-mandated interventions, need for residential placement). ○ Obesity, tobacco use, substance abuse, mood disorders, depression or anxiety, self-injurious non-suicidal behavior, suicide (attempted or completed), suicidal ideation, mortality. ○ Potential adverse effects of treatment, including changes in appetite, growth suppression, weight decrease, sleep disturbance, gastrointestinal symptoms, elevated blood pressure, increased heart rate, risk of sudden cardiac death, cardiac arrhythmias, conduction abnormalities, chemical leukoderma; priapism, tics or other movement disorders, hallucination, aggression, behavior changes, personality change, loss of spontaneity, number of adverse events. ○ Overtreatment, diversion and misuse of pharmacotherapy, parental stress, time demands/opportunity cost. *KQ 3* (monitoring): • Changes in treatment or dose. • Adverse effects of treatment. • Changes in intermediate and final outcomes.	
Timing	*KQ 1* (diagnosis): • For assessment of diagnostic accuracy: diagnostic follow-up must be within 4 months of the initial evaluation and must be completed before treatment is initiated. • For labeling: any time after the ADHD diagnosis. *KQ 2* (treatment) and *KQ 3* (monitoring): Any.	
Setting	*KQ 1* (diagnosis): Primary or specialty care settings. *KQ 2* (treatment) and *KQ 3* (monitoring): Any (including remote monitoring and telehealth).	
Study Design	• Original data. *KQ 1–3:* Randomized controlled trials (RCTs). *KQ 1* (diagnosis): For diagnostic accuracy, observational studies, including cross-sectional studies, are eligible if they include patients with diagnostic uncertainty and direct comparison of diagnosis in primary care to diagnosis by a specialist. *KQ 1* (diagnosis) and *KQ 2* (treatment): controlled clinical trials and prospective and retrospective observational studies with comparator; sample size: • ≥20 participants. • ≥100 participants for studies comparing two or more pharmacologic treatments. *KQ 3* (monitoring): no study size restriction.	Editorials, nonsystematic reviews, letters, case series, case reports, abstract-only, pre-post studies. Because studies with fewer than 20 subjects are often pilot studies or studies of lower quality, these are excluded. Given the research volume on pharmacologic treatment the sample size limit for non-RCTs is 100 participants, representing population study sizes that could substantially impact the assessment of the existing evidence base. Systematic reviews are not eligible for inclusion but will be retained.
Other limiters	• English-language publications. • *KQ 1* and *KQ 2:* Published in or after 2016 and not included in the prior AHRQ report on ADHD; in addition, we will use studies included in meta-analyses in the prior report for cumulative meta-analyses. • *KQ 3:* Monitoring strategies and long-term effects have no publication year restriction. • Journal manuscripts and trial record data with results.	Non-English language and abbreviated publications (abstracts, letters).

Note: FDA: Food and Drug Administration, KQ: Key Question.

Dated: July 11, 2022.

Marquita Cullom,

Associate Director.

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