EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Qualitative semi-structured interviews with AIM Team Leads	8	8	$49.83	$398.64
Qualitative semi-structured interviews with frontline staff	32	16	49.83	797.28
Focus group discussions with AIM Team Leads and frontline staff	40	40	49.83	1,993.20
Total	80	64		$3,189.12

* National Compensation Survey: Occupational wages in the United States May 2017 "U.S. Department of Labor, Bureau of Labor Statistics." Weighted mean hourly wage for obstetrician-gynecologists ($113.10; occupation code 29–1064; 30%); nurse-midwives ($49.83; occupation code 29–1161; 30%); registered nurses ($35.36; occupation code 29–1161; 20%); and nurse practitioners ($51.86; occupation code 29–1171; 20%).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 1, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–04502 Filed 3–4–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Management of Infantile Epilepsy

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 *Management of Infantile Epilepsy,* 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 April 5, 2021.

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 Centers (EPC) Program to complete a review of the evidence for *Management of Infantile Epilepsy.* 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 *Management of Infantile Epilepsy,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/management-infantile-epilepsy/research-protocol.*

This is to notify the public that the EPC Program would find the following information on *Management of Infantile Epilepsy* 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 and Contextual Questions

Key Question 1. What is the effectiveness and comparative effectiveness of pharmacologic treatments for infantile epilepsy (infants age 1 month to <3 years)?

Key Question 2. What is the effectiveness and comparative effectiveness of non-pharmacologic treatments for infantile epilepsy (*e.g.,* dietary therapies, surgery, and brain stimulation therapies), including comparisons to other non-pharmacologic and/or pharmacologic therapies?

Key Question 3. What are the harms or comparative harms of treatments for infantile epilepsy?

Contextual Question 1. What are the parental preferences for treatment options for infantile epilepsy?

Contextual Question 2. What are the harms or comparative harms of not treating infantile epilepsy?

PICOTS

[Population, intervention, comparator, outcome, timing, setting]

	Inclusion	Exclusion
Population	• Infants (1 month to <3 years) diagnosed with epilepsy • Subpopulations based on baseline seizure severity/frequency, history of previous treatment, length of gestation.	• West syndrome/infantile spasms. • Non-epileptic seizures. • Provoked seizures, including febrile seizures. • Metabolic epilepsies. • Status epilepticus. • Acute symptomatic seizures.
Intervention	• KQ 1, 3: Pharmacologic interventions • KQ 2, 3: Non-pharmacologic intervention: dietary therapies, surgery, brain stimulation, and gene therapy.	• Diagnostic research. • Provider/organization level interventions such as awareness campaigns. • Metabolic therapies. • Vitamin therapies. • Social and community services.
Comparator	• KQ1: Other pharmacologic interventions or usual care. • KQ2: Other pharmacologic or non-pharmacologic interventions or usual care. • KQ3: Inclusive of comparators for KQ1&2.	
Outcomes	• All-cause mortality. • SUDEP. • Hospitalization. • Seizure freedom. • Seizure frequency. • Seizure severity (including seizure duration, seizure burden, and status epilepticus). • Engel classification. • Progression to other seizure types or syndromes (*e.g.,* infantile spasms, Lennox-Gastaut Syndrome). • Time to seizure remission. • Neurodevelopment. • Quality of life (including eating). • Sleep outcomes (*e.g.,* total time spent asleep at night). • Behavioral function. • Cognitive function. • Functional performance (including school). • Social function. • Caregiver anxiety. • Caregiver quality of life. • General health status. • Cost of treatment. • Adverse events (infection, new neurological deficits, surgical complications, irritability, somnolence, dizziness, drug toxicity, etc.).	
Timing	Effectiveness: 12 week minimum follow-up. Harms: No minimum follow-up.	
Setting	Setting not limited.	

Dated: March 1, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–04538 Filed 3–4–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Information on the Use of Clinical Algorithms That Have the Potential To Introduce Racial/Ethnic Bias Into Healthcare Delivery

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

ACTION: Notice of Request for Information.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking information from the public on clinical algorithms that are used or recommended in medical practice and any evidence on clinical algorithms that may introduce bias into clinical decision- making and/or influence access to care, quality of care, or health outcomes for racial and ethnic minorities and those who are socioeconomically disadvantaged.

DATES: Comments must be submitted on or before May 4, 2021. The EPC Program will not respond individually to responders but will consider all comments submitted by the deadline.

ADDRESSES: Submissions should follow the Submission Instructions below. We prefer that comments be submitted electronically on the submission website. Email submissions may also be sent to: *epc@ahrq.gov*

FOR FURTHER INFORMATION CONTACT: Anjali Jain, Email: *Anjali.Jain@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality (AHRQ) is seeking information from the public on clinical algorithms that are used or recommended in medical practice and any evidence on clinical algorithms that may introduce bias into clinical decision-making and/or influence access to care, quality of care, or health outcomes for racial and ethnic minorities and those who are socioeconomically disadvantaged.

Information received in response to this request will be used to inform an AHRQ Evidence-Based Practice Center Program (EPC) evidence review and may inform other activities commissioned by or in collaboration with AHRQ. Established in 1997, the mission of the EPC Program (*https://effectivehealthcare.ahrq.gov/about/epc*) is to create evidence reviews that improve healthcare by supporting evidence-based decision-making by patients, providers, and policymakers. Evidence reviews summarize and synthesize existing literature and evidence using rigorous methods. AHRQ is conducting this review pursuant to sections 902 and 901(c) of the Public Health Service Act, 42 U.S.C. 299a and 42 U.S.C. 299(c).

AHRQ intends to commission an evidence review that will critically appraise the evidence on commonly used algorithms, including whether race/ethnicity is included as an explicit variable, and how algorithms have been developed and validated. The review would examine how race/ethnicity and related variables included in clinical algorithms impact healthcare use, patient outcomes and healthcare disparities. In addition, the review will identify and assess other variables with the potential to introduce bias such as prior utilization. The review will identify and review approaches to clinical algorithm development that avoid the introduction of racial and ethnic bias into clinical decision making and resulting outcomes.

For the purposes of this evidence review, clinical algorithms are defined as a set of steps that clinicians use to guide decision-making in preventive services (such as screening), in diagnosis, clinical management, or otherwise assessing or improving a patient's health. Algorithms are informed by data and research evidence and may include patient-specific factors or characteristics which may be sociodemographic factors such as race/ethnicity, physiologic factors such as, for example, blood sugar level, or others such as patterns of healthcare utilization.

When used appropriately, algorithms can improve disease management and patient health by creating efficiencies in place of individuals having to weigh multiple and complex factors when making a clinical judgement. As a result, the use of clinical algorithms has become widespread in healthcare and includes a heterogeneous set of tools including clinical pathways/guidelines, the establishment of norms and standards that may vary according to patient-specific factors, clinical decision support embedded in electronic health records (EHRs) or within medical devices, pattern recognition software used for diagnosis, and apps and calculators that predict patient risk and prognosis. Some clinical algorithms include information about a patient's race or ethnicity among its inputs and thus lead clinicians to decision-making that varies by race/ethnicity, including decisions about how best to diagnose and manage individual patients.

The purpose of this evidence review is to understand which algorithms are currently used in different clinical settings; the type and extent of their validation; their potential for bias with impact on access, quality, and outcomes of care; awareness among clinicians of these issues; and strategies for developing and testing clinical algorithms to assure that they are free of bias in order to inform the scope of a future evidence review. We are interested in understanding which algorithms are currently in use in clinical practice including those related to the use of clinical preventive services. How many include race/ethnicity and other factors that could lead to bias within the algorithm? We are interested in all algorithms including clinical pathways/guidelines, norms and standards (including laboratory values) that vary according to patient-specific factors such as race/ethnicity and related variables, clinical decision support embedded in EHRs, pattern recognition software, and apps and calculators for patient risk and prognosis. We are interested both in algorithms developed through traditional methods and through new and ongoing methods including machine learning and artificial intelligence. AHRQ seeks information

- From healthcare providers who use clinical algorithms to screen, diagnose, triage, treat or otherwise care for patients
- From laboratorians or technicians who use algorithms to interpret lab or radiology data
- From researchers and clinical decision support developers who develop algorithms used in healthcare for patients
- From clinical professional societies or other groups who develop clinical algorithms for healthcare
- From payers who use clinical algorithms to guide payment decisions for care for patients
- From healthcare delivery organizations who use clinical algorithms to determine healthcare practices and policies for patients
- From device developers who incorporate algorithms into device software to interpret data and set standards
- From patients whose healthcare and healthcare decisions may be informed by clinical algorithms