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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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

*E-mail 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 e-mail 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<br>• Subpopulations based on baseline seizure severity/frequency, history of previous treatment, length of gestation | • West syndrome/infantile spasms<br>• Non-epileptic seizures<br>• Provoked seizures, including febrile seizures<br>• Metabolic epilepsies<br>• Status epilepticus<br>• Acute symptomatic seizures |
| **Intervention** | • KQ 1, 3: Pharmacologic interventions<br>• KQ 2, 3: Non-pharmacologic intervention: dietary therapies, surgery, brain stimulation, and gene therapy | • Diagnostic research<br>• Provider/organization level interventions such as awareness campaigns<br>• Metabolic therapies<br>• Vitamin therapies<br>• Social and community services |
| **Comparator** | • KQ1: Other pharmacologic interventions or usual care<br>• KQ2: Other pharmacologic or non-pharmacologic interventions or usual care<br>• KQ3: Inclusive of comparators for KQ1&2 | |
| **Outcomes** | • All-cause mortality<br>• SUDEP<br>• Hospitalization<br>• Seizure freedom<br>• Seizure frequency<br>• Seizure severity (including seizure duration, seizure burden, and status epilepticus)<br>• Engel classification<br>• Progression to other seizure types or syndromes (e.g., infantile spasms, Lennox-Gastaut Syndrome)<br>• Time to seizure remission<br>• Neurodevelopment<br>• Quality of life (including eating)<br>• Sleep outcomes (e.g., total time spent asleep at night)<br>• Behavioral function<br>• Cognitive function<br>• Functional performance (including school)<br>• Social function<br>• Caregiver anxiety<br>• Caregiver quality of life<br>• General health status<br>• Cost of treatment | |

| | Inclusion | Exclusion |
|---|---|---|
| | • Adverse events (infection, new neurological deficits, surgical complications, irritability, somnolence, dizziness, drug toxicity, etc.) | |
| **Timing** | Effectiveness: 12 week minimum follow-up<br>Harms: No minimum follow-up | |
| **Setting** | Setting not limited | |

Dated: March 1, 2021.

**Marquita Cullom,**

*Associate Director.*

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