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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review

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 of *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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.):
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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 *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review*, including those that describe adverse events. The

entire research protocol, including the key questions, is also available online at: https://effectivehealthcare.ahrq.gov/topics/antipsychotics/research-protocol.

This is to notify the public that the EPC Program would find the following information on *Antipsychotics for the Prevention and Treatment of Delirium: A Systematic Review* 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*, please provide 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 will be very beneficial to the EPC 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.

The Key Questions

I. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to prevent delirium?

   A. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **prevent** delirium in **persons aged 65 years or older**?

   B. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **prevent** delirium in **persons with dementia**?

   C. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **prevent** delirium in **patients in an intensive care unit**?

   D. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **prevent** delirium in **patients in a post-acute care facility**?

   E. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **prevent** delirium in **patients in palliative or hospice care**?

   F. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **prevent** delirium in **patients in post-operative care**?

II. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to treat delirium?

A. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **treat** delirium in **persons aged 65 years or older**?

B. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **treat** delirium in **persons with dementia**?

C. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **treat** delirium in **patients in an intensive care unit**?

D. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **treat** delirium in **patients in a post-acute care facility**?

E. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **treat** delirium in p**atients in palliative or hospice care**?

F. What are the benefits and harms for antipsychotics compared to each other, placebo, or non-drug approaches to **treat** delirium in **patients in post-operative care**?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s):

I. KQ 1: Hospitalized adults, adults in post-acute care, adults in palliative or hospice care, or adults in post-operative care

II. KQ 2: Hospitalized adults , adults in post-acute care, adults in palliative or hospice care, or adults in post-operative care who have been diagnosed with delirium using a validated instrument

Interventions:

I. Antipsychotic drugs, including

   A. Any first-generation agent (chlorpromazine, droperidol, fluphenazine, haloperidol, loxapine, molindone, perphenazine, pimozide, prochlorperazine, thiothixene, thioridazine, trifluoperazine)

   B. Any second-generation agent (aripiprazole, asenapine, brexpiprazole, cariprazine, clozapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone)

II. We will only include studies where the effects of the antipsychotic drugs can be isolated.

Comparators

I. KQ 1: Non-drug approaches to preventing delirium, placebo, active control, usual care

II. KQ 2: Non-drug approaches to treating delirium, placebo, active control, usual care

Outcomes:

I. Intermediate outcomes

   A. Short-term delirium symptoms

   B. Delirium severity

   C. Delirium-free, coma-free days alive

   D. Duration of delirium

   E. Patient distress

   F. Use of rescue therapy

   G. Use of physical restraint

II. Final health or patient-centered outcomes

   A. Mortality

   B. Quality of life

   C. Cognitive and emotional functioning (includes functioning related to memory, communication, concentration, and understanding instructions)

   D. Long-term cognitive impairment (Change in cognition after delirium that has a long-term duration or is possibly permanent)

   E. Institutionalization (living in an assisted living facility or nursing home)

   F. Caregiver burden/strain

   G. Falls

   H. Memory of patient distress

III. Resource utilization

   A. Re-admissions to hospital or ICU

   B. Length of stay in ICU

   C. Length of stay in hospital

   D. Length of stay in skilled nursing facility

   E. Sitter use

F. Hospice enrollment

IV. Adverse effects of intervention(s)

A. Sedation

B. Weight gain

C. Changes in appetite

D. Cardiac effects

E. Neurologic effects

F. Paradoxical reactions

G. Hypersensitivity reactions

H. Inappropriate continuation of antipsychotic medication

I. Swallowing difficulties

J. Aspiration pneumonia

III. Timing:

A. Any duration of follow-up

IV. Settings:

A. Hospital setting

B. Post-acute care setting

C. Palliative care setting

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