

INCLUSION AND EXCLUSION CRITERIA BY POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN (PICOTS)—Continued

PICOTS elements	Inclusion criteria	Exclusion criteria
Timing .....	<ul style="list-style-type: none"> <li>Type 2 diabetes .....</li> <li>Minimum intervention length of 12 weeks Effect on growth, size, and body composition.                             <ul style="list-style-type: none"> <li>Minimum intervention length of 12 weeks.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Any intervention length &lt;12 weeks.</li> </ul>
Settings .....	<ul style="list-style-type: none"> <li>All except hospital and acute care .....</li> </ul>	<ul style="list-style-type: none"> <li>Hospital and acute care.</li> </ul>
Study design .....	<ul style="list-style-type: none"> <li>Randomized controlled trials .....</li> <li>Nonrandomized controlled trials, including quasi-experimental and controlled before-and-after studies.</li> <li>Prospective cohort studies .....</li> <li>Nested case-control studies .....</li> <li>Relevant systematic reviews, or meta-analyses (used for identifying additional studies).</li> </ul>	<ul style="list-style-type: none"> <li>In vitro studies, nonoriginal data (e.g., narrative reviews, scoping reviews, editorials, letters, or erratum), retrospective cohort studies, case series, qualitative studies, cost-benefit analysis, cross-sectional (i.e., nonlongitudinal) studies, survey.</li> </ul>
Publications .....	<ul style="list-style-type: none"> <li>Studies published in English only .....</li> <li>Studies published in peer-reviewed journals .....</li> <li>Studies published at and after the year 2000 ..</li> </ul>	<ul style="list-style-type: none"> <li>Non-English language studies.</li> </ul>

Abbreviations: BMI = body mass index; HbA<sub>1c</sub> = hemoglobin A<sub>1c</sub>; GI = gastrointestinal; KQ = Key Question; PICOTS = populations, interventions, comparators, outcomes, timing, and settings; RCT = randomized controlled trial; U.S. = United States

Dated: January 8, 2024.

**Marquita Cullom,**  
Associate Director.

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BILLING CODE 4160-90-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Supplemental Evidence and Data Request on Updating the Measurement Criteria for AHRQ's National Healthcare Quality and Disparities Report (NHQDR)**

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS. **ACTION:** Request for Supplemental Evidence and Data Submission.

**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 *Updating the Measurement Criteria for AHRQ's National Healthcare Quality and Disparities Report (NHQDR)*, 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 February 15, 2024.

**ADDRESSES:**

Email submissions: [epc@ahrq.hhs.gov](mailto: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:** Kelly Carper, Telephone: 301-427-1656 or Email: [epc@ahrq.hhs.gov](mailto: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 *Updating the Measurement Criteria for AHRQ's National Healthcare Quality and Disparities Report (NHQDR)*. AHRQ is conducting this 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 *Updating the Measurement Criteria for AHRQ's National Healthcare Quality and Disparities Report (NHQDR)*. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/measurement-criteria-qdr/protocol>.

This is to notify the public that the EPC Program would find the following information on *Updating the Measurement Criteria for AHRQ's National Healthcare Quality and Disparities Report (NHQDR)* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please indicate whether results are available on [ClinicalTrials.gov](https://clinicaltrials.gov) along with the [ClinicalTrials.gov](https://clinicaltrials.gov) trial number.

- For completed studies that do not have results on [ClinicalTrials.gov](https://clinicaltrials.gov), a summary, including the following elements, if relevant: 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 topic. In the list, please provide the [ClinicalTrials.gov](https://clinicaltrials.gov) trial number or, if the trial is not registered, the protocol for the study including, if relevant, 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 topic 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 topics 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 review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.*

**Guiding Questions**

The brief will be facilitated by guiding questions (GQs), documenting research and key informant input:

GQ1. Which prioritization criteria for health care quality measures have been proposed?

- What settings and intended use were the criteria developed for?
- How are the criteria defined and operationalized?
- In what context have these criteria been used?

- How are the criteria similar or different from the current NHQDR criteria?

GQ2. How should the current NHQDR measure selection prioritization criteria be updated?

- What is the operationalized definition of each updated prioritization criteria?

- What type of health care quality measures would help the NHQDR’s primary audience monitor the effectiveness of health policy levers?

GQ3. How should the new NHDQR measure selection prioritization criteria be applied?

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

**CRITERIA FOR INCLUSION/EXCLUSION OF STUDIES IN THE REVIEW**

Domain	Inclusion	Exclusion
Population .....	<ul style="list-style-type: none"> <li>• Publications that address quality of care indicators, criteria, or benchmarks. We will accept the authors’ definition of quality of care. Quality indicators may include care processes-related measures (e.g., follow-up post discharge, continuity of care, medication errors), health services utilization measures (e.g., hospital readmission, emergency department visit), care satisfaction (e.g., patient satisfaction, care needs met, trust in care provider), or health outcomes (e.g., mortality, physical functional status, mental functioning, quality of life) used as quality indicators; care disparities may either address differences in provided health services, focus on care services or health outcomes of priority populations.</li> </ul>	<ul style="list-style-type: none"> <li>• Publications not addressing quality of care, disparities, or social determinants of health.</li> </ul>
Concept .....	<ul style="list-style-type: none"> <li>• Publications that describe a process of developing, selecting, applying, comparing, evaluating, or prioritizing measures, i.e., procedures, guiding principles, suggested selection criteria, proposed decision rules, or consensus finding methods; publications must describe an empirical ongoing or completed process to select measures used to assess care quality of a healthcare delivery organization or healthcare system.</li> </ul>	<ul style="list-style-type: none"> <li>• Publications describing only the need for quality of care measures, only quality of care measures without describing the process of how to select measures, only discussing the importance of selecting measures, suggesting measures only for individual clinical areas or patient populations, or only describing hypothetical steps to select measures.</li> </ul>
Context .....	<ul style="list-style-type: none"> <li>• Healthcare, specifically healthcare delivery organizations ..</li> </ul>	<ul style="list-style-type: none"> <li>• Studies in contexts outside of healthcare, not specific to healthcare, or not applicable to the U.S. health care system.</li> </ul>
Other limiters .....	<ul style="list-style-type: none"> <li>• Reports published in English-language journal manuscripts, trial records, and gray literature in the public domain from the outlined sources.</li> </ul>	<ul style="list-style-type: none"> <li>• Data reported in abbreviated format (e.g., conference abstracts) will be excluded; studies not published in English.</li> <li>• Systematic reviews will be retained for reference mining.</li> </ul>

Searches will be conducted without date restriction.

Dated: January 8, 2024.

**Marquita Cullom,**

*Associate Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day–24–0621]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “National Youth Tobacco Survey 2024–2026” to the Office of Management and Budget (OMB) for review and approval. CDC

previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 5, 2023 to obtain comments from the public and affected agencies. CDC received five comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the