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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Supplemental Evidence and Data Request on Disparities and Barriers for Pediatric Cancer Survivorship Care

**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 *Disparities and Barriers for Pediatric Cancer Survivorship Care*, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 30 days after the date of publication of this Notice.

**ADDRESSES:**

*E-mail 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.):

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5600 Fishers Lane

Mail Stop 06E77D

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**FOR FURTHER INFORMATION CONTACT:** Jenae Benns, Telephone: 301-427-1496 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 Disparities and Barriers for Pediatric Cancer Survivorship Care. AHRQ is conducting this systematic review pursuant to Section 903 of the Public Health Service Act, 42 U.S.C. 299a-1.

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 *Disparities and Barriers for Pediatric Cancer Survivorship Care*, including those that describe adverse

events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/pediatric-cancer-survivorship/protocol>

This is to notify the public that the EPC Program would find the following information on *Disparities and Barriers for Pediatric Cancer Survivorship Care* 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.*

### **Guiding Questions (GQs)**

The brief will be facilitated by guiding questions, documenting research and Key Informant input.

- GQ1.** What are the disparities in survivorship care for pediatric cancer survivors?
- GQ2.** What are the barriers to survivorship care for pediatric cancer survivors who experience disparities?

- GQ3.** What are proposed strategies for addressing those barriers?
- GQ4.** What published and unpublished studies have assessed these strategies?
- GQ5.** What are future directions for research in addressing barriers to survivorship care for pediatric cancer survivors?

<b>PICOTSS (Populations, Interventions, Comparators, Outcomes, Timing, Settings, Study Designs) PICOTSS</b>	<b>Inclusion</b>	<b>Exclusion</b>
<b>Population</b>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Childhood cancer survivors (CCS) of all ages. We will accept the authors' definition of CCS. Mixed samples will be included where studies include at least 50% CCS or report a subgroup analysis. In studies not self-identifying as CCS research, we will apply the following criteria: Diagnosed before age 21, received primary acute treatment for cancer, currently in remission, eligible to receive survivorship care services, care plans, and/or models of follow-up care</li> </ul>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Studies that predominantly include other populations than CCS, that include patients diagnosed predominantly after the age of 20, that had other conditions than cancer, or that are currently undergoing treatment for cancer.</li> </ul>
<b>Independent variables and interventions</b>	<p>GQ1:</p> <ul style="list-style-type: none"> <li>Survivorship care. We will include studies addressing healthcare approaches aimed at the health and wellbeing of cancer survivors.</li> </ul> <p>GQ2:</p> <ul style="list-style-type: none"> <li>Barriers and facilitators of survivorship care for CCS</li> </ul> <p>GQ3, GQ4, GQ5:</p> <ul style="list-style-type: none"> <li>Strategies to address barriers to survivorship care and to reduce care disparities. We will include care initiatives, structured care programs, care plan, care models, and healthcare interventions aiming to address barriers or disparities. Strategies may target CCS (e.g., providing patient information), healthcare providers (e.g., initiating training), or healthcare systems (e.g., implementing health information technologies such as telemedicine).</li> </ul>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Studies without reference to survivorship care and studies not addressing care disparities, barriers to care, or strategies outside of healthcare.</li> </ul>

<b>PICOTSS (Populations, Interventions, Comparators, Outcomes, Timing, Settings, Study Designs) PICOTSS</b>	<b>Inclusion</b>	<b>Exclusion</b>
<b>Comparators</b>	<p>GQ1, GQ2:</p> <ul style="list-style-type: none"> <li>We will accept the authors' choice of a participant characteristic comparator. Studies may compare subgroups to the general population of CCS or compare multiple participant subgroups defined by participant characteristics (e.g., race/ethnicity, socioeconomic status, gender, rural residence, educational attainment or patient or their parents, other disparate population).</li> </ul> <p>GQ3:</p> <ul style="list-style-type: none"> <li>Strategies do not need to document alternative care models in detail as long as the difference of the proposed survivorship care strategy to usual care is described.</li> </ul> <p>GQ4, GQ5:</p> <ul style="list-style-type: none"> <li>Studies comparing participant subgroups as defined in GQ1 and GQ2 and studies comparing to other care strategies (no intervention, waitlist, usual care, other active strategies aiming to address barriers or disparities).</li> </ul>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Studies not addressing patient characteristics or intervention characteristics.</li> </ul>
<b>Outcomes</b>	<p>GQ1, GQ2:</p> <ul style="list-style-type: none"> <li>Disparities and barriers (causes of disparity) in: <ul style="list-style-type: none"> <li>Any patient outcomes related to utilization of survivorship care services, care plans, or models of care</li> <li>Intermediate health outcomes and adverse events (short-term)</li> <li>Mortality (long-term, not related to cancer)</li> <li>Late effects and morbidity (including psychosocial)</li> <li>Quality of life and wellbeing and satisfaction with care</li> <li>Cost and resource utilization</li> </ul> </li> </ul> <p>GQ3:</p> <ul style="list-style-type: none"> <li>Strategies will be documented regardless of any information on outcome effects, but strategies need to aim to prevent, reduce, or mitigate disparities and barriers to survivorship care.</li> </ul> <p>GQ4:</p> <ul style="list-style-type: none"> <li>Changes (reduction) in disparities between comparison groups for outcomes listed in GQ1 and GQ2</li> </ul>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Studies that do not relate to disparities or barriers to survivorship care for pediatric survivors</li> </ul>

<b>PICOTSS (Populations, Interventions, Comparators, Outcomes , Timing, Settings, Study Designs) PICOTSS</b>	<b>Inclusion</b>	<b>Exclusion</b>
	<p>GQ5:</p> <ul style="list-style-type: none"> <li>Ongoing and upcoming studies need to indicate that the study will report on outcomes eligible for GQ1, GQ2, or GQ4</li> </ul>	
<b>Timing</b>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>No timing restriction apply. Studies may address CCS who recently or long in the past experienced pediatric cancer and are now in remission.</li> </ul>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>No exclusions apply</li> </ul>
<b>Setting(s)</b>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>All care settings applicable to US settings will be eligible, including primary, secondary, and tertiary care; inpatient and outpatient care; pediatric and adult care context.</li> </ul>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Studies in resource-limited settings such as developing countries will be reviewed for comparability with US settings</li> </ul>
<b>Study design and other limiters</b>	<p>All GQs</p> <ul style="list-style-type: none"> <li>English-language publications.</li> </ul> <p>GQ1, GQ2, GQ4, GQ5:</p> <ul style="list-style-type: none"> <li>Primary studies reporting empirical data (including both quantitative and qualitative data).</li> </ul> <p>GQ1, GQ2:</p> <ul style="list-style-type: none"> <li>Studies may either report on distinct subgroups, e.g., dividing the sample by geographic characteristic and reporting data separately for rural and for urban participants or studies may report associations with participant characteristics, e.g., reporting correlations with a factor of interest such as gender differences.</li> </ul> <p>GQ3:</p> <ul style="list-style-type: none"> <li>Strategies have to have been empirically tested in a research study reporting on the outcomes of interest or have been suggested by an authoritative source such as a clinical practice guideline or relevant professional organization.</li> </ul> <p>GQ 4:</p> <ul style="list-style-type: none"> <li>Studies with concurrent (e.g., randomized controlled trial) or historic comparator (e.g., organizational pre-post studies). Studies with results published in clinicaltrials.gov will be included regardless of whether a journal publication is available.</li> </ul> <p>GQ5:</p>	<p>All GQs:</p> <ul style="list-style-type: none"> <li>Evaluations reported only in abbreviated format (e.g., in a conference abstract) with the exception of trial records.</li> <li>Studies exclusively reported in non-English publications.</li> <li>Systematic reviews will be retained for reference mining but are not eligible for inclusion.</li> </ul>

<b>PICOTSS (Populations, Interventions, Comparators, Outcomes, Timing, Settings, Study Designs) PICOTSS</b>	<b>Inclusion</b>	<b>Exclusion</b>
	<ul style="list-style-type: none"> <li>• Ongoing and upcoming studies have to have a published protocol or are registered in a research registry.</li> </ul>	

Dated: July 9, 2020.

**Virginia Mackay-Smith,**

*Associate Director.*

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