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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Mixed Methods Review - Integrating Palliative Care with Chronic Disease Management in Ambulatory 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 *Mixed Methods Review - Integrating Palliative Care with Chronic Disease Management in Ambulatory 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 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 Mixed Methods Review – Integrating Palliative Care with Chronic Disease Management in Ambulatory Care. 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 *Mixed Methods Review – Integrating Palliative Care with Chronic Disease Management in Ambulatory Care*, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/palliative-care-integration/protocol

This is to notify the public that the EPC Program would find the following information on *Mixed Methods Review – Integrating Palliative Care with Chronic Disease Management in Ambulatory 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.

Key Questions (KQ)

Five questions about the integration of palliative care in ambulatory care will be addressed:

1. How can we identify those patients who could benefit from palliative care in ambulatory care settings?
2. What educational resources are available for patients and caregivers in ambulatory care about palliative care?
3. What palliative care decision making tools are available for clinicians, patients and caregivers in ambulatory care?
4. What educational resources are available for non-palliative care clinicians about palliative care in ambulatory settings?
5. What are the models for integrating palliative care into ambulatory settings?

For each of these questions, three parts will be addressed:

- What is available? (part a of questions)
- What is the effectiveness? (part b of questions)
- How is it implemented? (part c of questions)

The following are the Key Questions to be addressed in this mixed methods review:

KQ 1:

KQ1a. What prediction models, tools, triggers and guidelines and position statements are available about how to identify when and which patients with serious life-threatening chronic illness or conditions in ambulatory settings could benefit from palliative care?

KQ1b. What is the effectiveness of prediction models, tools and triggers for identifying when and which patients with serious life-threatening chronic illness or conditions in ambulatory settings could benefit from palliative care?

KQ1c. How have prediction models, tools and triggers for identifying when and which patients with serious life-threatening chronic illness or conditions in ambulatory settings could benefit from palliative care been implemented? What is the evidence for how, when and for which patients they could best be implemented in care?

KQ 2:

KQ2a. What educational materials and resources are available about palliative care and palliative care options for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers?

KQ2b. What is the effectiveness of educational materials and resources about palliative care and palliative care options for patients with serious life-threatening chronic illness or conditions and their caregivers in ambulatory settings?

KQ2c. How have educational materials and resources about palliative care and palliative care options for patients with serious life-threatening chronic illness or conditions and their caregivers in ambulatory settings been implemented? What is the evidence for how, when and for which patients and caregivers they could best be implemented in care?

KQ 3:

KQ3a. What palliative care shared decision-making tools are available for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers?

KQ3b. What is the effectiveness of palliative care shared decision-making tools for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers?

KQ3c. How have palliative care shared decision-making tools been implemented for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers? What is the evidence for how, when and for which patients and caregivers they could best be implemented in care?

KQ 4:

KQ4a. What palliative care training and educational materials are available for non-palliative care clinicians caring for patients with serious life-threatening chronic illness or conditions in ambulatory settings?

KQ4b. What is the effectiveness of palliative care training and educational materials (with or without other intervention components) for non-palliative care clinicians caring for patients with serious life-threatening chronic illness or conditions in ambulatory settings?

KQ4c. How have palliative care training and educational materials (with or without other intervention components) for non-palliative care clinicians caring for patients with serious life-threatening chronic illness or conditions in ambulatory settings been implemented? What is the evidence for how, when and for which clinicians they could best be implemented in care?

KQ 5:

> **KQ5a**. What models (i.e., stepped care, consultative care, shared care, collaborative care, coaching, integrating social workers into practice, and palliative care approaches provided by non-palliative care specialists) for integrating palliative care have been developed for patients with serious life-threatening chronic illness or conditions in ambulatory settings?
>
> **KQ5b.** What is the effectiveness of models (i.e., stepped care, consultative care, shared care, collaborative care, coaching, integrating social workers into practice, and palliative care approaches provided by non-palliative care specialists) or multimodal interventions for integrating palliative care for patients with serious life-threatening chronic illness or conditions in ambulatory settings?
>
> **KQ5c.** What are components of models for integrating palliative care in ambulatory settings? What models have been implemented for key subpopulations? What components and characteristics of these models contribute to their effective implementation? What is the evidence for how, when and for which patients they could best be implemented in care?

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

- **Population(s)**
  - Adults age 18 or older with serious life-threatening chronic illness or conditions (other than those adults only with cancer) and their caregivers, being seen in ambulatory settings (KQ 1,2,3,5)
  - Clinicians practicing in ambulatory settings listed below (KQ 4)

- **Interventions:**
  - KQ1: prediction models, tools or triggers to identify patients for palliative care in ambulatory settings
  - KQ2: educational materials and resources for patients and/or caregivers about palliative care in ambulatory settings
  - KQ3: palliative care shared decision-making tools and resources for clinicians and patients and/or caregivers in ambulatory settings

  - KQ4: palliative care training or educational materials for non-palliative care clinicians in ambulatory settings
  - KQ5: models for integrating palliative care in ambulatory settings

- **Comparators (for part (b) KQ):**
  Comparators between:
  - KQ1: prediction models, tools or triggers to identify patients for palliative care in ambulatory settings
  - KQ2: educational materials and resources for patients and/or caregivers about palliative care in ambulatory settings
  - KQ3: palliative care shared decision-making tools and resources for clinicians and patients and/or caregivers in ambulatory settings
  - KQ4: palliative care training or educational materials for clinicians in ambulatory settings
  - KQ5: models for integrating palliative care or multimodal interventions in ambulatory settings
  - As well as with usual care for all KQs

- **Outcomes (for part (b) KQ):**
  - Intermediate (Excludes clinician self-report)
    - Knowledge (clinicians, patients, caregivers) (KQ2, KQ4)
    - Awareness (clinicians, patients, caregivers) (KQ2, KQ4)
    - Skills (clinicians) (KQ4)
  - Final (All apply to all KQ) (In hierarchy from patient-centered to clinician to health system. All patient or caregiver-reported outcomes must be measured by a validated instrument. All outcomes must relate to components of care relevant to serious, life-threatening chronic illness or conditions.)
    - Patient or caregiver satisfaction
    - Patient or caregiver health-related quality of life
    - Patient or caregiver symptoms of depression or anxiety or psychological well-being
    - Caregiver burden, caregiver impact or caregiver strain

        - Patient symptoms or symptom burden (includes multidimensional symptom tools and key symptoms of pain, dyspnea, fatigue). This must include patient-reported symptom measurement (or caregiver-reported for patients unable to report).
        - Concordance between patient preferences for care and care received
        - Clinician job satisfaction or burnout, perceptions of teamwork
        - Healthcare utilization (use and length of hospice care, hospitalizations, advance directive documentation) and costs and resource use (use of outpatient clinician services, including palliative care)
    - Adverse effects
        - Medication side effects
        - Dropouts

- **Timing**
    - Any timing

- **Settings**
    - Ambulatory primary and specialty care, including geriatrics, nephrology, pulmonology, cardiology, and neurology
    - US-based studies, as systems of care differ in other countries

Dated: 15 January 2020.

Virginia L. Mackay-Smith,
Associate Director, Office of the Director, AHRQ.
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