access, utilization, cost, safety, and quality of hospital, physician, and other services. Disseminates data, tools, and statistics to facilitate and inform public and private health policy analysis, clinical studies, and socioeconomic research to inform public and private healthcare policy.

Division of Survey Operations (DSO): Responsible for the MEPS data collection, processing and distribution activities. These responsibilities include directing data collection for the three major MEPS surveys, preparing data files for public use, conducting workshops on the appropriate use of MEPS data and the development of a website for disseminating MEPS products. Publishes statistical briefs, research findings and a series of methodological reports. Administers a data center at which researchers can, with approved projects and under specific technical controls and privacy protocols, access data that cannot be released to the public for use in specific research activities. Maintains liaisons with individuals and organizations engaged in health services research both within and outside the federal government.

All delegations and redelegations of authority to officers and employees of the Agency for Healthcare Research and Quality that were in effect immediately prior to the effective date of this reorganization shall continue in effect pending further redelegation provided they are consistent with this reorganization.

These changes are effective upon date of signature.

Dated: September 18, 2019.

Gopal Khanna,

Director.

[FR Doc. 2019–20218 Filed 9–18–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Therapies for Clinically Localized Prostate Cancer

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 *Therapies for Clinically Localized Prostate Cancer,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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: Comments must be received on or before 30 days after date of publication of this notice.

ADDRESSES:

Email 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 *Therapies for Clinically Localized Prostate Cancer*. 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 *Therapies for Clinically Localized Prostate Cancer,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/prostate-cancer-therapies/protocol*.

This is to notify the public that the EPC Program would find the following information on Therapies for Clinically Localized Prostate Cancer 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 email 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 1: What are the comparative effectiveness and harms of CLPC therapies?

(1) Watchful waiting
(2) Active surveillance
(3) Androgen deprivation therapy (ADT)
(4) Focal therapies
  (a) Brachytherapy
  (b) Cryotherapy
  (c) High-intensity focused ultrasound (HIFU)
  (d) Laser ablation

(e) Photodynamic therapy
(f) Irreversible electroporation
(5) Whole gland therapies
(a) Brachytherapy
(b) Cryotherapy
(c) External beam radiation therapy
(i) three-dimensional conformal radiotherapy
(ii) intensity-modulated radiation therapy
(iii) proton beam therapy
(iv) stereotactic body radiation therapy
(d) Radical prostatectomy
(i) open
(ii) laparoscopic
(1) without robotic assistance
(2) with robotic assistance
(6) Combination of above

KQ 2: How do patient characteristics modify comparative effectiveness and harms of CLPC therapies?

(1) Age
(2) Race/ethnicity
(3) Comorbidities
(4) Health status

KQ 3: How do tumor characteristics modify comparative effectiveness and harms of CLPC therapies?

(1) Baseline PSA
(2) Gleason score
(3) Tumor index scores (*e.g.,* Cancer of the Prostate Risk Assessment Score [CAPRA], D'Amico Risk Classification for Prostate Cancer, etc.)
(4) Biomarker Status
(a) Decipher (Genomic Classifier)
(b) Oncotype Dx (Genomic Prostate Score)
(c) Prolaris (Cell Cycle Progression)

KQ 4: How do provider/hospital characteristics modify comparative effectiveness of RP compared to other therapies?

(1) Geographic region
(2) Hospital type
(3) Provider volume
(4) Institutional volume

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

Population(s)

- Treatment naïve men with CLPC (stages T1 to T3)

Interventions

KQ1 to 3

(1) Watchful waiting (WW)
(2) Active surveillance (AS)
(3) Androgen deprivation therapy (ADT)
(4) Focal therapies
(a) Brachytherapy
(b) Cryotherapy
(c) High-intensity focused ultrasound (HIFU)
(d) Laser ablation
(e) Photodynamic therapy
(f) Irreversible electroporation
(5) Whole gland therapies
(a) Brachytherapy
(b) Cryotherapy
(c) External beam radiation therapy
(i) Three-dimensional conformal radiotherapy
(ii) Intensity-modulated radiation therapy
(iii) Proton beam therapy
(iv) Stereotactic body radiation therapy
(d) Radical prostatectomy
(i) Open
(ii) Laparoscopic
(1) Without robotic assistance
(2) With robotic assistance
(6) Combination of above

KQ4

(1) Radical prostatectomy (RP)

Comparators

KQ1 to KQ4

- Any other intervention of listed above except certain within category comparisons (*e.g.,* nerve-sparing vs non-nerve sparing prostatectomy; different dosage/frequency/timing/duration of same therapy)

Outcomes

KQ1 to KQ3

- Overall survival/mortality
- Prostate cancer specific survival/mortality
- Metastatic-progression free survival
- Metastases (lymph nodes/distant)
- Health status
- Quality of life (measured with validated instruments)
- Prostate-cancer related quality of life (measured with validated instruments)

KQ4

- Overall survival/mortality
- Prostate cancer specific survival/mortality
- Metastatic free survival/metastases (lymph nodes/distant)

Harms

KQ1 to KQ3

Common and serious treatment side effects:

- Bowel, bladder, and sexual/erectile dysfunction
- Serious adverse effects associated with ADT such as cognitive impairment, MACE, fractures

Timing

KQ1 to KQ3

Follow up from treatment initiation:

- Mortality/survival outcomes/metastases: 5 years or more
- Health status, quality of life and harms: 1 year or more

KQ4

Follow up from treatment initiation:

- Mortality/survival outcomes/metastases: 5 years or more

Setting

KQ1 to KQ4

- All settings

Study Design

KQ1 to KQ4

(1) RCTs
(2) Non-RCT if:
(a) Comparative
(b) Concurrent
(c) Multicenter (enrolling patients treated at multiple locations)
(d) ≥500 patients
(e) Some method to control for selection bias (propensity scores, instrumental variables, multivariate regression)
(f) Prospective data collection

Dated: September 16, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–20303 Filed 9–18–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review: Assessing Models of Coordinated Services for Low-Income Children and Their Families (AMCS) (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; ACF; HHS

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new study, Assessing Models of Coordinated Services for Low-Income Children and Their Families (AMCS).

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.