TABLE 2—EPC PROPOSED PICOTS AND CORRESPONDING INCLUSION AND EXCLUSION CRITERIA: KEY QUESTIONS 5 AND 6 ON SPECIFIC PROCEDURES IN PATIENTS WITH CHRONIC LOW BACK PAIN DUE TO DEGENERATIVE SPINE DISEASE—Continued

	Inclusion	Exclusion
Study designs	KQ 5 • RCTS for effectiveness/efficacy outcomes • Prospective NRSIs that control for confounding will be considered for effectiveness in the absence of RCTs • NRSIs for harms must be specifically designed to evaluate/report on serious AE/harms and that control for confounding OR focused on rare or long-term harms KQ 6 • Predictive/prognostic modeling studies evaluating the association of procedure response impact on outcomes that control for confounding	KQ 5, 6 • NRSI that do not control for confounding • NRSI that include historical controls • NRSI with fewer than 50 patients per treatment arm • Case reports, case-series, single-arm and pre-post studies • Publication types: Conference abstracts or proceedings, editorials, letters, white papers, citations that have not been peer-reviewed, single site reports of multi-site studies • Studies not in English

Serious adverse events are defined as events that are life-threatening or anything needing additional medical attention. AE = adverse event; DLS = degenerative lumbar spondylolisthesis; EQ–5D = EuroQol 5D scale; ESI = epidural steroid injection; FDA = Food and Drug Administration; IONM = intraoperative neuro monitoring; KQ = Key Question; LBP = low back pain; MCID = minimum clinically important difference; NRSI = nonrandomized studies of intervention; ODI = Oswestry Disability Index; RCT = randomized controlled trial; RF = radiofrequency ablation; RMD = Rolland-Morris Disability Questionnaire; SSED = Summary of Safety and Effectiveness Data; SF–36/12 = Short Form 36 or 12 questionnaire; VAS = visual analog scale.

Dated: January 7, 2025.

Marquita Cullom,

Associate Director.

[FR Doc. 2025–00548 Filed 1–13–25; 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 Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review

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 *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: 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 February 13, 2025.

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: Kelly Carper, Telephone: 301–427–1656 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 *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review.*

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 *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/hypofractionated-radiation-therapy/protocol.*

This is to notify the public that the EPC Program would find the following information on *Primary Hypofractionated Radiation Therapy for Localized Prostate Cancer: A Systematic Review* 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 along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on 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 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://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.

Key Questions (KQ)

KQ 1: For patients with localized prostate cancer receiving external beam radiation therapy (EBRT) with curative intent, what are the benefits and harms of moderate hypofractionation compared to conventional fractionation?

KQ 1a: Do findings vary with respect to patient characteristics (*e.g.,* age, race and ethnicity), pretreatment characteristics (*e.g.,* risk group, prostate gland volume, lower urinary tract symptoms, prior prostate procedures), treatment targets (*i.e.,* prostate with or without treatment of pelvic lymph nodes), and use of adjunctive therapies (*e.g.,* with or without neoadjuvant or adjuvant androgen deprivation therapy)?

KQ 2: For patients with localized prostate cancer receiving EBRT with curative intent, what are the benefits and harms of ultra-hypofractionation compared to moderate hypofractionation or conventional fractionation?

KQ 2a: Do findings vary with respect to patient characteristics (*e.g.,* age, race, and ethnicity), pretreatment characteristics (*e.g.,* risk group, prostate gland volume, lower urinary tract symptoms, prior prostate procedures), treatment targets (*i.e.,* prostate with or without treatment of pelvic lymph nodes), and use of adjunctive therapies (*i.e.,* with or without neoadjuvant or adjuvant androgen deprivation therapy)?

KQ 3: For patients with localized prostate cancer receiving moderate or ultra-hypofractionated EBRT with curative intent, what are the benefits and harms of different dose-fractionation regimens?

KQ 3a: Do findings vary with respect to pretreatment characteristics (*i.e.,* tumor stage, disease risk, urinary tract symptoms, prior prostate procedures)?

KQ 4: For patients with localized prostate cancer receiving moderate or ultra-hypofractionated EBRT with curative intent, what are the benefits and harms associated with different target volumes (*i.e.,* prostate alone, prostate with seminal vesicles, prostate with seminal vesicles and pelvic lymph nodes; with or without focal intraprostatic boosts)?

KQ 4a: Do findings vary with respect to pretreatment characteristics (*i.e.,* imaging)?

KQ 5: For patients with localized prostate cancer receiving moderate or ultra-hypofractionated EBRT with curative intent, what are the benefits and harms of different treatment planning and delivery techniques?

Contextual Question

Does the utilization of fractionation schedule (*i.e.,* conventional fractionation, moderate hypofractionation, and ultra-hypofractionation) differ by factors such as age, race, ethnicity, socioeconomic status, or geography?

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

	Inclusion criteria	Exclusion criteria
Preliminary PICOTS criteria		
Population	KQs 1–5. Adult aged ≥18 years with localized prostate cancer (stages T1 to T4N0M0) who have elected to receive EBRT as their primary treatment regardless of pretreatment characteristics. KQs 1a, 2a: Consider patient characteristics (*e.g.,* age, race and ethnicity), pretreatment characteristics (*e.g.,* prostate cancer risk group, prostate gland volume, presence of lower urinary tract symptoms), use of adjunctive therapies (*e.g.,* androgen deprivation therapy).	Individuals aged <18 years, those with non-localized stage of prostate cancer at enrollment.
Interventions	All KQs. Radiation therapy administered as a primary treatment KQ 1. MHF (2.4 to 3.4 Gy per fraction). KQ 2. UHF (≥5.0 Gy per fraction). KQ 3. Various dose-fractionation regimens (MHF, UHF). KQ 4. Various target volumes (MHF, UHF) (*e.g.,* prostate, seminal, vesicles, pelvic lymph nodes, focal intraprostatic boosts). KQ 5. Various treatment planning and delivery techniques. • Advanced imaging for target delineation (any pretreatment imaging, *i.e.,* CT, MRI, MR-linac, PET, urethral contrast). • Dose-volume criteria for OARs (urethra). • Image-guidance techniques (*i.e.,* cone-beam CT, intraprostatic fiducial markers, MRI, electromagnetic tracking). • Delivery techniques (*i.e.,* IMRT, VMAT [term ARCS] protons [IMPT, passive scatter], SBPT, SBRT/SABR, 3D CRT). • Rectal-sparing technologies (*e.g.,* rectal spacers). • Online adaptive radiotherapy (treatment planning software). • Patient preparation for treatment planning and daily treatment (*e.g.,* daily enemas, full bladder, empty rectum).	Other treatments and techniques. Salvage radiation therapy; adjuvant or neoadjuvant radiation therapy.
Comparators	KQ 1. CF (1.8 to 2.0 Gy per fraction) KQ 2. CF, MHF. KQ 3. Dose-fractionation regimens compared to each other. KQ 4. Target volumes compared to each other [all grouped by type of hypofractionation (MHF and UHF). KQ 5. Treatment planning and delivery techniques compared to each other	Other comparators.
Outcomes	KQ 1—KQ 5. Overall and prostate cancer-specific survival, local recurrence, metastases, biochemical recurrence-free survival, acute and late gastrointestinal toxicity, acute and late genitourinary toxicity, patient reported outcomes (*i.e.,* GI, GU, ED) and quality of life.	Other outcomes.
Timing	Any followup duration	NA

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Inclusion criteria	Exclusion criteria
Setting	KQ 1—KQ 5. All clinical settings	NA
Study Design	KQs 1, 2. Randomized controlled trials	KQs 1, 2: Other designs.
	KQs 3–5. Randomized controlled trials. Comparative cohort studies with concurrent control groups, conducted within the same clinical setting. Other observational studies with concurrent control groups, that control for confounders.	KQs 3–5: Uncontrolled cohort studies, case-control studies, case reports, case series, cost-effectiveness and other modeling studies.
	Studies conducted in countries rated as very high on the Human Development Index.[a]	Studies using nonconcurrent comparators (*e.g.,* historical controls).
		Studies comparing methods across different settings/clinics.
		Observational studies that do not control for confounders.

Abbreviations: CF = conventionally fractionated external beam radiation therapy; CT = computed tomography; CRT = conventional radiotherapy; EBRT = external beam radiation therapy; ED = erectile dysfunction; GI = gastrointestinal issues; GU = genitourinary issues; Gy = gray; IMPT = intensity modulated proton therapy; KQ = key question; MHF = moderately hypofractionated radiation therapy; MRI = magnetic resonance imaging; MR-linac = MRI-guided linear accelerator; NA = not applicable; OARs = organs at risk; PET = positron emission tomography; PICOTS = population, interventions, comparators, outcomes, timing, and setting; SABR = stereotactic ablative radiotherapy; SBPT = stereotactic body proton therapy; SBRT = stereotactic body radiation therapy; UHF = ultra-hypofractionated radiation therapy; VMAT = volumetric modulated arc therapy.

[a] United Nations Development Programme. Human Development Index. Retrieved from *https://hdr.undp.org/data-center/human-development-index#/indicies/HDI.*

Dated: January 7, 2025.

Marquita Cullom,

Associate Director.

[FR Doc. 2025–00547 Filed 1–13–25; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10777, CMS–R–235 and CMS–10662]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by March 17, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10777 Conditions of Participation for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)

CMS–R–235 Data Use Agreement (DUA) Limited Data Set (LDS) Forms Research Identifiable Files (FIF) Forms

CMS–10662 Administrative Simplification HIPAA Compliance Review

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the