

service providers to adopt a robocall mitigation program and file a description of that program in the Robocall Mitigation Database as well as requiring all classes of providers to file additional information in the Robocall Mitigation Database. On May 18, 2023, the Commission adopted an Order modifying some of these requirements. See *Call Authentication Trist Anchor, et al.*, WC Docket No. 17–97 et al., Seventh Report and Order et al., FCC 23–37 (adopted May 18, 2023).

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Treatment of Stage I–III Squamous Cell Anal 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 *Treatment of Stage I–III Squamous Cell Anal 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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* on or before October 5, 2023.

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 *Treatment of Stage I–III Squamous Cell Anal Cancer*. 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 *Treatment of Stage I–III Squamous Cell Anal Cancer*. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/anal-cancer-treatment/protocol>.

This is to notify the public that the EPC Program would find the following information on *Treatment of Stage I–III Squamous Cell Anal Cancer* 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://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.

Key Questions (KQ)

KQ 1. What are the effectiveness and harms of different modalities of initial treatment for stages I–III squamous cell anal cancer?

KQ 2. What are the effectiveness and harms of different modalities of radiation therapy for initial treatment of stages I–III squamous cell anal cancer?

KQ 3. What are the effectiveness and harms of different radiation therapy doses, volumes, and fractionation schema for initial treatment of stage I–III squamous cell anal cancer?

KQ 4. What are the effectiveness and harms of different combinations of chemotherapy and radiation therapy, and dose de-escalation or dose escalation for initial treatment of stages I–III squamous cell anal cancer?

KQ 5. What are the effectiveness and harms of immunotherapy for initial treatment of stages I–III squamous cell anal cancer?

KQ 6. What are the effectiveness and harms of different frequencies and modalities for post-treatment surveillance strategies after initial treatment of stages I–III squamous cell anal cancer?

For all KQs, do the outcomes differ by patient characteristics such as age, sex, immunocompromised status, or other characteristics associated with health inequities (such as race/ethnicity)?

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

	Inclusion	Exclusion
Population: All KQ	<p>Adults with stages I–III squamous cell anal cancer (anal canal and anal margin).</p> <p>Patient characteristics such as age, sex, immunocompromised status, or other characteristics associated with health inequities (such as race/ethnicity).</p>	<p>Adults with:</p> <ul style="list-style-type: none"> • Stage IV anal cancer. • Lower rectal cancer that has spread to the anal canal. • Non-squamous cell anal cancer (e.g., adenocarcinomas, undifferentiated cancer). <p>Studies including mixed populations with Stages I–IV squamous cell anal cancer which contain 20% or greater proportion of stage IV squamous cell anal cancer.</p>
Interventions: KQ1	<p>Alone or in combination as neoadjuvant/adjuvant or as induction/maintenance:</p> <ul style="list-style-type: none"> • Surgery, radiation therapy, or chemotherapy 	<ul style="list-style-type: none"> • Reconstructive surgery. • Palliative therapy (includes chemotherapy with palliative intent). • Treatment for premalignant lesions. • Palliative therapy.
KQ2	<p>Different modalities of radiation therapy such as, but not limited to, IMRT, proton radiation therapy, and Brachytherapy boost.</p>	<ul style="list-style-type: none"> • Palliative therapy.
KQ3	<p>Radiation therapy; varying:</p> <ul style="list-style-type: none"> • Doses • Target (primary and nodal) volumes • Fractionation schema. 	<ul style="list-style-type: none"> • Palliative therapy.
KQ4	<ul style="list-style-type: none"> • Chemotherapy and radiation therapy combinations (e.g., 5-Fluorouracil, Mitomycin-C, Cisplatin). • Variations in dose of: ○ Radiation therapy ○ Chemotherapy. 	<ul style="list-style-type: none"> • Palliative therapy.
KQ5	<p>Immunotherapy (e.g., pembrolizumab, nivolumab).</p>	
KQ6	<p>Post-treatment surveillance strategies:</p> <ul style="list-style-type: none"> • Frequency. • Modalities (e.g., MRI, PET scans, biopsy, DRE, anoscopy, flexible sigmoidoscopy). • Strategies for surveillance post non-initial treatment. 	<ul style="list-style-type: none"> • Screening for primary prevention. • Initial staging.
Comparison: KQ1	<p>Alone or in combination as neoadjuvant/adjuvant or as induction/maintenance:</p> <ul style="list-style-type: none"> • Surgery, radiation therapy, or chemotherapy 	<ul style="list-style-type: none"> • Reconstructive surgery. • Palliative therapy (includes chemotherapy with palliative intent). • Treatment for premalignant lesions. • Palliative therapy.
KQ2	<p>Comparators for different modalities of radiation therapy such as, but not limited to, 3-D CRT, photon or electron radiation therapy, and external beam radiation therapy boost.</p>	<ul style="list-style-type: none"> • Palliative therapy.
KQ3	<p>Radiation therapy; varying:</p> <ul style="list-style-type: none"> • Doses • Target (primary and nodal) volumes • Fractionation schema. 	<ul style="list-style-type: none"> • Palliative therapy.
KQ4	<ul style="list-style-type: none"> • Chemotherapy and radiation therapy combinations (e.g., 5-Fluorouracil, Mitomycin-C, Cisplatin). • Variations in dose ○ Radiation therapy ○ Chemotherapy. 	<ul style="list-style-type: none"> • Palliative therapy.
KQ5:	<p>Other treatment (e.g., chemotherapy, radiation therapy, chemotherapy + radiation therapy).</p>	
KQ6	<p>Post-treatment surveillance strategies:</p> <ul style="list-style-type: none"> • Frequency • Modalities (e.g., MRI, PET scans, biopsy, DRE, anoscopy, flexible sigmoidoscopy). 	<ul style="list-style-type: none"> • Screening for primary prevention. • Initial staging. • Strategies for surveillance post non-initial treatment.
Outcomes: All KQ	<ul style="list-style-type: none"> • Overall survival. • Disease specific survival. • Disease-free survival (including persistence, recurrence, or relapse). • Colostomy-free survival. • Local control. • Complete clinical response. • Salvage rate. • Sphincter preservation. • Health-related quality of life. 	

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

	Inclusion	Exclusion
Timing: All KQ	<ul style="list-style-type: none"> • Treatment breaks (frequency or duration), treatment discontinuation, interruptions, or median treatment days. • Bleeding per rectum. • Functional outcomes (e.g., fecal or urinary incontinence, erectile dysfunction, sexual dysfunction, use of vaginal dilators). • Harms of treatment including acute and late toxicity (e.g., myelosuppression, gastrointestinal toxicity, such as diarrhea, vomiting, and bowel obstruction, secondary malignancy, radiation dermatitis, radiation proctitis, radiation cystitis, pelvic insufficiency fractures, vaginal stenosis). 	Case reports, case series, commentaries, cross-sectional studies, reviews, qualitative studies, studies with sample size less than 30 patients (or less than 15 per treatment group/arm), non-randomized studies with unspecified or poorly defined intervention/treatment protocol (e.g., lack of names of chemotherapy agents used), non-randomized studies with analytic techniques that don't allow drawing causal inferences.
Setting: All KQ	No restrictions on duration of treatments or follow-up.	
Study design: All KQ	Cancer care settings.	
	Randomized controlled trials, non-randomized controlled trials, observational cohort with concurrent comparator, interrupted time-series, and other quasi-experimental designs using appropriate analytic techniques.	

Abbreviations: 3-D CRT= three-dimensional conformal radiation therapy; DRE= digital rectal exam; IMRT=intensity-modulated radiation therapy; KQ=key question; MRI= magnetic resonance imaging; PET= positron emission tomography; RCT=randomized controlled trial; VMAT= Volumetric modulated arc therapy.

Marquita Cullom,
Associate Director.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project “Use of Open-Ended Responses to Explore Disparities in Patient Experience.” This proposed information collection was previously published in the **Federal Register** on June 27th, 2023, and allowed 60 days for public comment. AHRQ received no substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 5, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Use of Open-Ended Responses To Explore Disparities in Patient Experience

The Consumer Assessment of Healthcare Providers and Systems (CAHPS) program, which is sponsored by AHRQ, has the purpose of advancing the scientific understanding of the patient experience of care, including the development and testing of new surveys and/or approaches to data collection to promote or improve the collection of consumer reports and evaluations of their experiences with health care.

This Project has the following goals:

(1) Use open-ended (narrative) responses to provide context, detail, and understanding regarding observed differences in patient experience based on race, ethnicity, gender, and preferred language.

(2) Use Clinician and Group-CAHPS Narrative Item Set (NIS)-generated narrative data to examine potential algorithmic bias in natural language programs (NLP) that could potentially be used to code large quantities of narrative data.

(3) Where algorithmic bias is uncovered, use this analysis to identify adjustments that can be applied to both the input for these programs or the outputs.

This project is being conducted by AHRQ through its contractor, the RAND Corporation, pursuant to AHRQ’s statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness, and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

Online survey: Data will be collected from a sample of 4,998 survey