- For adverse events: immediate

Settings

- Primary care (outpatient) or acute care setting, preferentially
- Outpatient rheumatology practices/ academic medical centers

Dated: August 26, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–20689 Filed 9–2–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Emerging Approaches To Diagnosis and Treatment of Non-Muscle-Invasive Bladder Cancer

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information 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 of Emerging Approaches to Diagnosis and Treatment of Non-Muscle-Invasive Bladder Cancer, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before October 3, 2014.

ADDRESSES: Online submissions: *http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/.* Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: *SIPS@epc-src.org.*

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 58653 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Emerging Approaches to Diagnosis and Treatment of Non-Muscle-Invasive Bladder Cancer.

The EHC 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 Emerging Approaches to Diagnosis and Treatment of Non-Muscle-Invasive Bladder Cancer, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1941.*

This notice is to notify the public that the EHC Program would find the following information on Emerging Approaches to Diagnosis and Treatment of Non-Muscle-Invasive Bladder 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 ClinicafTrials.gov along with the ClinicalTrials.gov trial number.
- For completed studies that do not have results on ClinicalTrials.gov, please provide 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 will be very beneficial to the EHC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can 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 EHC 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 EHC Program Web site 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: *http://effectivehealthcare.AHRO.gov/index.cfm/join-the-email-list1/.*

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. The entire research protocol, is also available online at: *http://effectivehealthcare.AHRO.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1941.*

The Key Questions

Key Question 1

What is the diagnostic accuracy of various urinary biomarkers compared with other urinary biomarkers or standard diagnostic methods (cystoscopy, cytology, and imaging) in (1) persons with signs or symptoms warranting evaluation for possible bladder cancer or (2) persons undergoing surveillance for previously treated bladder cancer?

- Does the diagnostic accuracy differ according to patient characteristics (e.g., age, sex, ethnicity), or according to the nature of the presenting signs or symptoms?

Key Question 2

For patients with non-muscle-invasive bladder cancer, does the use of a formal risk-adapted assessment approach to treatment decisions (e.g.,

Guidelines of the European Association of Urology or based on urinary biomarker tests) decrease mortality or improve other outcomes (e.g., recurrence, progression, need for cystectomy, quality of life) compared with treatment not guided by an assessed risk-adapted approach?

Key Question 3

For patients with non-muscle-invasive bladder cancer treated with transurethral resection of bladder tumor (TURBT), what is the effectiveness of various intravesical chemotherapeutic or immunotherapeutic agents for decreasing mortality or improving other outcomes (e.g., recurrence, progression, need for cystectomy, quality of life) compared with other agents, TURBT alone, or cystectomy?

- What is the comparative effectiveness of various chemotherapeutic or imnnunotherapeutic agents, as monotherapy or in combination?
- Does the comparative effectiveness differ according to tumor characteristics, such as histology, stage, grade, size, or molecular/genetic markers?
- Does the comparative effectiveness of various chemotherapeutic or immunotherapeutic agents differ according to dosing frequency, duration of treatment, and/or the timing of administration relative to TURBT?
- Does the comparative effectiveness differ according to patient characteristics, such as age, sex, ethnicity, performance status, or medical comorbidities?

Key Question 4

For patients with high risk non-muscle-invasive bladder cancer treated with TURBT, what is the effectiveness of external beam radiation therapy (either alone or with systemic chernotherapy/immunotherapy) for decreasing mortality or improving other outcomes compared with intravesical chemotherapy/immunotherapy alone or cystectomy?

Key Question 5

In surveillance of patients treated for non-muscle-invasive bladder cancer, what is the effectiveness of various urinary biomarkers to decrease mortality or improve other outcomes compared with other urinary biomarkers or standard diagnostic methods (cystoscopy, cytology, and imaging)?

- Does the comparative effectiveness differ according to tumor characteristics, such as histology, stage, grade, size, or molecular/genetic markers?
- Does the comparative effectiveness differ according to the treatment used (i.e., specific chemotherapeutic or immunotherapeutic agents and/or TURBT)?
- Does the comparative effectiveness differ according to the length of surveillance intervals?
- Does the comparative effectiveness differ according to patient characteristics, such as age, sex, or ethnicity?

Key Question 6

For initial diagnosis or surveillance of patients treated for non-muscle-invasive bladder cancer, what is the effectiveness of blue light or other methods of augmented cystoscopy compared with standard cystoscopy for recurrence rates, progression of bladder cancer, mortality, or other clinical outcomes?

Key Question 7

What are the comparative adverse effects of various tests for diagnosis and post-treatment surveillance of bladder cancer, including urinary biomarkers, cytology, and cystoscopy?

Key Question 8

What are the comparative adverse effects of various treatments for non-muscle-invasive bladder cancer, including intravesical chemotherapeutic or immunotherapeutic agents and TURBT?

- How do adverse effects of treatment vary by patient characteristics, such as age, sex, ethnicity, performance status, or medical connorbidities such as chronic kidney disease?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Population(s)

- For KQ 1, 6, and 7: Adults with signs or symptoms of possible bladder cancer (e.g., gross or microscopic hematurla, irritative voiding symptoms)
- For KQ 2: Adults with non-muscle-invasive bladder cancer (stages Ta, Tis, or Ti)
- For KQ 3 and 8: Adults with non-muscle invasive bladder cancer treated with TURBT
- For KQ 4 and 8: Adults with high-risk non-muscle invasive bladder cancer treated with TURBT
- For KQs 1 and 5 through 7: Adults undergoing surveillance following treatment for non-muscle invasive bladder cancer

Interventions

- For KQ 1, 5, and 7: Urinary biomarkers [a]
- For KQ 2: Risk-adapted treatment approaches
- For KQ 3a, 3b, 3c, 3d, and 8: Intravesical chemotherapeutic or immunotherapeutic agents [b]
- For KQ 4: External beam radiation therapy, with or without systemic chemotherapy or immunotherapy
- For KQ 6: Blue light or other methods of augmented cystoscopy

Comparators

- For KQ 1, 5, and 7: Other urinary biomarkers or standard diagnostic methods (cystoscopy, cytology, and imaging)
- For KQ 2: Treatment not guided by risk-adapted approach
- For KQ 3a, 3b, 3c, 3d, and 8: Other intravesical chemotherapeutic or innmunotherapeutic agent, different dose or duration of intravesical chemotherapy or immunotherapy, or transurethral resection of bladder tumor (TURBT) alone
- For KQ 4: Intravesical chemotherapeutic or immunotherapeutic agents or cystectomy

Outcomes

- For KQ 1 and 5: Diagnostic accuracy, using cystoscopy with biopsy as the reference standard
- For KQ 2, KQ 3, KQ 4, KQ 5: Mortality, disease-specific and all-cause
- For KQ 2, KQ 3, KQ 4, KQ 5: Need for cystectomy
- For KQ 2, KQ 3, KQ 4, KQ 5, KQ 6: Recurrence of cancer
- For KQ 2, KQ 3, KQ 4, KQ 5: Progression of cancer
- For KQ 2, KQ 3, KQ 4, KQ 5: Quality of life
- For KQ 7: Adverse effects of diagnostic testing (e.g., false-positives, labeling, anxiety, complications of cystoscopy)
- For KQ 8: Adverse effects of treatment (e.g., cystitis, urinary urgency, urinary frequency, incontinence, hematuria, pain, urosepsis, myelosuppression

Timing

Any duration of follow-up

Settings

- Inpatient settings
- Outpatient settings

[a] Restricted to tests that are approved for diagnosis of bladder cancer by the U.S. Food and Drug Administration (BTAstat® [BTA], Alere NMP228, BladderChek® [NMP22], UroVysion® [FISH] and ImmunoCytrm [immunocytology]) or available in the U.S. and classified as a Laboratory Developed Test by the FDA (CxBladderrm).

[b] Chemotherapeutic and immunotherapeutic agents of interest include: mitomycin; apaziquone; paclitaxel; gemcitabine; thiotepa; valrubicin; doxorubicin; bacillus Calnnette-Guerin (BCG); and interferon.

Dated: August 26, 2014.

Richard Kronick,

AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–14AAO]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Testing Act Early Messages and Materials for ''Learn the Signs. Act Early.''—Phase II,—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC initiated the ''Learn the Signs. Act Early.'' (LTSAE) campaign in 2004 in an effort to improve the likelihood that children with developmental disabilities are identified and connected with appropriate services at the earliest age possible. To this end, the campaign's overall goal has been to empower parents to ''Act Early'' if they have concerns about their child's development. Children from families insured by Medicaid and those from families with low incomes are at higher risk for developmental delays and disabilities, and thus are the target audience for the campaign.

The study described in this information collection request seeks to assess the impact of ''Act Early'' messages embedded within LTSAE campaign materials. To achieve this goal, we will work with our contractor, Westat, to test revised draft messages and materials with low-income parents through focus groups and intercept interviews administered via the web on a tablet device. Parents/guardians who are age 18–55 and who have children age 5 or younger will recruited from six primary care practices (3 in the Baltimore, Maryland metropolitan area and 3 in the Atlanta, Georgia metropolitan area) to participate in focus groups followed by an intercept interview.

Selected primary care practices will see children as part of their patient population and consist of a substantial number of low income families. Each of the six selected practices will receive study promotional materials, including a poster to hang in the office and waiting room as well as handouts to leave at the front desk. These materials will advertise the focus groups and outline eligibility criteria.

Parents interested in participating will be advised to call an 800 number to be screened and scheduled for a group discussion (if eligible). The 800 number will be staffed by the Westat study team who will be responsible for screening and scheduling. Representatives from each of the practices will be provided with brief ''talking points'' and study FAQs to refer to if interested parents have any basic questions about the study. It is estimated that 80 respondents will have to be screened in order to recruit 40 participants for the focus groups.

The focus groups will have 10 participants each. Four focus groups will be conducted in two locations (the metropolitan areas of Atlanta, Georgia and Baltimore, Maryland) with a total of 40 participants. Parents/guardians will be asked to complete an informed consent, which will take approximately 15 minutes to review and the focus group discussion using the moderator's guide will take 60 minutes to complete. Both of these focus group activities will have a total burden of 50 hours.

We plan to conduct a total of 40 intercept interviews. The intercept interviews will take place in the waiting rooms or right outside the waiting rooms. Parents will be recruited as they are waiting for their appointment. It is estimated that 80 respondents will have to be screened in order to recruit 40 participants. Twenty interviews will be conducted in each of two locations (Atlanta, Georgia and Baltimore, Maryland). The intercept interview will be conducted as a computer-assisted personal interviewing (CAPI) and will take each respondent approximately 15 minutes to complete, for an estimated total burden of 10 hours.

The total estimated burden for this data collection is 74 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response in hours)
Parents/Guardians	Focus Group Screener	80	1	5/60
Parents/Guardians	Focus Group Informed Consent	40	1	15/60
Parents/Guardians	Focus Group Moderator's Guide	40	1	1
Parents/Guardians	Intercept Interview Screener	80	1	5/60