

article published in 2013 in Medical Care Research and Review is available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3959996/>. Given the importance of care coordination for stakeholders and patients, AHRQ proposes to add a composite measure to the CG-CAHPS core survey. Since two of the items are already part of the core survey, this new composite requires the addition of only one item to the core survey.

The new three-item care coordination composite would consist of “Follow up on test results” (from the CG-CAHPS core survey), “Knows important information about medical history” (from the CG-CAHPS core survey), and “Provider talked about all prescription medicines being taken” (from the PCMH Item Set).

With these changes, including the addition of the care coordination measure, the final core CG-CAHPS Survey will be reduced from 34 items to 31 items.

#### **Patient-Centered Medical Home (PCMH) Item Set**

The PCMH Item Set is a collection of supplemental items that ask about experiences with the domains of a medical home. The combination of the core CG-CAHPS Survey with the PCMH Item Set constitutes the CAHPS PCMH Survey. The PCMH Survey has been used by the National Committee for Quality Assurance (NCQA) as part of its PCMH Recognition Program (see below, Related Efforts). AHRQ proposes the following changes to the PCMH Item Set.

**Shared decision making:** AHRQ proposes moving three items to the general set of supplemental items. Rationale: The items require large sample sizes to achieve acceptable unit-level reliability.

**Self-management support:** AHRQ proposes retaining two items. Rationale: While reliability estimates were mixed for different data sets, stakeholders have deemed these items critical to PCMH Item Set.

**Attention to mental or emotional health:** AHRQ proposes retaining one item “Things that cause worry or stress” and moving the other two items—“Depression screening” and “Personal or family problems”—to the general set of supplemental items. Rationale: AHRQ agrees with NCQA’s view that three items are not necessary to capture comprehensiveness. The retained item is most correlated with the overall composite.

**Information on getting care on evenings, weekends, and holidays:** AHRQ proposes retaining this item,

which is also regarded by NCQA’s stakeholders as critical for inclusion for PCMH Item Set.

**Getting care on evenings, weekends, and holidays:** AHRQ proposes moving this item to the general set of supplemental items. Rationale: The number of responses in most practice-based surveys is insufficient to achieve reliability.

**Days wait for urgent care:** AHRQ proposes moving this item to the general set of supplemental items. Rationale: AHRQ supports NCQA’s proposal regarding this item.

**Reminders between visits:** AHRQ proposes moving this item to the general set of supplemental items. Rationale: AHRQ supports NCQA’s proposal regarding this item.

**Care coordination items:** The PCMH Item Set includes two items related to care coordination. These items did not combine to form a composite measure. As noted above, AHRQ proposes moving the item “Provider talked about all the prescription medicines being taken” into the core survey for the new measure of care coordination. AHRQ also proposes changing the current, “Yes-No response”, scale for this item to a, “Never/Sometimes/Usually/Always” frequency response, scale. The second item, “Provider informed and up-to-date on care from specialists” would remain in the PCMH Item Set.

#### **Related Efforts**

AHRQ has been working closely with the CMS, our Federal partner in the CAHPS Consortium, throughout this process to achieve alignment with the CAHPS Survey for ACOs and the CAHPS for PQRS Survey. For specific questions about these surveys, contact the ACO CAHPS team at [acocahps@hcqis.org](mailto:acocahps@hcqis.org) or 1-855-472-4746 or the PQRS CAHPS team at [pqrscahps@hcqis.org](mailto:pqrscahps@hcqis.org).

As noted, NCQA currently uses the CAHPS PCMH Survey as part of its PCMH Recognition Program. NCQA has issued a separate proposal for changes to the survey that may be used for the PCMH program in the future. For specific questions about the use of the PCMH Survey by NCQA, contact their customer support at (888) 275-7585 or [customersupport@ncqa.org](mailto:customersupport@ncqa.org).

Dated: January 13, 2015.

**Richard Kronick,**  
AHRQ Director.

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**BILLING CODE 4160-90-M**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Agency for Healthcare Research and Quality**

#### **Scientific Information Request on Imaging for Pretreatment Staging of Small Cell Lung 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 Imaging for Pretreatment Staging of Small Cell Lung Cancer, which is currently being conducted by the AHRQ’s Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

**DATES:** Submission Deadline on or before February 20, 2015.

#### **ADDRESSES:**

*Online submissions:* <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-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](mailto: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](mailto:SIPS@epc-src.org).

**SUPPLEMENTARY INFORMATION:** The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for Imaging for Pretreatment Staging of Small Cell Lung Cancer.

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 Imaging for Pretreatment Staging of Small Cell Lung 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=2020>.

This notice is to notify the public that the EPC Program would find the following information on Imaging for Pretreatment Staging of Small Cell Lung 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, 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 EPC 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 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 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.AHRQ.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 available online at: <http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2020>.

### The Key Questions

#### Question 1

What are the test concordance and comparative accuracy of imaging tests (MDCT, PET/CT, MRI, PET/MRI, EBUS, EUS, bone scintigraphy) for the pretreatment staging of small cell lung cancer?

- Test concordance
- Sensitivity
- Specificity
- Positive Predictive Value
- Negative Predictive Value
- Positive Likelihood Ratio
- Negative Likelihood Ratio

#### Question 2

When used for the pretreatment staging of small cell lung cancer, what is the comparative effectiveness of imaging tests (MDCT, PET/CT, MRI, PET/MRI, EBUS, EUS, bone scintigraphy) on later outcomes?

- Choice of treatment (e.g., surgery, chemotherapy, radiation)
- Timeliness of treatment
- Tumor response
- Harms due to overtreatment or undertreatment
- Survival
- Quality of life

#### Question 3

To what extent are the following factors associated with the comparative accuracy or effectiveness of imaging tests (MDCT, PET/CT, MRI, PET/MRI, EBUS, EUS, bone scintigraphy) when used for the pretreatment staging of small cell lung cancer?

- comorbidities
- body habitus
- tumor characteristics

PICOTS (Population, Intervention, Comparator, Timing, Setting)  
Population(s)  
Adults with diagnosed SCLC or combined SCLC

### Interventions

- Any of the following imaging tests when used for pretreatment staging:
  - MDCT
  - PET/CT
  - MRI
  - PET/MRI
  - EBUS
  - EUS
  - Bone scintigraphy

### Comparators

- Single test (one of the above) vs. single test (another one of the above)
- Single test (one of the above) vs. single test (a specific variant of the same modality)
- Single test (one of the above) vs. multiple tests (more than one of the above)
- Multiple test (more than one of the above) vs. other multiple tests (more than one of the above)
- Test comparisons for patients with comorbid illnesses vs. those without (KQ3)
- Test comparisons at different levels of body habitus (KQ3)
- Test comparisons for different tumor characteristics (KQ3)

### Outcomes

- Intermediate outcomes
  - Test concordance (the percentage of patients for whom two imaging tests give the same result or different results)
  - Sensitivity (KQ1 and KQ3) (separately for different portions of the anatomy such as mediastinal lymph nodes, brain, etc.)
  - Specificity (KQ1 and KQ3) (separately for different portions of the anatomy such as mediastinal lymph nodes, brain, etc.)
  - Timeliness of treatment (KQ2 and KQ3)
  - Choice of treatment (KQ2 and KQ3)
  - Tumor response (KQ2 and KQ3)
- Patient-centered outcomes
  - Survival (KQ2 and KQ3)
  - Quality of life (KQ2 and KQ3)
  - Harms due to overtreatment or undertreatment (KQ2 and KQ3)

### Timing

- For test concordance: no minimum follow-up
- For accuracy: no minimum follow-up
- For timeliness of treatment, timing is the outcome itself
- For choice of treatment, no minimum follow-up

- For tumor response, no minimum follow-up
- For harms due to overtreatment or undertreatment, no minimum follow-up
- For survival and quality of life, at least six months minimum follow-up

#### Setting

Any setting.

Dated: December 29, 2014.

**Richard Kronick,**

*AHRQ Director.*

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**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Scientific Information Request on Treatments for Fecal Incontinence

**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 Treatments for Fecal Incontinence, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

**DATES:** Submission Deadline on or before February 20, 2015.

#### ADDRESSES:

*Online submissions:* <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-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](mailto: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](mailto:SIPS@epc-src.org).

#### SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for Treatments for Fecal Incontinence.

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 Treatments for Fecal Incontinence, 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=2013>.

This notice is to notify the public that the EPC Program would find the following information on Treatments for Fecal Incontinence (FI) 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](http://ClinicalTrials.gov) along with the [ClinicalTrials.gov](http://ClinicalTrials.gov) trial number.

- For completed studies that do not have results on [ClinicalTrials.gov](http://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](http://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 EPC 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 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 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.AHRQ.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 available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2013>.

#### The Key Questions

##### Key Question 1

What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of FI in affected adults?

##### Key Question 2

What adverse effects are associated with specific treatments for adults with FI?

#### PICOTS

The PICOTS Framework (Population, Intervention, Comparator, Outcomes, Timing, Setting) will be identified for each key question.

#### Population

We will include adults with FI and classify them within the etiologic categories listed below, and by adult age groups (geriatric versus other). Whenever possible, we will examine treatment effects within etiologic subgroups of adults, since affected individuals are highly heterogeneous and not all treatments are feasible for specific subgroups. Patients with FI due to spinal cord injury will be separately evaluated. Adults with fistulas will be excluded. The possible associations of