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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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

E-mail 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 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 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 e-mail 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 potions of the anatomy such as mediastinal lymph nodes, brain, etc.)
    - Specificity (KQ1 and KQ3) (separately for different potions 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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