will be included
- For bone health outcomes, only RCTs of greater than 1 year in duration will be included

Comparators

- As described for KQ 1.

Outcomes

- As specified in the original 2009 report, unless otherwise noted:
  - CVD intermediate outcomes
  - Cancer intermediate outcomes (colorectal adenoma, aberrant crypt cells, and mammographic breast density)
  - Bone health intermediate outcomes (only bone mineral density/content)
  - Pregnancy-related intermediate outcomes
  - Pre-eclampsia
  - High blood pressure with or without proteinuria

Timing

- As described for KQ 1, except for intermediate bone health for which studies of less than 1 year in duration will be excluded.

Settings

- As described for KQ 1.

Key Question 3

What is the association between serum 25(OH)D concentrations and clinical outcomes?*

Populations

- As described for KQ 1.

Interventions

- Serum concentration of 25(OH)D or 1,25 (OH)2D and the method used.

Comparators

- The serum concentration of 25(OH)D or 1,25 (OH)2D and the method used for the placebo or other comparison group.

Outcomes

- As described for KQ 1.

Timing

- As described for KQ 1.

Settings

- As described for KQ 1.

Key Question 4

What is the effect of vitamin D or combined vitamin D and calcium intake on serum 25(OH)D concentrations?

Populations

- As described for KQ 1.

Interventions

- Randomized controlled trials (RCTs) identified to answer all other KQs.

Comparators

- Placebo or lower dose supplement.

Outcomes

- Dose-response relationship between intake levels and indices of exposure.

Timing

- As described for KQs 1 and 2.

Settings

- As described for KQs 1 and 2.

Key Question 5

What is the association between serum 25(OH)D concentration and surrogate or intermediate outcomes?

Populations

- As described for KQ 2.

Interventions

- As described for KQ 2.

Comparators

- As described for KQ 2.

Outcomes

- As described for KQ 2.

Timing

- As described for KQ 2.

Settings

- As described for KQ 2.

Dated: July 11, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–17177 Filed 7–17–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Imaging Tests for the Staging of Colorectal 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 on imaging tests for the staging of colorectal cancer (e.g., Chest x-ray, computed tomography, multidetector computed tomography (MD–CT), CT colonography, magnetic resonance imaging (MRI), transabdominal ultrasound (TUS), endoscopic ultrasound (EUS), transrectal ultrasound (TRUS), positron emission tomography (PET), positron emission tomography combined with computed tomography (PET/CT fusion), or positron emission tomography combined with magnetic resonance imaging (PET/MRI fusion)) from medical device manufacturers. Scientific information is being solicited to inform our Comparative Effectiveness Review of Imaging Tests for the Staging of Colorectal Cancer, which is currently being conducted by one of the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on these devices will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness 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).

AHRQ is republishing this document due to errors found on our first publication of June 27, 2013 (*http://www.gpo.gov/fdsys/pkg/FR-2013-06-27/pdf/2013-15288.pdf*). Please disregard the June 27 publication.

DATES: *Submission Deadline by July 29, 2013.*

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.

Print submissions: Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. 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: Robin Paynter, Research Librarian, Telephone: 503–220–8262 ext. 58652 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned one of the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness

review of the evidence for *Imaging Tests for the Staging of Colorectal 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 systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on *Imaging Tests for the Staging of Colorectal Cancer,* including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1510.*

This notice is a request for information about the following:

- A list of all completed studies your company has sponsored for this indication, and if *the results are available on ClinicalTrials.gov along with the CT.gov trial number.*
- For *completed studies that do not have results on CT.gov,* a summary that includes 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, and effectiveness/efficacy and safety results.
- In addition, *ongoing studies your company has sponsored for this indication.* In the list, please provide the CT.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.

Your contribution is very beneficial to this program. The contents of all submissions will be available to the public upon request. Materials submitted must be publicly available or materials that can be made public. Materials that are considered confidential; marketing materials; pharmacoeconomic, pharmacokinetic or pharmacodynamic studies; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care 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.AHRQ.gov/index.cfm/join-the-email-list1/.*

Key Question 1

What is the comparative effectiveness of imaging techniques for pretreatment staging of patients with primary and recurrent colorectal cancer?

a. What is the test performance of the imaging techniques used (singly, in combination, or in a specific sequence) to stage colorectal cancer when compared with a reference standard?

b. What is the impact of alternative imaging techniques on intermediate outcomes, including stage reclassification and changes in therapeutic management?

c. What is the impact of alternative imaging techniques on clinical outcomes?

d. What are the adverse effects or harms associated with using imaging techniques, including harms of test-directed management?

e. How is the comparative effectiveness of imaging techniques modified by the following factors:

i. Patient-level characteristics (e.g., age, sex, body mass index)

ii. Disease characteristics (e.g., tumor grade)

iii. Imaging technique or protocol characteristics (e.g., use of different tracers or contrast agents, radiation dose of the imaging modality, slice thickness, timing of contrast)

Key Question 2

What is the comparative effectiveness of imaging techniques for restaging patients with primary and recurrent colorectal cancer after initial treatment?

a. What is the test performance of the imaging techniques used (singly, in combination, or in a specific sequence) to restage colorectal cancer when compared with a reference standard?

b. What is the impact of alternative imaging techniques on intermediate outcomes, including stage reclassification and changes in therapeutic management?

c. What is the impact of alternative imaging techniques on clinical outcomes?

d. What are the adverse effects or harms associated with using imaging techniques, including harms of test-directed management?

e. How is the comparative effectiveness of imaging techniques modified by the following factors:

i. Patient-level characteristics (e.g., age, sex, body mass index)

ii. Disease characteristics (e.g., tumor grade)

iii. Imaging technique or protocol characteristics (e.g., use of different tracers or contrast agents, radiation dose of the imaging modality, slice thickness, timing of contrast)

PICOTS Criteria (Population, Intervention, Comparator, Outcomes, Timing, Setting)

Populations

- Adult patients with an established diagnosis of primary colorectal cancer
- Adult patients with an established diagnosis of recurrent colorectal cancer

Interventions

Noninvasive imaging using the following tests (alone or in combination) to assess the stage of colorectal cancer:

- CT
- PET/CT
- MRI
- Endoscopic ultrasound

Combinations of particular interest include endoscopic ultrasound to evaluate the T stage combined with PET/CT or CT to evaluate the N and M stages.

Reference Standards To Assess Test Performance

- Histopathological examination of tissue
- Intraoperative findings
- Clinical followup

Histopathology of surgically resected specimens is the reference standard for pretherapy staging. In patients undergoing surgery, the nodal (N) stage and spread of the tumor to nearby regional structures and other organs is assessed intraoperatively, either by palpation or ultrasound. However, in patients with metastatic disease who undergo palliative care, a combination of initial biopsy results and clinical followup serves as the reference standard.

Clinicians use the results from the imaging modality or modalities to arrive at a stage determination that is compared against the stage established by the reference standard. These comparisons tell us how many people were correctly classified in the various stages of the disease and allow us to calculate the test performance metrics of sensitivity, specificity, and accuracy. The selection of the reference standard is important in evaluating the true performance of an imaging modality for staging.

Comparators

- Any direct comparisons of the imaging tests of interest
- Any direct comparisons of variations of any of the imaging tests of interest (e.g., diffusion-weighted MRI vs. T2-weighted MRI)

Comparators thought to be of particular clinical interest are listed below:

- For colon cancer: A contrast-enhanced CT of the chest, abdomen, and pelvis versus whole-body PET/CT versus a contrast-enhanced MRI of the chest, abdomen, and pelvis
- For rectal cancer: A contrast-enhanced CT of the abdomen and pelvis versus an MRI of the abdomen and pelvis
- For rectal cancer: Endoscopic ultrasound versus MRI
- For suspected liver metastasis: CT scan versus MRI or PET/CT of the abdomen
- For suspected widespread metastasis, CT of the chest, abdomen, and pelvis versus whole-body PET/CT or contrast-enhanced MRI of the chest, abdomen, and pelvis

We note that this list is based on a preliminary literature search and discussions with a limited number of clinicians and the Technical Expert Panel (TEP). Thus, we do not anticipate that the listed items cover all of the comparisons of interest. We expect that additional comparisons will be identified during the literature review.

Outcomes

- Test performance outcomes.
  - Test performance (e.g., sensitivity, specificity, understaging, and overstaging) against a reference standard test (pathological examination, intraoperative findings, clinical followup).
- Intermediate outcomes.
  - Stage reclassification.
  - Changes in therapeutic management.
- Clinical outcomes.
  - Overall mortality.
  - Colorectal cancer–specific mortality.
  - Quality of life and anxiety.
  - Need for additional staging tests, including invasive procedures.
  - Need for additional treatment, including surgery, radiotherapy, or chemotherapy.
  - Resource utilization related to testing and treatment (when reported in the included studies).
  - Adverse effects and harms.
  - Harms of testing per se (e.g., radiation exposure).
  - Harms from test-directed treatments (e.g., overtreatment, undertreatment).

Timing

- Primary staging.
- Interim restaging.
- Duration of followup will vary by outcome (e.g., from no followup for test performance measurements to many years for mortality).

Setting

- Any setting will be considered.

Dated: July 11, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–17176 Filed 7–17–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0307]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

The Gonococcal Isolate Surveillance Project (GISP), OMB No. 0920–0307 exp. 12/31/2013)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain Office of Budget and Management (OMB) approval to revise the data collection for the Gonococcal Isolate Surveillance Project (GISP) (OMB No. 0920–0307, expires 12/31/2013). CDC seeks a three-year approval to conduct the GISP project. Revisions to this ICR consist of removing 4 variables from Form 1: Demographic/Clinical Data. The four variables to be removed are: (1) Total monthly number of gonococcal infections; (2) date of birth of the patient; (3) zip code of the patient; and (4) reason for visit. The variables to be removed have not proven useful at the federal level and removal of the variables will not increase or decrease the burden. The objectives of GISP are: (1) To monitor trends in antimicrobial susceptibility of strains of *Neisseria gonorrhoeae* in the United States and (2) to characterize resistant isolates. Surveillance of *N. gonorrhoeae* antimicrobial resistance is important because: (1) Nearly all gonococcal infections are treated empirically and susceptibility testing data are not routinely available in clinical practice; (2) *N. gonorrhoeae* has consistently demonstrated the ability to develop resistance to the antimicrobials used for treatment; (3) effective treatment of gonorrhea is a critical component of gonorrhea control and prevention, and (4) untreated or inadequately treated gonorrhea can cause serious reproductive health complications. GISP is the only source in the United States of critical national, regional, and site-specific gonococcal antimicrobial resistance data. GISP provides information to support informed and scientifically-based treatment recommendations.

GISP was established in 1986 as a voluntary surveillance project and now involves 5 regional laboratories and 30 publicly funded sexually transmitted disease (STD) clinics around the country. The STD clinics submit up to 25 gonococcal specimens (or isolates) per month to the regional laboratories, which measure susceptibility of the isolates to multiple antimicrobial drugs. Limited demographic and clinical information corresponding to the isolates (and that do not allow identification of the patient) are submitted directly by the clinics to CDC.

During 1986–2012, GISP has demonstrated the ability to effectively achieve its objectives. The emergence of resistance in the United States to penicillin, tetracyclines, and fluoroquinolones among *N. gonorrhoeae* isolates was identified through GISP. Increased prevalence of fluoroquinolone-resistant *N. gonorrhoeae* (QRNG), as documented by GISP data, prompted CDC to update treatment recommendations for gonorrhea in CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006 and to release an MMWR article stating that CDC no longer recommended fluoroquinolones for treatment of gonococcal infections. Recently, GISP isolates demonstrated increasing minimum inhibitory concentrations of cefixime, which can be an early warning of impending