OPA will utilize these data in three main ways:

First, OPA needs to prepare grantees and Title X centers to respond to changes in the health system. As more individuals obtain health insurance, OPA needs to understand how individual Title X centers may be affected. Second, OPA invests in national training centers that are charged with providing national training, resources and technical assistance to grantees. Data collected from this effort will be used to inform the work of the training centers so they can better support the Title X grantees. Third, this data will help OPA better understand challenges affecting Title X centers in order to better work with HHS entities and national stakeholders to provide resources to Title X centers. Data will be collected through an online data collection tool directly from grantees and from Title X centers.

Likely Respondents: This annual reporting requirement is centers that receive funding (either directly from OPA or through a subrecipient or grantee agency) for family planning services authorized and funded by the Title X Family Planning Program [''Population Research and Voluntary Family Planning Programs'' (Pub. L. 91–572)], which was enacted in 1970 as Title X of the Public Health Service Act (Section 1001 of Title X of the Public Health Service Act, 42 United States Code [U.S.C.] 300).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information.

Based on some pilot work, the total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average annualized burden per response (hours)	Annualized total burden (hours)
Grantees	Sustainability Assessment—Grantees.	92	1	0.66	60.72
Service Sites	Sustainability Assessment—Sites	4,168	1	0.66	2,750.88
Totals		4,260			2811.60

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015–01099 Filed 1–22–15; 8:45 am]

BILLING CODE 4150–48–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Noninvasive Testing for Coronary Artery Disease

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 ''Noninvasive Testing for Coronary Artery Disease'', 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 23, 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.

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 ''Noninvasive Testing for Coronary Artery Disease''.

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 ''Noninvasive Testing for Coronary Artery Disease'', 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=2017.*

This notice is to notify the public that the EPC Program would find the following information on ''Noninvasive Testing for Coronary Artery Disease'' 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=isplayproduct&productID=2017.*

The Key Questions

In stable, symptomatic patients with suspected coronary artery disease (CAD) who do not have previously diagnosed CAD and who have had a resting electrocardiogram (ECG):

1. For patients considered to be *at very low or low risk* for CAD, what is the comparative effectiveness of anatomic tests (compared with each other, standard of care, or no testing):

(a) For improving primary clinical health outcomes (*e.g.,* quality of life, avoiding myocardial infarction)? In the absence of comparative studies linking testing with outcomes, do the tests predict future clinical events (predictive accuracy)?

(b) What are the adverse effects, consequences, or harms of testing?

(c) How do noninvasive tests differ in terms of clinical management based on test results, including referral for coronary angiography or additional noninvasive testing?

(d) What harms are associated with additional testing following anatomic tests?

(e) Is there differential effectiveness or harm based on patient characteristics (*e.g.,* sex, age, comorbidities)?

2. For patients considered to be at *very low or low risk* for CAD, what is the comparative effectiveness of functional tests (compared with each other, standard of care, or no testing):

(f) For improving primary clinical health outcomes (*e.g.,* quality of life, avoiding myocardial infarction)? In the absence of comparative studies linking testing with outcomes, do the tests predict future clinical events (predictive accuracy)?

(g) What are the adverse effects, consequences or harms of testing?

(h) How do noninvasive tests differ in terms of clinical management based on test results, including referral for coronary angiography or additional noninvasive testing?

(i) What harms are associated with additional testing following anatomic tests?

(j) Is there differential effectiveness or harm based on patient characteristics (*e.g.,* sex, age, comorbidities) or the patient's ability to exercise?

3. For patients considered to be at *intermediate to high risk* for CAD, what is the comparative effectiveness of anatomic tests (compared with each other standard of care, or no testing):

(k) For improving primary clinical health outcomes (*e.g.,* quality of life, avoiding myocardial infarction)? In the absence of comparative studies linking testing with outcomes, do the tests predict future clinical events (predictive accuracy)?

(l) What are the adverse effects, consequences, or harms of testing?

(m) How do noninvasive tests differ in terms of clinical management based on test results, including referral for coronary angiography or additional noninvasive testing?

(n) What harms are associated with additional testing following anatomic tests?

(o) Is there differential effectiveness or harm based on patient characteristics (*e.g.,* sex, age, comorbidities)?

4. For patients considered to be at *intermediate to high risk* for CAD, what is the comparative effectiveness of functional tests (compared with each other, standard of care, or no testing):

(p) For improving primary clinical health outcomes (*e.g.,* quality of life, avoiding myocardial infarction)? In the absence of comparative studies linking testing with outcomes, do the tests predict future clinical events (predictive accuracy)?

(q) What are the adverse effects, consequences, or harms of testing?

(r) How do noninvasive tests differ in terms of clinical management based on test results, including referral for coronary angiography or additional noninvasive testing?

(s) What harms are associated with additional testing following anatomic tests?

(t) Is there differential effectiveness or harm based on patient characteristics (*e.g.,* sex, age, comorbidities) or the patient's ability to exercise?

5. What is the comparative effectiveness of anatomic tests versus functional tests in those who are at *very low or low risk* for CAD?

(u) For improving primary clinical health outcomes (*e.g.,* quality of life, avoiding myocardial infarction)?

(v) What are the adverse effects, consequences or harms of testing?

(w) How do noninvasive tests differ in terms of clinical management based on test results, including referral for coronary angiography or additional noninvasive testing?

(x) What harms are associated with additional testing following anatomic tests?

(y) Is there differential effectiveness or harm based on patient characteristics (*e.g.,* sex, age, comorbidities) or the patient's ability to exercise?

6. What is the comparative effectiveness of anatomic tests versus functional tests in those who are at *intermediate to high risk* for CAD?

(z) For improving primary clinical health outcomes (*e.g.,* quality of life, avoiding myocardial infarction)?

(aa) What are the adverse effects, consequences or harms of testing?

(bb) How do noninvasive tests differ in terms of clinical management based on test results, including referral for coronary angiography or additional noninvasive testing?

(cc) What harms are associated with additional testing following anatomic tests?

(dd) Is there differential effectiveness or harm based on patient characteristics (*e.g.,* sex, age, comorbidities) or the patient's ability to exercise?

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

Patient Population of Interest and Pre-Test Risk of CAD:

The patient population is stable, symptomatic patients with suspected CAD who do not have previously diagnosed CAD and who have had a resting ECG. The definitions of risk categories are based on those described in the ACCF/AHA 2012 Guideline.[8] In general, patient presentation and symptoms are primarily used to inform pre-test probability in the population of interest. The review will attempt to stratify studies based on these characteristics if definitions are not provided.

- Include patients whose risk for CAD may be considered as follows:
  - Those considered to be at *very low or low risk* of CAD based on having none or only one of the following:
    - Patient age and gender (female <65 years old, male <55 years old)
    - Negative family history for CAD
    - <2 CAD risk factors (including hypertension, diabetes, smoking, dyslipidemia, metabolic syndrome)
    - New onset angina/chest pain (including noncardiac or atypical chest pain, angina equivalents, unstable angina without non-ST-segment elevation myocardial infarction [NSTEMI], ST-segment elevation myocardial infarction [STEMI])
    - Normal or non-diagnostic resting ECG
  - Those considered to be at *intermediate to high risk* of CAD based on having two or more of the following:
    - Patient age and gender (female ≥65 years old, male ≥55 years old)
    - Positive family history for CAD
    - ≥2 CAD risk factors (including hypertension, diabetes, smoking, dyslipidemia, metabolic syndrome)
    - New onset or progressive angina/chest pain or those with prolonged angina at rest (or relieved with rest or nitroglycerin) or nocturnal angina (angina including typical, atypical, definite, probable)
    - Possible ECG changes (*e.g.,* T-wave, NSTEMI) or nondiagnostic ECG
    - Presence of other vascular disease (carotid disease, peripheral artery disease [PAD])
    - Exclude patients with any of the following characteristics:
      - Unstable angina with elevated serum cardiac biomarkers, ECG changes, etc.
      - Definite acute coronary syndrome (ACS), Non-ST-Elevation Acute Coronary Syndromes (NSTE–ACS), NSTEMI, STEMI
      - Asymptomatic patients, including those being screened prior to surgery

Interventions

This systematic review will focus on widely available noninvasive tests used for diagnosis of CAD or dysfunction that results in symptoms attributable to myocardial ischemia. Coronary artery calcium scoring has been included since it has been proposed primarily for its ability to exclude the presence of obstructive disease but not necessarily to confirm the presence of flow-limiting stenosis.

Interventions for inclusion are:

- Functional tests (including exercise, vasodilator and/or dobutamine as stressor where appropriate)
  - Exercise electrocardiogram without imaging
  - Exercise/pharmacologic echocardiography (with or without myocardial echo contrast)
  - Exercise/pharmacologic cardiac nuclear imaging
    - SPECT
    - PET
    - Pharmacologic stress MRI
    - CT perfusion
- Anatomic imaging
  - Coronary calcium scoring via electron beam CT (EBCT) or multidetector CT (MDCT)
    - CCTA

Comparators

Comparisons between noninvasive tests included in the interventions; comparisons with no testing or standard of care. (Contextual information will be provided in the background only for comparisons of noninvasive tests with invasive coronary angiography with or without FFR and for comparison between noninvasive tests on traditional diagnostic test measures such as sensitivity and specificity.)

Outcomes

- Clinical outcomes
  - Quality of life (QOL)
  - Change in angina (*e.g.,* worsening)
  - MI
  - Heart failure
  - Stroke
  - Death
  - Hospitalization for cardiovascular events (acute coronary syndrome, heart failure, arrhythmias)
  - Dysrhythmia
- Intermediate outcomes
  - Need for additional testing (including referral for invasive testing)
  - Management based on revised post-test risk stratification, including:
    - Guideline-directed medical therapy (GDMT), including management of lipids, blood pressure, and diabetes; counseling related to diet, physical activity, smoking cessation, alcohol use, and management of psychological factors; use of additional therapies to reduce risk of MI and death (*e.g.,* antiplatelet therapy).
    - Any need for subsequent revascularization (percutaneous coronary intervention [PCI] or coronary artery bypass grafting [CABG])
    - Harms, risks and consequences of testing
      - Procedural harms, adverse events of testing (*e.g.,* renal failure, allergy, nephrogenic systemic fibrosis, contrast-related harms, adverse reactions to drugs for stress tests), vascular complications
      - Consequences of testing (*e.g.,* radiation exposure, psychological consequences, consequences of additional testing or incidental findings)

Setting

Nonemergent inpatient settings or ambulatory/outpatient settings, including emergency department.

Timing

At time of first test for evaluation using a noninvasive test other than resting ECG.

Dated: December 29, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2015–00763 Filed 1–22–15; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Strategies to Treat and Manage Infantile Hemangioma

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

ACTION: Request for Scientific Information Submissions.