(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.

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 Strategies to Treat and Manage Infantile Hemangioma, 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, 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 71m 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 Strategies to Treat and Manage Infantile Hemangioma.

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 *Strategies to Treat and Manage Infantile Hemangioma,* 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=2016.*

This notice is to notify the public that the EPC Program would find the following information on *Strategies to Treat and Manage Infantile Hemangioma* 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 *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=2016.*

The Key Questions

Our Contextual Questions (CQs) are as follows:

CQ1

What is known about the natural history of infantile hemangiomas, by hemangioma site and subtype? What are the adverse outcomes of untreated infantile hemangiomas? What characteristics of the hemangioma (*e.g.,* subtype, size, location, number of lesions) indicate risk of significant medical complications that would prompt immediate medical or surgical intervention?

CQ2

What is the evidence that five or more cutaneous hemangiomas are associated with an increased risk of occult hemangiomas?

Our Key Questions (KQs) are as follows:

KQ1

Among newborns, infants, and children up to 18 years of age with known or suspected infantile hemangiomas, what is the comparative effectiveness (benefits/harms) of various imaging modalities for identifying and characterizing hemangiomas?

- Does the comparative effectiveness differ by location and subtype of the hemangioma?

KQ2

Among newborns, infants, and children up to 18 years of age with infantile hemangiomas who have been referred for pharmacologic intervention, what is the comparative effectiveness (benefits/harms) of corticosteroids or beta-blockers?

KQ3

Among newborns, infants, and children up to 18 years of age with infantile hemangiomas for whom treatment with corticosteroids or beta-blockers is unsuccessful what is the comparative effectiveness of second line therapies including immunomodulators and angiotensin-converting enzyme inhibitors?

KQ4

Among newborns, infants, and children up to 18 years of age with infantile hemangiomas who have been

referred for surgical intervention, what is the comparative effectiveness (benefits/harms) of various types of surgical interventions (including laser and resection)?

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

KQ 1

Population

Newborns, infants, and children up to 18 years of age with known or suspected infantile hemangiomas.

Intervention(s)

Diagnostic imaging:
- Magnetic resonance imaging
- Computed tomography
- Magnetic resonance angiography
- Echocardiography
- Ultrasonography
- Endoscopy

Comparator

- Other workup evaluation approaches for treatment planning
- Other imaging modalities

Outcomes

- Ability to identify presence, number, and extent of hemangiomas and associated structural anomalies (sensitivity and specificity)
- Harms including, but not limited to, effects of sedation or imaging dye

Timing

- Immediate and short-term (≤3 months)
- Long-term (>3 months)

Setting

Inpatient and outpatient settings (*e.g.,* pediatric radiology clinic, otolaryngology clinics, dermatology clinics, pediatric surgical unit)

KQs 2, 3, and 4

Population

Newborns, infants, and children up to 18 years of age with infantile hemangiomas.

Intervention(s)

KQ2 Pharmacologic interventions
- Systemic (*e.g.,* propranolol) or topical (*e.g.,* timolol) beta-blockers
- Corticosteroids (topical, intralesional, or systemic)

KQ3 Pharmacologic interventions
- Immunosuppressants (*e.g.,* sirolimus)
- Immunomodulators (*e.g.,* imiquimod, interferon)
- Antineoplastics (*e.g.,* intralesional bleomycin, intravenous vincristine)
- Angiotensin-converting enzyme inhibitors
- Antiangiogenic agents

KQ4 Surgical interventions

Laser treatment
- Pulsed dye
- Fractionated laser
- Argon
- Carbon dioxide
- Neodymium (Nd): Yttrium Aluminium Garnet YAG
- Erbium

Surgical treatment
- Cryotherapy
- Resection
- Embolization
- Radiofrequency ablation therapy

Comparator

KQ2, 3
- No treatment
- Other pharmacologic interventions
- Observation
- Complementary and alternative medicine (CAM) (*e.g.,* massage, compression therapy, essential oils)

KQ4
- No treatment
- Other laser or surgical interventions
- Observation
- CAM (*e.g.,* massage, compression therapy, essential oils)

Outcomes

Intermediate outcomes (KQ2, 3, 4)
- Size/volume of hemangioma
- Impact on vision
- Aesthetic appearance as assessed by clinician or parent
- Degree of ulceration
- Harms
- Quality of life

Final outcomes (KQ2, 3, 4)
- Marked improvement of hemangiomas
- Prevention of disfigurement
- Resolution of airway obstruction
- Preservation of vision
- Preservation of organ function (*e.g.,* thyroid function, cardiac function)
- Resolution of ulceration
- Psychological impact on the patient
- Harms including: pain, bleeding, sequelae of scarring, skin atrophy, venous prominence, disfigurement, distortion of anatomic landmarks, ulceration, infection, hypopigmentation

Timing

KQ2, 3
- Immediate and short-term (≤2 years of age)
- Long-term (>2 years of age)

KQ4
- Immediate and short-term (≤3 months)
- Long-term (>3 months)

Setting

Inpatient and outpatient settings (*e.g.,* pediatric radiology clinic, otolaryngology clinics, dermatology clinics, pediatric surgical unit)

Dated: December 30, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2015–00766 Filed 1–22–15; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15LB]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology