genetic testing for CYP2C19 variants predict intermediate and clinical outcomes following treatment initiation?

a. What is the analytic validity (technical test performance) of the various assays used for CYP2C19 genetic testing?

b. What is the clinical validity (predictive accuracy) of genetic testing for predicting intermediate and clinical outcomes in patients who are receiving clopidogrel therapy?

c. Do the following factors modify the association between genetic test results and clinical outcomes?

i. Co-medications.

ii. Patient-level factors (*e.g.,* race or ethnicity, age, sex, disease severity, or comorbidities).

iii. Test-related factors (*e.g.,* between-assay differences).

iv. System-level factors (*e.g.,* settings where testing is performed).

Key Question 2

In patient populations receiving clopidogrel therapy, does phenotypic testing of platelet reactivity predict intermediate and clinical outcomes?

a. What is the analytic validity (technical test performance) of the various assays used in phenotypic testing of platelet reactivity?

b. What is the clinical validity (predictive accuracy) of phenotypic testing for predicting intermediate and clinical outcomes in patients who are receiving clopidogrel therapy?

c. Do the following factors modify the association between phenotypic test results and clinical outcomes?

i. Co-medications.

ii. Patient-level factors (*e.g.,* race or ethnicity, age, sex, disease severity, or comorbidities).

iii. Test-related factors (*e.g.,* between-assay differences).

iv. System-level factors (*e.g.,* settings where testing is performed).

Key Question 3

What is the comparative effectiveness of alternative test-and-treat strategies (including a no-testing strategy) for therapeutic decision making regarding antiplatelet therapy among patients who are candidates for clopidogrel-based treatment?

a. What is the comparative effectiveness of the following testing strategies on therapeutic decision making, platelet reactivity during followup, and clinical outcomes in patients who are candidates for antiplatelet treatment?

i. Genetic testing for CYP2C19.

ii. Genetic testing for CYP2C19 followed by phenotypic testing for platelet reactivity.

iii. Phenotypic testing for platelet reactivity.

iv. No testing.

b. How do modifying factors (*e.g.,* race or ethnicity, age, sex, comorbidities, diet, or the time between conducting the test and obtaining results) affect the association of alternative phenotypic or genetic test-and-treat strategies and patient outcomes? Alternative test-guided treatments can include non-clopidogrel antiplatelet agents or high-dose clopidogrel regimens.

Key Question 4

What are the potential adverse effects or harms from genetic or phenotypic testing per se or from test-directed treatments?

Dated: December 2, 2011.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2011–32047 Filed 12–13–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Intravascular Diagnostic and Imaging Medical Devices

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 manufacturers of intravascular diagnostic and imaging medical devices, including: Fractional Flow Reserve (FFR), Coronary Flow Reserve (CFR), Intravascular Ultrasound (IVUS), Intravascular Ultrasound (VH–IVUS) with Virtual Histology, Optical Coherent Tomography (OCT), Near-Infrared Spectroscopy (NIR), Angioscopy, Intravascular Magnetic Resonance Imaging (MRI), Elastrography, and Thermography. Scientific information is being solicited to inform our Comparative Effectiveness Review of Intravascular Diagnostic Procedures and Imaging Techniques versus Angiography Alone, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device 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.

DATES: Submission Deadline on or before January 13, 2012.

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 of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: (503) 494–0147 or Email: *ehcsrc@ohsu.edu.*

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for intravascular diagnostic procedures and imaging techniques versus angiography alone.

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 intravascular diagnostic and imaging medical devices, 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/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=766#3456.*

This notice is a request for industry stakeholders to submit the following:

• A current product label, if applicable (preferably an electronic PDF file).

• Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.

• Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide 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 withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.

• Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law. 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 Questions

• Key Question 1: For patients undergoing diagnostic coronary angiography to evaluate the presence/extent of Coronary Artery Disease (CAD) in order to decide on the necessity for coronary intervention, what is the impact of using an IVDx technique—when compared to angiography alone—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

• Key Question 2: For patients undergoing Percutaneous Coronary Intervention (PCI), what is the impact of using an Intravascular Diagnostic Device (IVDx) technique to guide the PCI procedure (either immediately prior to or during the procedure)—when compared to angiography-guided PCI—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

• Key Question 3: For patients having just undergone a PCI, what is the impact of using an IVDx technique to evaluate the success of PCI immediately after the procedure—when compared to angiography alone—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

• Key Question 4: How do different IVDx techniques compare to each other in their effects on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

• During diagnostic coronary angiography for the evaluation of the presence/extent of CAD and the potential necessity of coronary intervention?

• During PCI to guide the procedure?

• Immediately after PCI to evaluate the success of PCI?

• Key Question 5: What factors (e.g., patient/physician characteristics, availability of prior noninvasive testing, type of PCI performed) influence the effect of IVDx techniques—when compared to angiography (or among different IVDx techniques)—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

• During diagnostic coronary angiography for the evaluation of the presence/extent of CAD and the potential need for coronary intervention?

• During PCI to guide the procedure?

• Immediately after PCI to evaluate the success of PCI?

Dated: November 23, 2011.

Carolyn M. Clancy,

AHRQ, Director.

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BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12–12BW]

Agency Forms Undergoing Paperwork Reduction Act Review

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 the CDC Reports Clearance Officer at (404) 639–5960 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery—new—Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD).

As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the CDC has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et. seq.*).

To request additional information, please contact Daniel L. Holcomb, Reports Clearance Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.