DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on the Use of Natriuretic Peptide Measurement in the Management of Heart Failure

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 medical device manufacturers of natriuretic peptide measurement assays. Scientific information is being solicited to inform our Comparative Effectiveness Review of Use of Natriuretic Peptide Measurement in the Management of Heart Failure, 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 Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review.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 February 27, 2012.


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• Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. Where 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primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/ enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.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

## Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ’s information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ’s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency’s subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 17, 2012.

Carolyn M. Clancy,
Director.
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-list/.

The Key Questions

Key Question 1: In patients presenting to the emergency department or urgent care facilities with signs or symptoms suggestive of heart failure (HF):
1. What is the test performance of BNP and NT-proBNP for HF?
2. What are the optimal decision cut points for BNP and NT-proBNP to diagnose and exclude HF?
3. What determinants affect the test performance of BNP and NT-proBNP (e.g., age, gender, comorbidity)?

Key Question 2: In patients presenting to a primary care physician with risk factors, signs, or symptoms suggestive of HF:
1. What is the test performance of BNP and NT-proBNP for HF?
2. What are the optimal decision cut points for BNP and NT-proBNP to diagnose and exclude HF?
3. What determinants affect the test performance of BNP and NT-proBNP (e.g., age, gender, comorbidity)?

Key Question 3: In HF populations, is BNP or NT-proBNP measured at admission, discharge or change between admission and discharge an independent predictor of morbidity and mortality outcomes?

Key Question 4: In HF populations, does BNP measured at admission, discharge or change between admission and discharge add predictive information to other prognostic methods?

Key Question 5: Is BNP or NT-proBNP measured in the community setting an independent predictor of morbidity and mortality outcomes in general populations?

Key Question 6: In patients with HF, does BNP assisted therapy or intensified therapy compared to usual care, improve outcomes?

Key Question 7: What is the biological variation of BNP and NT-proBNP in patients with HF and without HF?

Dated: January 17, 2012.
Carolyn M. Clancy,
Director, AHRQ.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting Requirements for the Older American Act Title VI Grant Program

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing an opportunity for public comment on the proposed extension of an existing collection of information by the agency.

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Performance Reports for Title VI grants.

DATES: Submit written or electronic comments on the collection of information by March 26, 2012.

ADDRESSES: Submit electronic comments on the collection of information to: Margaret.Graves@aoa.hhs.gov. Submit written comments on the collection of information to Margaret Graves, Administration on Aging, Washington, DC 20201 or by fax at (202) 357–3560.

FOR FURTHER INFORMATION CONTACT: Margaret Graves at (202) 357–3502 or Margaret.Graves@aoa.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA’s functions, including whether the information will have practical utility; (2) the accuracy of AoA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

AoA estimates the burden of this collection of information as follows: Annual submission of the Program Performance Reports are due 90 days after the end of the budget period and final project period. Respondents: Federally Recognized Tribes, Tribal and Native Hawaiian Organizations receiving grants under Title VI, Part A, Grants for Native Americans; Title VI, Part B, Native Hawaiian Program and Title VI, Part C, Native American Caregiver Support Program.

Estimated Number of Responses: 256. Total Estimated Burden Hours: 640.

Kathy Greenlee,
Assistant Secretary for Aging.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-12–0805]

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) 639–7570 or send an