disincentives to quality of care and enhancing regulatory oversight of hospitals; and a national messaging plan to raise awareness of HAIs among the hospitals and family caregivers. The Action Plan also delineates specific measures and five-year goals to focus efforts and track national progress in reducing the most prevalent infections. In addition, the plan intended to enhance collaboration with non-government stakeholders and partners at the national, regional, state, and local levels to strengthen coordination and impact of efforts.

Recognizing the need to coordinate prevention efforts across healthcare facilities, HHS began to transition into the second phase (Phase Two) of the Action Plan in late 2009. Phase Two expands efforts outside of the acute care setting into outpatient facilities (e.g., ambulatory surgical centers, end-stage renal disease facilities). The healthcare and public health communities are increasingly challenged to identify, respond to, and prevent healthcare-associated infections across the continuum of settings where healthcare is delivered. The public health model's population-based perspective can be deployed to enhance healthcare-associated infection prevention, particularly given the shifts in healthcare delivery from the acute care (Phase One) to ambulatory (Phase Two) and other settings.

Moreover, healthcare personnel can acquire and transmit influenza from patients or transmit influenza to patients and other health care personnel. Results of several studies indicate that higher vaccination coverage among health care personnel is associated with lower incidence of nosocomial influenza, influenza-like illness, or mortality during influenza season. In addition, the proportion of healthcare-associated cases among hospitalized patients decreases as well, suggesting that increased staff vaccination can contribute to the decline in the number of healthcare-associated influenza cases.

The Steering Committee drafted two strategies or modules that address healthcare-associated infection prevention in ambulatory surgical centers and end-stage renal disease facilities. An additional module addresses influenza vaccination of health care personnel. Similar to its Phase One efforts, Phase Two healthcare-associated infection reduction strategies expect to be executed through research and guideline development, implementation of national quality improvement initiatives at the provider level, and creation of payment policies that promote infection control and reduction in healthcare facilities.

To assist the Steering Committee in obtaining broad input in the development of the three draft modules, HHS, through this request for information (RFI), is seeking comments from stakeholders and the general public on the revised draft *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination.* The revised draft can be found at *http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html.*

II. Information Request

The Office of Healthcare Quality, on behalf of the HHS Steering Committee for the Prevention of Healthcare-Associated Infections, requests input on the revised draft *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination.*

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in preventing and reducing healthcare-associated infections. Some examples of these organizations include, but are not limited to the following:

—General public
—Healthcare, professional, and educational organizations/societies
—Caregivers or health system providers (e.g., physicians, physician assistants, nurses, infection preventionists)
—State and local public health agencies
—Public health organizations
—Foundations
—Medicaid- and Medicare-related organizations
—Insurers and business groups
—Collaboratives and consortia.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. The submission of written materials in response to the RFI should not exceed 10 pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses, however, we request that comments are identified by Chapter, Section, and page number so they may be addressed accordingly. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

Dated: April 19, 2012.

Don Wright,

Deputy Assistant Secretary for Health.

[FR Doc. 2012–9868 Filed 4–24–12; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Medical Devices To Treat Otitis Media With Effusion

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 otitis media with effusion medical devices, such as tympanostomy tubes and autoinflation devices. Scientific information is being solicited to inform our Comparative Effectiveness Review of Otitis Media with Effusion (OME) Treatments, 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 May 25, 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 otitis media with effusion treatments.

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 treatments for otitis media with effusion, 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=1013#5070.*

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/.*

The Key Questions (KQs)

KQ 1: What is the comparative effectiveness of the following treatment options (active treatments and watchful waiting) in affecting clinical outcomes or health care utilization in patients with OME? Clinical outcomes include changes in: OME signs (middle ear fluid) and symptoms (fullness in ear, difficulty in hearing), objective hearing thresholds, episodes of Acute Otitis Media (AOM), and vestibular function such as balance and coordination. Treatment options include:

a. Tympanostomy tubes
b. Adenoidectomy with or without myringotomy
c. Myringotomy
d. Oral or topical nasal steroids
e. Autoinflation
f. Complementary and alternative medical procedures
g. Watchful waiting
h. Variations in surgical technique or procedure

KQ 2: What is the comparative effectiveness of the different treatment options listed in KQ 1 (active treatments and watchful waiting) in improving functional and health-related quality-of-life outcomes in patients with OME? Outcomes include: Hearing, speech and language development, auditory processing, academic achievement, attention and behavioral outcomes, health-related quality of life, and patient and parent satisfaction with care.

KQ 3: What are the differences in harms or tolerability among the different treatment options?

KQ 4: What are the comparative benefits and harms of treatment options in subgroups of patients with OME? Subgroups include:

a. Patients of different age groups
b. Patients of different racial/ethnic backgrounds
c. Patients in different socioeconomic status groups
d. Patients with comorbidities such as craniofacial abnormalities (e.g., cleft palate), Down syndrome, and existing speech, language, and hearing problems
e. Patients with a medical history of AOM or OME (with and without clinical hearing loss)

KQ 5: Is the comparative effectiveness of treatment options affected by the following: Health insurance coverage, physician specialty, type of facility of the treatment provider, geographic location, continuity of care, or prior inoculation with the pneumococcal vaccine?

Dated: April 12, 2012.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2012–9818 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Local Therapies for the Treatment of Stage I Non-Small Cell Lung Cancer and Endobronchial Obstruction Due to Advanced Lung Tumors

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 Conventional Two-Dimensional External Beam Radiotherapy (2D–EBRT), 3-dimensional conformal radiation therapy (3D–CRT), Intensity-modulated radiation therapy (IMRT), Stereotactic body radiation therapy (SBRT), Proton beam radiotherapy (PBR), Brachytherapy, Radiofrequency ablation, Endobronchial debridement and stents, and Nd-YAG Laser Therapy medical devices. Scientific information is being solicited to inform our Comparative Effectiveness Review of Local Therapies for the Treatment of Stage I Non-Small Cell Lung Cancer and Endobronchial Obstruction Due to Advanced Lung Tumors, 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