

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
New RoPR Record entered manually through self-registration process	16	1	55/60	14.67
New RoPR Record entered through <i>ClinicalTrials.gov</i> pathway	65	1	45/60	48.75
Review/update existing RoPR Record created through self-registration process	33	1	20/60	11
Review/update existing RoPR Record created through <i>ClinicalTrials.gov</i> pathway	132	1	15/60	33
Total	246			107.42

Exhibit 2 shows the estimated cost time to participate in the RoPR. The estimated at an average of \$4,017.51 burden associated with the respondent's total cost burden to respondents is annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate †	Total cost burden
New RoPR Record entered manually through self-registration process	16	14.67	\$37.40	\$548.66
New RoPR Record entered through <i>ClinicalTrials.gov</i> pathway	65	48.75	37.40	1,823.25
Review/update existing RoPR Record created through self-registration process	33	11	37.40	411.40
Review/update existing RoPR Record created through <i>ClinicalTrials.gov</i> pathway	132	33	37.40	1,234.20
Total	246	107.42	37.40	4,017.51

† Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. National Compensation Survey: Occupational wages in the United States May 2015, "U.S. Department of Labor, Bureau of Labor Statistics." Available at: <https://www.bls.gov/oes/current/oes290000.htm>.

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 health care research and health care 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.

Sharon B. Arnold,
Deputy Director.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update

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

ACTION: Request for supplemental evidence and data 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 *Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to

published and unpublished pertinent scientific information will improve the quality of this review.

DATES: Submission Deadline on or before August 14, 2017.

ADDRESSES:

Email submissions: SEADS@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 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503–220–8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update*. AHRQ is conducting

this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2481>.

This is to notify the public that the EPC Program would find the following information on *Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update* 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. Materials submitted must be publicly available or able to 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: <https://www.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 Key Questions

- I. In patients with nonvalvular atrial fibrillation, what are the comparative diagnostic accuracy and impact on clinical decision-making (diagnostic thinking, therapeutic and patient outcome efficacy) of available clinical and imaging tools and associated risk factors for predicting thromboembolic risk?
- II. In patients with nonvalvular atrial fibrillation, what are the comparative diagnostic accuracy and impact on clinical decision-making (diagnostic thinking, therapeutic, and patient outcome efficacy) of clinical tools and associated risk factors for predicting bleeding events?
- III. What are the comparative safety and effectiveness of specific anticoagulation therapies, antiplatelet therapies, and procedural interventions for preventing thromboembolic events:
 - A. In patients with nonvalvular atrial fibrillation?
 - B. In specific subpopulations of patients with nonvalvular atrial fibrillation?

Contextual Question

What are currently available shared decision-making tools for patient and provider use for stroke prophylaxis in atrial fibrillation, and what are their relative strengths and weaknesses?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Populations

Inclusion

- I. Humans
- II. Adults (age ≥ 18 years of age)

- III. Patients with nonvalvular AF (including atrial flutter):
 - A. Paroxysmal AF (recurrent episodes that self-terminate in less than 7 days)
 - B. Persistent AF (recurrent episodes that last more than 7 days until stopped)
 - C. Permanent AF (continuous)
 - D. Patients with AF who experience acute coronary syndrome
- IV. Subgroups of interest for KQ3 include (but are not limited to):
 - A. Age
 - B. Sex
 - C. Race/ethnicity
 - D. Presence of heart disease
 - E. Type of AF
 - F. Comorbid conditions (such as moderate to severe chronic kidney disease (eGFR < 60), dementia)
 - G. When in therapeutic range
 - H. When non-adherent to medication
 - I. Previous thromboembolic event
 - J. Previous bleed
 - K. Pregnant

Exclusion

Patients who have known reversible causes of AF (including but not limited to postoperative, hyperthyroidism).

All subjects are < 18 years of age, or some subjects are under < 18 years of age but results are not broken down by age.

Intervention

Inclusion

KQ 1: Clinical and imaging tools and associated risk factors for assessment/evaluation of thromboembolic risk:

- I. Clinical tools include:
 - A. CHADS2 score
 - B. CHADS2-VASc score
 - C. Framingham risk score
 - D. ABC stroke risk score
- II. Individual risk factors include:
 - A. INR level
 - B. Duration and frequency of AF
 - C. Age
 - D. Prior stroke
 - E. Type of AF
 - F. Cognitive impairment
 - G. Falls risk
 - H. Presence of heart disease
 - I. Presence and severity of CKD
 - J. DM
 - K. Sex
 - L. Race/ethnicity
 - M. Cancer
 - N. HIV
- III. Imaging tools include:
 - A. Transthoracic echo (TTE)
 - B. Transesophageal echo (TEE)
 - C. CT scans
 - D. Cardiac MRIs

KQ 2: Clinical tools and individual risk factors for assessment/evaluation of intracranial hemorrhage bleeding risk:

- I. Clinical tools include:
- HAS-BLED score
 - HEMORR2HAGES score
 - ATRIA score
 - Bleeding Risk Index
 - ABC Bleeding Risk score
- II. Individual risk factors include:
- INR level
 - Duration and frequency of AF
 - Age
 - Prior stroke
 - Type of AF
 - Cognitive impairment
 - Falls risk
 - Presence of heart disease
 - Presence and severity of CKD
 - DM
 - Sex
 - Race/ethnicity
 - Cancer
 - HIV
- KQ 3: Anticoagulation, antiplatelet, and procedural interventions:
- I. Anticoagulation therapies:
- VKAs: Warfarin
 - Newer anticoagulants (direct oral anticoagulants [DOACs])
 - Direct thrombin Inh-DTI: Dabigatran
 - Factor Xa inhibitors:
 - Rivaroxaban
 - Apixaban
 - Edoxaban
- II. Antiplatelet therapies:
- Clopidogrel
 - Aspirin
 - Dipyridamole
 - Combinations of antiplatelets
 - Aspirin-dipyridamole
- III. Procedures:
- Surgeries (e.g., left atrial appendage occlusion, resection/removal)
 - Minimally invasive (e.g., Atriclip, LARIAT)
 - Transcatheter (WATCHMAN, AMPLATZER, PLAATO)

Exclusion

None.

Comparator

Inclusion

KQ 1: Other clinical or imaging tools listed for assessing thromboembolic risk.

KQ 2: Other clinical tools listed for assessing bleeding risk.

KQ 3: Other anticoagulation therapies, antiplatelet therapies, or procedural interventions for preventing thromboembolic events.

Exclusion

For KQ 3, studies that did not include an active comparator.

Outcomes

Inclusion

- I. Assessment of clinical and imaging tool efficacy for predicting

thromboembolic risk and bleeding events (KQ1 and 2):

- Diagnostic accuracy efficacy
- Diagnostic thinking efficacy (defined as how using diagnostic technologies help or confirm the diagnosis of the referring provider)
- Therapeutic efficacy (defined as how the intended treatment plan compares with the actual treatment pursued before and after the diagnostic examination)
- Patient outcome efficacy (defined as the change in patient outcomes as a result of the diagnostic examination)

Patient-centered outcomes for KQ3 (and for KQ1 [thromboembolic outcomes] and KQ2 [bleeding outcomes] under “Patient outcome efficacy”):

II. Thromboembolic outcomes:

- Cerebrovascular infarction
- TIA
- Systemic embolism (excludes PE and DVT)

III. Bleeding outcomes:

- Hemorrhagic stroke
- Intracerebral hemorrhage
- Extracranial hemorrhage
- Major bleed (stratified by type and location)
- Minor bleed stratified by type and location)

IV. Other clinical outcomes:

- Mortality
 - All-cause mortality
 - Cardiovascular mortality
- Myocardial infarction
- Infection
- Heart block
- Esophageal fistula
- Cardiac tamponade
- Dyspepsia
- Health-related quality of life
- Functional capacity
- Health services utilization (e.g., hospital admissions, outpatient office visits, ER visits, prescription drug use)
- Long-term adherence to therapy
- Cognitive function

Exclusion

Study does not include any outcomes of interest.

Timing

Inclusion

Timing of follow-up not limited.

Exclusion

None.

Settings

Inclusion

Inpatient and outpatient.

Exclusion

None.

Study design

Inclusion

- Original peer-reviewed data
- N ≥ 20 patients
- RCTs, prospective and retrospective observational studies

Exclusion

Not a clinical study (e.g., editorial, nonsystematic review, letter to the editor, case series, case reports).

Abstract-only or poster publications; articles that have been retracted or withdrawn.

Because studies with fewer than 20 subjects are often pilot studies or studies of lower quality, we will exclude them from our review.

Systematic reviews, meta-analyses, or methods articles (used for background and component references only).

Language

Inclusion

- English-language publications
- Published on or after August 1, 2011

Exclusion

Non-English-language publications. Relevant systematic reviews, meta-analyses, or methods articles (will be used for background only).

Sharon B. Arnold,
Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From the Catholic Health Initiatives Patient Safety Organization, LLC

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. AHRQ has accepted a notification of voluntary relinquishment from the