

- 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.*

[FR Doc. 2017-14701 Filed 7-12-17; 8:45 am]

**BILLING CODE 4160-90-P**

## **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

Catholic Health Initiatives Patient Safety Organization, LLC of its status as a PSO, and has delisted the PSO accordingly.

**DATES:** The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on June 15, 2017.

**ADDRESSES:** Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.ahrq.gov/listed>.

**FOR FURTHER INFORMATION CONTACT:** Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: [psa@ahrq.hhs.gov](mailto:psa@ahrq.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732-70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" 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. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the Catholic Health Initiatives Patient Safety Organization, LLC, a component entity of the Catholic Health Initiatives, PSO number P0162, to voluntarily relinquish its status as a PSO. Accordingly, the Catholic Health Initiatives Patient Safety Organization, LLC was delisted effective at 12:00 Midnight ET (2400) on June 15, 2017.

The Catholic Health Initiatives Patient Safety Organization, LLC has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.ahrq.gov>.

**Sharon B. Arnold,**

*Deputy Director.*

[FR Doc. 2017-14702 Filed 7-12-17; 8:45 am]

**BILLING CODE 4160-90-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Advisory Committee on Training in Primary Care Medicine and Dentistry**

**AGENCY:** Health Resources and Service Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice of charter amendment.

**SUMMARY:** The Department of Health and Human Services is hereby giving notice that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) has been amended. The effective date of the renewed charter is May 31, 2017.

**FOR FURTHER INFORMATION CONTACT:** Kennita R. Carter, M.D., Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: Kennita R. Carter, M.D., Designated Federal Official, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, 15N-116, Rockville, Maryland 20857; (2) call 301-945-3505; or (3) send an email to [KCarter@hrsa.gov](mailto:KCarter@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The Committee provides advice and recommendations on policy and program development to the Secretary of the Department of Health and Human Services (Secretary) concerning the medicine and dentistry activities under section 747 of the Public Health Services (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. The Committee is responsible for preparing and submitting an annual report to the Secretary and Congress describing the activities of the Committee, including findings and recommendations made by the Committee.

Amendment of the ACTPCMD charter clarifies the authorization and duties of the Committee regarding medicine and dentistry as it operates and conducts its business.

A copy of the ACTPCMD charter is available on the ACTPCMD Web site at <https://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/index.html>. A copy of the charter is also available on the Federal Advisory Committee Act (FACA) database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site for the FACA database is <http://www.facadatabase.gov/>.

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2017-14648 Filed 7-12-17; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special