

March 7, 2016

Office of Science Policy, Engagement,
Education, and Communications (OSP/EEC)
National Heart, Lung, and Blood Institute, NIH
Attn.: Strategic Visioning Team
31 Center Dr., Building 31, Room 4A10
Bethesda, MD, 20892-2480

Dear Strategic Visioning Team,

The undersigned members of the AFib Optimal Treatment Task Force appreciate the opportunity to comment on the National Heart Lung and Blood Institute's (NHLBI) [Draft Strategic Research Priorities](#). We have been engaged throughout the NHLBI's Strategic Visioning process and we submitted a critical challenge as part of this process in May of 2015. We understand that NHLBI solicited input from its Advisory Council and Board of External Experts on the submitted compelling questions and critical challenges to identify the highest priorities for the Institute. The criteria used to narrow down these high priorities were "timeliness, feasibility, and overall potential to advance fields of study." **Based on these criteria we urge you to reconsider our proposed critical challenge aimed at improving stroke and bleeding risk tools for anticoagulation decision-making.**

As you know, AFib is the most common form of cardiac arrhythmia, affecting about 1 in 20 patients age 65 or older, and 1 in 10 patients age 80 or older. Those living with AFib are at an increased risk of stroke and AFib-related strokes are deadlier than non-AFib-related stroke, with roughly twice the mortality rate. Additionally, the condition is associated with an approximate doubling of the risk of all-cause mortality and is a contributory cause of death for around 99,000 Americans each year. To reduce stroke risk, patients with AFib are often treated with anticoagulant or antiplatelet therapy, both of which increase the risk of bleeding. While oral anticoagulation is highly effective at reducing stroke risk, elderly patients are often not anticoagulated, owing in part to under-appreciation of the stroke risk associated with AFib, the tendency of some health care professionals to prioritize bleeding risk over stroke prophylaxis, and concern over falls and bleeding risk.

On October 16, 2014 we convened a [symposium](#) with representatives from federal agencies (including NHLBI, NINDS, and the NIA), patient advocacy groups, and medical professional societies to discuss those factors leading to undertreatment of older AFib patients and to identify gaps in current clinical practice, education, research, and policy. Symposium participants concluded that an integrated, national effort is needed to promote adoption of best practices, develop alternate reimbursement models, expand patient and caregiver education on stroke risk and treatment, leverage existing initiatives, and address gaps in research on stroke and bleeding in AFib.

Our proposed critical challenge to NHLBI was intended to close one of the research gaps identified at the symposium: to expand research on bleeding risk in elderly patients and to subsequently develop a more accurate single-risk stratification tool that would enhance anticoagulation decision-making for the elderly population and reduce stroke incidence. See below.

“Goal 2: Reduce Human Disease

Restoring Balance to Stroke Prevention in Older AFib Patients

Improving tools for Anticoagulation Decision-Making

Details on the impact of addressing this CQ or CC:

AFib increases stroke risk by five-fold and doubles the risk that a stroke will result in permanent disability. While oral anticoagulation (OAC) is highly effective at reducing stroke risk, elderly patients are often under-anticoagulated. This is in part due to an under-appreciation of the stroke risk associated with AFib and the tendency of some health care professionals to prioritize perceived bleeding risk over stroke prophylaxis. Because current bleeding risk assessment tools are imperfect and largely unable to predict patients who are likely to have bleeding complications, they are often not utilized—or if used, do not truly predict which patients are at risk of a bleed. An improved bleeding risk tool is critical to improved risk assessment in the elderly. That bleeding risk tool should then be combined with the stroke risk tool for single risk stratification to streamline anticoagulation decision-making.

Feasibility and challenges of addressing this CQ or CC:

Developing effective integrated risk assessment tools is feasible only if there is consensus on the validity of the clinical information being provided. The approach to this critical challenge is two-fold. First, needed research that improves the reliability of bleeding risk assessment in the elderly should be pursued. Second, stroke and bleeding risk tools should be combined into a single risk stratification tool. This will require significant investment and focus, but the resulting bleeding risk assessment combined with the accepted *CHA2DS2-VASc score*, would significantly impact the 40 - 60% of patients who are currently not on an anticoagulant and are at increased risk of stroke and death.

Name of idea submitter and other team members who worked on this idea:

AFib Optimal Treatment Task Force”

AFib has proven to be a major economic burden for the United States. At least \$6.65 billion in health care costs are attributable to the condition each year. The \$6.65 billion a year estimate for direct health care costs from AFib may in fact be extremely low. One study estimates that Medicare pays \$15.7 billion per year to treat newly diagnosed AFib patients. Based on demographic factors, the American Heart Association estimates the annual healthcare expenditures related to stroke can be expected to increase to \$140 billion by 2030.

Due to the prevalence of AFib, the aging of the U.S. population, and the cost of this disease, we feel that NHLBI should include our critical challenge as part of the Institute's final Strategic Research Priorities. Research into more predictive risk assessment tools is essential to improving anticoagulation rates and reducing the burden of AFib. Thank you for considering our views. If you have any questions or require additional information, please contact Cynthia Bens at cbens@agingresearch.org or (202) 293-2856.

Sincerely,

AF Association
Alliance for Aging Research
American Foundation for Women's Health/StopAfib.org
Anticoagulation Forum
ClotCare.org
Mended Hearts, Inc.
Men's Health Network
Preventive Cardiovascular Nurses Association