November 13, 2015

Thomas Frieden, MD, MPH Director Centers for Disease Control and Prevention 1600 Clifton Road NE Atlanta, GA 30329

Dear Dr. Frieden,

The undersigned organizations include members of the AFib Optimal Treatment Task Force who are working to advance recognition and care for individuals suffering from atrial fibrillation (AFib). The AFib Optimal Treatment Task Force was formed by the Alliance for Aging Research in 2011 to address disparities in the diagnosis and prophylactic treatment of stroke among the AFib population. We appreciate the opportunity to comment on the Center for Disease Control and Prevention's (CDC) Healthy People 2020 goals.

AFib is the most common form of cardiac arrhythmia, affecting about 5% of patients age 65 or older, and 10% of patients age 80 or older. Individuals with AFib are at a five times greater risk of stroke and AFib-related strokes are deadlier and more severe than non-AFib-related strokes, 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.

We request two additions to the existing <u>Heart Disease and Stroke Prevention Healthy</u> <u>People 2020 goal</u>. We believe that this goal should be updated to include 1) AFib as a modifiable (controllable) risk factor for stroke, and 2) addressing the underanticoagulation of older AFib patients as an emerging issue in heart disease and stroke.

AFib as a modifiable risk factor for stroke

The American Stroke Association lists AFib among the risk factors for stroke that can be "changed, treated, or controlled." In addition, in May 2014 the American Heart Association/American Stroke Association updated their stroke prevention guidelines to include routine screening for AFib in women age 75 and older. The guidelines state that:

AF is a major modifiable stroke risk factor, independently associated with a 4- to 5-fold increased risk of IS [ischemic stroke]. AF is responsible for 1.5% to 25% of all IS depending on the age group. Anticoagulation is the most effective therapeutic strategy to reduce the risk of stroke.

Recognizing AFib as not only a leading risk factor for stroke, but as a modifiable one, will help drive awareness about the need for appropriate use of anticoagulants to significantly reduce the devastating impact of AFib-related stroke.

Under-anticoagulation of older AFib patients as an emerging issue

To reduce stroke risk, patients with AFib are often treated with anticoagulant or antiplatelet therapy, both of which increase the risk of bleeding—from minor bleeding to fatal hemorrhage. While oral anticoagulation is highly effective at reducing stroke risk (reducing stroke risk by as much as 80% in AFib patients), the literature cites that older patients are often underanticoagulated, with estimates as low as 30% of octogenarians with AFib receiving intervention. This failure to prescribe anticoagulants to older patients is driven by many factors including: 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 bleeding associated with falls and frailty.

We recognize that older patients have both higher stroke and bleeding risk, which can complicate the treatment decision. However, we also recognize that some healthcare professionals and patients may look for any reason not to treat with anticoagulants. In the SAFE-II study, 88% of patients with AFib treated by primary physicians were not prescribed anticoagulation. Reasons why patients were not anticoagulated included: low compliance (23%), fear of hemorrhage (22%), or potential contraindication (44%), with the latter including advanced age, cognitive impairment, and falls/gait disturbance, among others. Additionally, some practitioners may view a bleeding event in an anticoagulated patients as more their fault than a thromboembolic event in an un-anticoagulated patient.

Experts are generally united in the opinion that the net benefit of ischemic stroke prevention through anticoagulation supersedes bleeding risk concerns for most AFib patients and that therefore, assessment of bleeding risk is not an opportunity to look for contraindications, but rather an opportunity to address correctable risk factors for bleeding. However, underanticoagulation among older AFib patients persists and as the U.S. population continues to age, this problem will grow.

About the AFib Optimal Treatment Task Force

The AFib Optimal Treatment Task Force convened a <u>symposium</u> on October 16, 2014 with representatives from federal agencies, patient advocacy groups, and medical professional societies to discuss the factors leading to under-treatment of older AFib patients and to identify gaps in current clinical practice, education, research, and policy. Symposium participants recommended an integrated, national effort 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. To carry forward these recommendations, the Task Force is pursuing report language in the Fiscal Year 2016 appropriations bill for the Department of Labor, Health and Human Services, and Related Agencies that would prioritize communication of National Institute of Aging falls prevention information to specialists and direct the CDC to publish a *Vital Sign* on AFib. In addition, this language calls for the establishment of Healthy People 2020 goals on AFib stroke prevention.

Task Force members have also participated in the National Heart Lung and Blood Institute's strategic visioning process to encourage AFib as a renewed focus area for research. Representatives from the Task Force were invited to attend an expert workshop on the use of oral anticoagulants held by the Patient Centered Outcomes Research Institute in June of 2015. This workshop resulted in key questions that would serve as the basis for targeted funding announcements of outcomes-based research on anticoagulation treatment for venous thromboembolism and atrial fibrillation. Lastly, the Task Force continues one-on-one meetings with congressional offices and federal agencies, including the Agency for Health Research and Quality, the National Institutes of Health, MEDPAC and the CDC, to see how we might further improve the clinical experience for older adults with atrial fibrillation.

Conclusion

Thank you again for the opportunity to comment on Healthy People 2020. We appreciate your full consideration of our views on how CDC can refine Healthy People 2020 to better serve the health needs of America's aging population. The Department of Health and Human Services launched Healthy People with four overarching objectives: attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; achieve health equity, eliminate disparities, and improve the health of all groups; create social and physical environments that promote good health for all; and promote quality of life, healthy development, and healthy behaviors across all life stages. We feel strongly that our requested revisions to the existing Heart Disease and Stroke Prevention Healthy People 2020 goal will assist CDC in more fully realizing these overarching objectives for Healthy People program. If you have any questions or would like additional information, please do not hesitate to contact Cynthia Bens at 202-293-2856 or by email at cbens@agingresearch.org.

Sincerely,

AF Association
Alliance for Aging Research
American Foundation for Women's Health/StopAfib.org
The Anticoagulation Forum
ClotCare.org
Mended Hearts
Men's Health Network
National Stroke Association
OWL- The Voice of Women 40+
Society for Women's Health Research
WomenHeart: The National Coalition for Women with Heart Disease