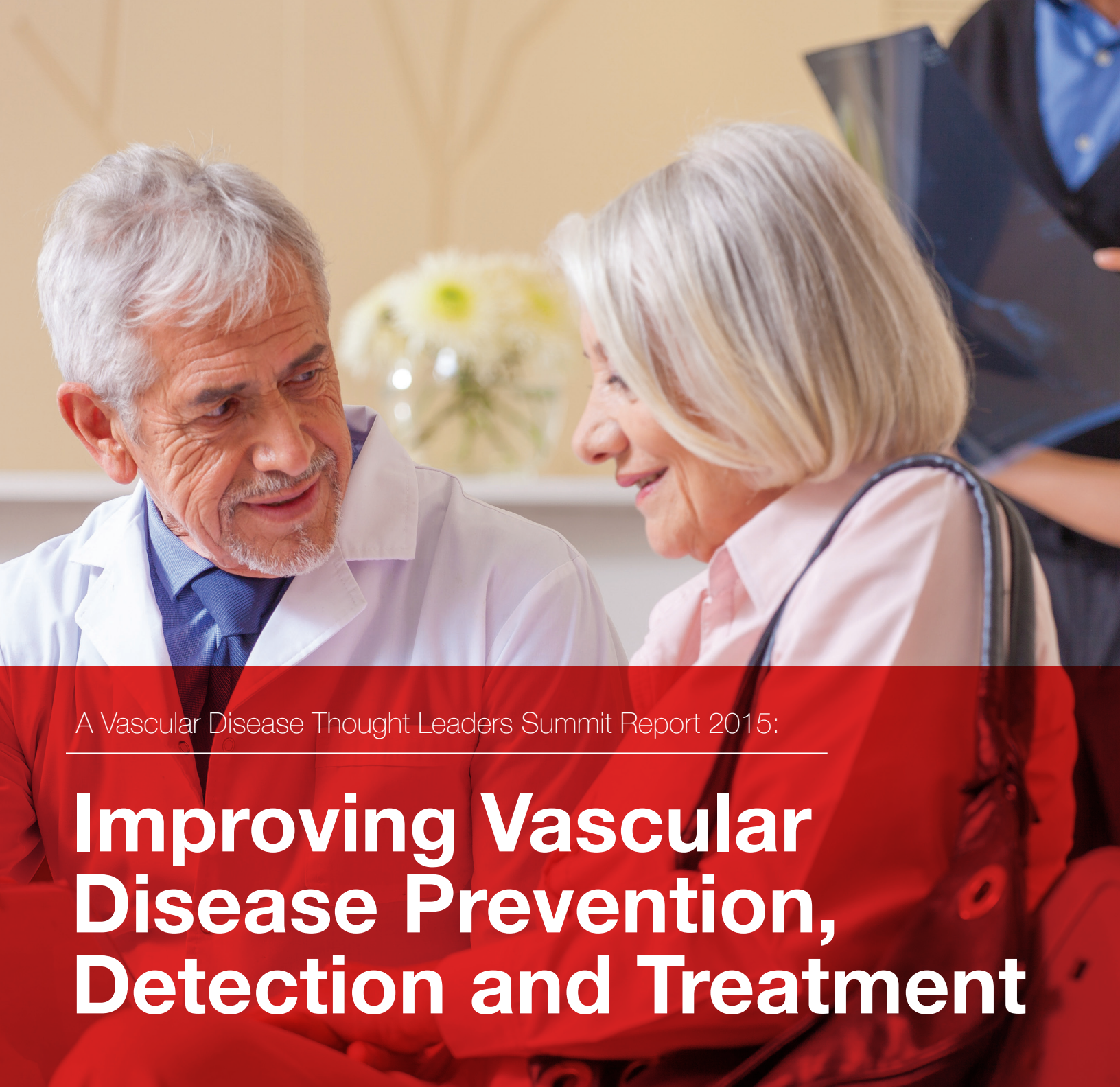

A Vascular Disease Thought Leaders Summit Report 2015:

Improving Vascular Disease Prevention, Detection and Treatment

A Conference Report from the American Heart Association

American Heart Association | American Stroke Association®

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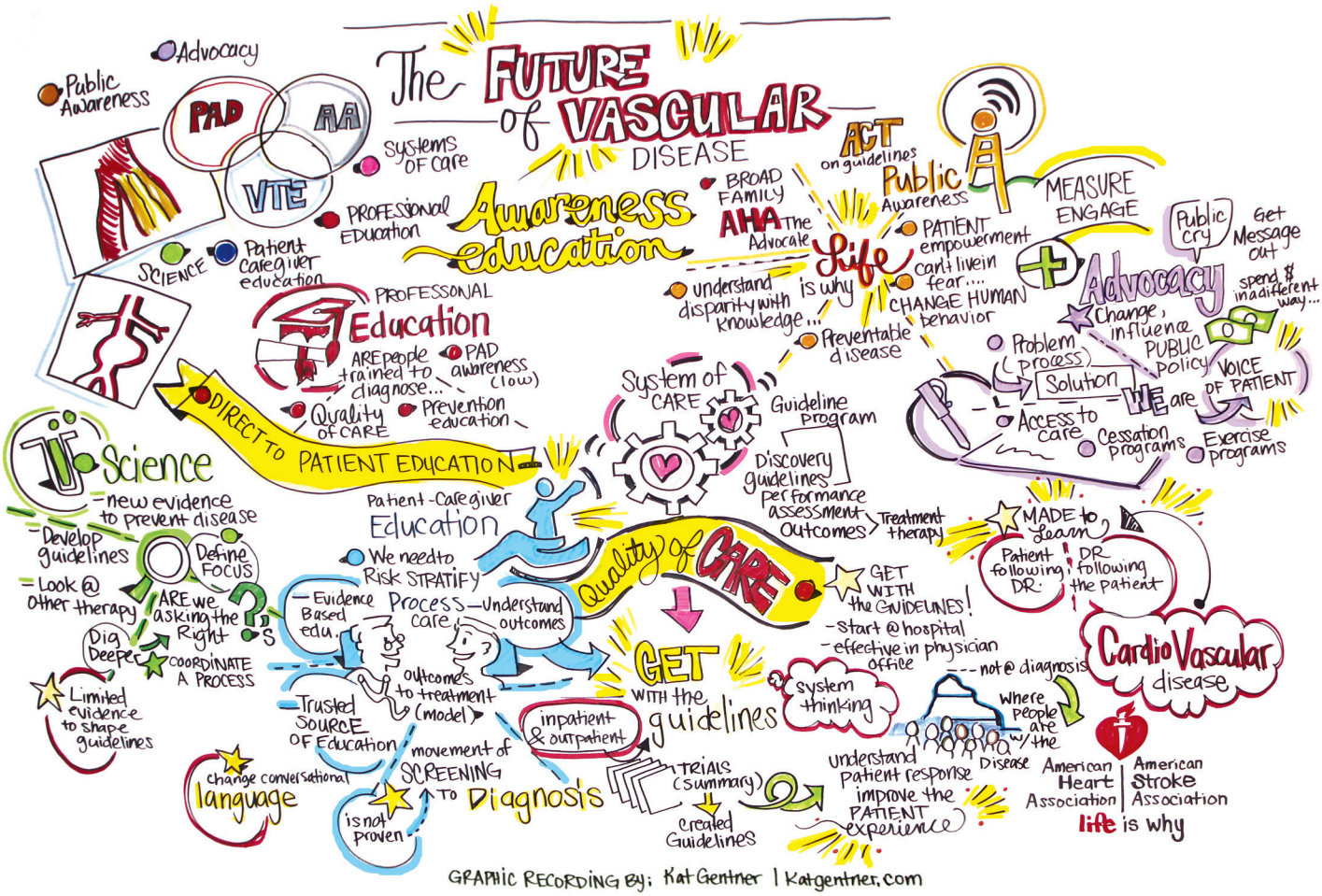

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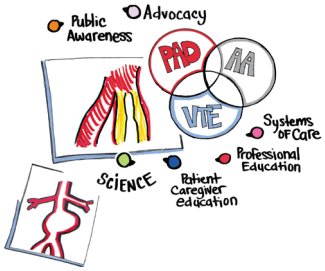
KEY WORDS:

AHA Conference Proceedings, vascular disease, peripheral artery disease, venous thromboembolism, aortic aneurysm, public awareness, advocacy, education, systems of care

ABOUT THE SUMMIT



BACKGROUND:

Vascular diseases, including atherosclerotic peripheral vascular diseases, aortic aneurysms, and venous thromboembolism are prevalent in the U.S. and other nations. When unrecognized or inadequately treated, these disorders may be life threatening and disabling. The therapeutic landscape for these conditions is on the cusp of evolution with new therapies and devices in development; yet health professional and patient awareness is low. This presents an opportunity for new education and awareness efforts geared to both healthcare providers and patients.

MEETING PURPOSE AND SCOPE:

This American Heart Association (AHA) Thought Leaders Summit provided a forum to identify opportunities to increase public awareness, patient detection, and professional education in order to improve outcomes of patients with vascular diseases. Summit participants included scientists, clinicians, and patients, as well as representatives from federal health agencies and industry.

The ideas and opinions shared by participants will help guide the AHA's involvement in vascular disease in areas of science, professional education, patient care, health education, and public awareness. Improved health education, prevention and management of vascular disease are consistent with the overall mission of the American Heart Association.

The AHA has long been committed to supporting a wide range of activities in scientific research, professional education, guidelines, quality initiatives, and public health–all with the common goal of identifying new ways to prevent, detect, and treat cardiovascular disease and stroke.
The scope of discussion at the summit was limited to peripheral (non-coronary) atherosclerotic vascular disease, particularly peripheral artery disease (PAD), aortic and peripheral aneurysms, and venous disease, primarily venous thromboembolism (VTE).

MEETING GOALS:

This summit's proceedings are intended to help the AHA:

- Determine an appropriate leadership role in vascular disease prevention, diagnosis and treatment
- Define AHA priorities and opportunities to improve the diagnosis and treatment of vascular disease and align these opportunities with the 2017-2020 strategic plan and 2020 goals
- Consider near-term opportunities to apply effective methods of provider and patient education
- Pursue fundable opportunities to ensure that educational tools and resources are available for health professionals and the public in order to address the changing needs of the treatment landscape
- Determine the best methods to engage strategic alliances to support our efforts

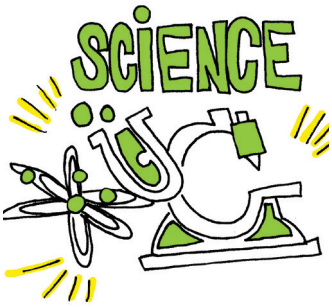
Priority suggestions to the AHA resulting from the summit included: developing public awareness campaigns for PAD, VTE and aortic aneurysms; creating quality initiatives for PAD and VTE; implementing professional education programs and developing standardized vascular knowledge content for practitioners; enhancing formal training and promoting the recognition of vascular medicine; funding research that focuses on vascular disease; and advocating for more effective detection and treatment for vascular diseases. The conclusions resulting from these proceedings will be used to generate a road map for the AHA's role in atherosclerotic peripheral vascular disease, aortic aneurysm, and venous thromboembolism.

INTRODUCTION

The American Heart Association is a global leader in the cardiovascular and stroke fields and has a long history in discovery, dissemination and application of scientific knowledge. Recognizing the importance of prevention, diagnosis, and treatment of vascular disease and the broad range of individuals working in the science, professional education, patient care, and health education of vascular diseases, the AHA convened a Vascular Disease Summit on August 20, 2015 in Boston, Massachusetts. Expert participants representing scientists, clinicians, and patients, as well as representatives from federal health agencies, attended in person to debate and discuss critical issues in vascular disease. Additional academic experts and AHA staff also provided input by giving strategic advice during the planning stage and commenting on the drafts of the proceedings.

The conference format included short presentations by groups of topic experts with extensive time committed to panel discussion and audience interactions. Session topics included peripheral (non-coronary) atherosclerotic vascular disease focusing on peripheral artery disease, aortic and peripheral aneurysms, primarily abdominal aortic aneurysms (AAA), and venous thromboembolism. Facilitated breakout sessions took place, where various stakeholders from six areas, comprising Science Research and Dissemination, Professional Education, Patient and Caregiver Education, Systems of Care and Quality, Public Awareness, and Advocacy, developed scenarios in response to the questions: What are the opportunities or unmet needs most critical to make an impact in Prevention, Diagnosis and Initial and Ongoing Treatment of PAD, VTE and AAA? What are the strengths of AHA's portfolio, and what gaps are unmet by AHA and others? What would AHA need to do in order to be a stronger leader and is there anything AHA should not do? The final facilitated breakout session addressed the question, "What possible roles might the AHA play in each of these domains?"

THE FUTURE OF VASCULAR DISEASE



RESEARCH AND SCIENCE DISSEMINATION

Significant accomplishments have been made in the treatment of peripheral vascular disorders. There have been major advances in the science of vascular biology leading to novel insights into the pathogenesis of atherosclerosis and thrombosis, the role of endothelial function in health and disease, and the identification of targets for new therapies. The biology of aortic aneurysms is being explored, and potential new treatments for aortic disease are emerging. Discovery science has yielded novel classes of oral anticoagulant drugs for treating venous thromboembolism.

Treatments for peripheral atherosclerotic vascular disease have been derived primarily from larger cardiovascular outcome trials, targeting patients with various manifestation of coronary artery disease. Those trials, including the Heart Protection Study (HPS)[1], the Heart Outcomes Prevention Evaluation (HOPE)[2], and Clopidogrel versus Aspirin in Patients at Risk of Ischaemic Events (CAPRIE)[3], enrolled subgroups of patients with PAD. Based on the subgroup analyses, we have gained a basic understanding of the efficacy of lipid lowering therapies, ACE inhibitors, and antiplatelet drugs in preventing the systemic cardiovascular complications associated with atherosclerosis. There is a more limited understanding of limb specific therapies, but evidence from the TRA2°P trial with vorapaxar suggests that novel antithrombotic therapies may improve limb specific endpoints such as acute limb ischemia[4]. Clinical trials of patients with VTE have demonstrated the efficacy of oral anticoagulants, such as warfarin, and more recently, the thrombin and factor Xa inhibitors, in preventing recurrent VTE.

The American Heart Association has contributed greatly to advance and disseminate the knowledge base for the diagnosis and treatment of vascular disorders. PAD clinical

practice guidelines[5], consensus documents such as the Atherosclerotic Vascular Disease Conference Proceedings[6] and scientific statements including PAD in Women[7], Measurement and Interpretation of the Ankle-Brachial index[8], Management of Massive and Submassive Pulmonary Embolism, Iliofemoral Deep Vein Thrombosis, and Chronic Thromboembolic Pulmonary Hypertension[9], and the Prevention, Diagnosis, and Treatment of the Post-thrombotic Syndrome[10] have informed physicians and the public on best practices to manage peripheral vascular diseases.

Current research priorities for consideration include studying the biology of atherosclerosis and thrombosis in PAD and determining whether it has unique characteristics that distinguish it from vascular disease in other regions. Specific examples include assessing the platelet phenotype differences and the role of diabetes in peripheral atherosclerosis. Research endeavors should also address unmet clinical management questions in PAD, such as determining the optimal antiplatelet therapy, and in particular, the role of aspirin, other antiplatelet therapies, and adjuvant anticoagulant therapy in patients with stable PAD and in those undergoing revascularization. In addition, scientific investigation should be directed at developing medical therapies that slow the progression of aortic aneurysms as well as conducting comparative effectiveness trials of the new non-vitamin K antagonist oral anticoagulants for the prevention and treatment of venous thromboembolism.

The AHA can help frame and prioritize the broader agenda for peripheral vascular diseases by helping to identify key research questions and addressing the unmet needs for these disorders. New research methodologies should be considered to address these issues. For example, the Patient-Centered Outcomes Research Institute (PCORI) networks include Clinical Data Research Networks and Patient Priority Research Networks. These will allow for integration of study sites across the country with central funding and central data repositories using more pragmatic trial design to answer these questions.

The AHA could not only help to identify the key research questions but could also galvanize funding for this research and identify appropriate pathways for dissemination of new knowledge. Translation of important research findings should ultimately lead to improved vascular care.

PROFESSIONAL EDUCATION

Since implementation of the Affordable Care Act in 2010, Medicare has steadily rolled out new alternative payment models and care delivery systems that reward quality over volume. Central to these new payment models is the primary care provider (PCP) who is under increasing pressure to selectively triage appropriate patients to specialists for care. For patients with peripheral atherosclerotic vascular, aneurysmal, or venous thromboembolic disease, it is unclear if current PCP knowledge and training are ready to meet this demand.

In 2001 Hirsch and coworkers[11] evaluated PAD disease detection, awareness and treatment in 350 primary care practices as part of the PARTNERS Program. These investigators found that while 83 percent of patients with PAD were aware of their diagnosis, only 49 percent of their PCPs were aware that their patient had PAD. In addition, patients with PAD as their only cardiovascular diagnosis were less likely to be treated for hyperlipidemia or hypertension and were less likely to be prescribed an anti-platelet agent when compared to patients with a diagnosis of coronary artery disease. In 2004 a white paper from the Vascular Disease Foundation[12] stated that while the adverse outcomes of PAD are known, patient and physician awareness of PAD are low despite the fact that treatment efficacy is proven and PAD is easily detected by physical examination or noninvasive vascular testing. There have been very few additional studies over the last 10 years to evaluate how much this problem has improved, but data that are available suggest that there has been minimal improvement. For example Goodney and coworkers[13], using Medicare claims data, have shown that among diabetic patients at risk for PAD and admitted with a diagnosis of lower extremity cellulitis, less than 10 percent of patients had been compliant with the HEDIS / ADA (Health Care Effectiveness Data and Information Compliance Set / American Diabetes Association) measures in the year before or after the index admission. Brooke and coworkers have demonstrated the importance of good primary care in preventing limb loss[14]. Again using Medicare claims data, these investigators showed a significant improvement in amputation- free survival following revascularization in diabetic patients who were cared for in Hospital Referral Regions in which there was high quality primary care.

High quality primary care was measured as the percent of diabetic patients who underwent annual HgBA1C and lipid profile measurements.

Compliance with abdominal aortic aneurysm screening since the introduction of the SAAAVE Act in 2007 is improving but remains poor. In 2007, 1.5 percent of eligible Medicare enrollees underwent screening. This has increased to only 6.0 percent in 2012[15].

The awareness and prevention of venous thromboembolic disease has improved in hospitalized patients. This is particularly true for surgical patients due in large part to in-hospital quality metrics such as the Surgical Care Improvement Project (SCIP) measures and Hospital Acquired Conditions (HAC) that are now tied to reimbursement. In a 2009 study, 71 percent of surgical patients received appropriate venous thromboembolic prophylaxis compared to 48 percent of medical patients[16]. These numbers are likely to have improved by 2015, again due to coupling of prevention of venous thromboembolic complications to reimbursement.

The summary statement by Dr Hirsch and coworkers[11] over 10 years ago appears to remain an accurate assessment of the current knowledge and awareness of PAD by primary care providers. While more intensive efforts by the AHA to improve provider PAD education opportunities is paramount, alternative strategies may be considered such as direct to patient educational efforts. This has been shown to result in improved physician and public awareness in conditions such as stroke and could serve as a good model for PAD.

PATIENT AND CAREGIVER EDUCATION

PAD epitomizes a cardiovascular condition in which there are a variety of treatment options that variably impact outcomes (death, limb loss, claudication, physical activity and quality of life). Different patients would be expected to derive different benefits and risks from treatment. While evidence-based guidelines provide directions for an ideal treatment, they cannot take into account each individual's unique demographic, comorbidity and disease severity characteristics. To improve the consistency of care and to enable patients to be more engaged in shared medical decision-making, guideline-based care must be individualized. Thus, innovative approaches and tools for patient and caregiver education are needed.

The foundation of these tools is the modeling of the heterogeneity of treatment benefits (and risks), based on patients' demographic and clinical characteristics, so that the estimated outcomes of alternative treatment strategies (e.g. smoking cessation, exercise, medication use and adherence, peripheral and surgical revascularization) can be generated. These outcomes (survival, myocardial infarction, limb loss, and health status) then need to be incorporated into shared medical decision-making tools, so that a transparent estimate of the outcomes of alternative treatments can be shared with patients and their caregivers and customized treatment plans developed.

The AHA has a critical opportunity to accomplish this vision. It can serve as an 'honest broker' for clinical trial and observational registry datasets from which models of the heterogeneity of treatment benefit can be created. It can work with patients and providers to define the best way to present this information so that it is most readily understood. It can then work with health systems and advocacy groups to define how best to implement this into routine clinical care and guide payers in developing compensation schemes when shared decision-making is used by providers.

SYSTEMS OF CARE AND QUALITY

In 2001, the Institute of Medicine initiated a national effort to improve the quality of care by publishing Crossing the Quality Chasm[17]. It described the six aims to improve care as safe, effective, patient-centric, timely, efficient and equitable. The foundation of a national effort to achieve these aims is dissemination of practice guidelines from which selected measurable performance measures are derived. It is well recognized that guidelines have not been uniformly adopted into practice. In 2001 the AHA initiated the Get-with-the-Guidelines program (GWTG) to ensure secondary prevention for patients hospitalized with CAD. Current GWTG efforts

also include atrial fibrillation, heart failure, resuscitation and stroke. The American College of Cardiology concurrently focused on the appropriate use of procedures such as noninvasive imaging, cardiac catheterization and revascularization. Many payers have adopted Appropriate Use Criteria (AUC). Payers have also introduced incentives to adhere to performance measures with pay-for-performance programs, while the states have used public reporting to evaluate which physicians and hospitals have the best outcomes. More recently the AHA initiated Mission Lifeline, an effort to improve timely reperfusion for patients with acute myocardial infarction. The program approach is based upon a system of care that brings together all of the stakeholders in a coordinated effort. The AHA GWTG program and Mission Lifeline systems of care have been particularly successful in achieving improved care. Peripheral vascular disease is underdiagnosed and undertreated, and there is evidence that guideline recommendations are not being adequately followed in practice. The AHA should consider the creation of national vascular disease quality initiatives such as a PAD or VTE Get with the Guidelines or a Mission Lifeline type of System of Care for peripheral vascular disease. Programs such as these could significantly improve the identification and treatment of patients with vascular disease.

PUBLIC AWARENESS

The American Heart Association provides leadership by ensuring that the science base is leveraged to prevent, diagnose, and treat individuals at risk for, or who suffer from, cardiovascular disease (CVD). The association's mission, which originally concentrated on heart disease, was later expanded to include stroke. In 2015, it is recognized that a maximally effective CVD mission should encompass the full burden of vascular diseases.

Atherosclerotic peripheral vascular disease, chronic venous disease and venous thromboembolism, and aortic and branch aneurysmal disease contribute to high rates of CVD morbidity and mortality. Yet, peripheral vascular diseases are associated with low rates of detection and treatment, compared to heart disease and stroke[18]. Vascular disease management assumes a lesser priority when there is little public awareness and limited clinician education to generate a patient-physician dialogue, creating a cycle that decreases timely disease detection and treatment and increases the likelihood of adverse cardiovascular outcomes. With less favorable access to resources for vascular disease, compared to heart disease and stroke, both the public and health professionals routinely miss opportunities to address vascular health. When individuals with non-coronary vascular diseases are not aware of their risk, they cannot recognize hallmark symptoms, seek a prompt diagnosis from informed clinicians, nor participate with autonomy to effect ideal treatment choices.

Atherosclerotic lower extremity PAD is among the most prevalent, morbid and mortal of all cardiovascular diseases, affecting more than 202 million people globally and more than 8 million individuals in the United States[19]. Individuals with PAD suffer about a 5 percent annual rate of major adverse cardiovascular events[20], yet it is known that there is very low public awareness of PAD's prevalence and risk. In a US national survey, fewer than one in four adults with risk factors and walking impairment have any awareness of PAD[21]. Of the "PAD aware" individuals, less than one in seven were aware that PAD is the single most important cause of leg amputation. Comparable data have been published from Canadian, Dutch, and other populations[22, 23]. National data also indicate a low awareness of PAD among primary care clinicians[11]. Without greater public and physician awareness of PAD, it is unlikely that even classic PAD ischemic symptoms would be recognized, reported to physicians, and treated.

These data have led to efforts to improve public PAD awareness and knowledge. In 2003, the National Heart, Lung, and Blood Institute, joined by the nonprofit Vascular Disease Foundation, the American Heart Association, and other societies, convened the "NHLBI Workshop on Peripheral Arterial Disease (PAD): Developing A Public Awareness Campaign"[24]. This work created common messages, culturally appropriate media tools, and a "PAD Style Guide" to ensure that all national stakeholders would use a common, easy to understand set of terms[24]. Since then, other stakeholders have created relatively small, non-sustained public awareness campaigns, but most of these have been focused more on practice-building than unbiased public vascular health literacy.

Similarly, awareness of VTE is woefully low; less than one in 10 Americans knows about deep vein thrombosis and is

familiar with its symptoms or risk factors[25]. VTE is the most common cause of maternal and in-hospital death in the United States. At least 80,000 VTE hospital events occur in pregnant women. VTE incidence of more than one in 1,000 (diagnosed cases) and impact on 300,000 to 600,000 Americans per year[26] have an immense health impact and public health cost. Although it is feasible to prevent VTE using known prophylactic measures, such measures are unlikely to be used in a "VTE unaware" public.

Abdominal aortic aneurysm causes over 15,000 preventable deaths[19, 27], but there is limited public awareness data. While AAA is associated with fear of death, few individuals know that a history of a first order relative with an AAA, or that male tobacco exposure, defines a cohort in whom AAA screening is known to be effective.

Our public and health professional vascular disease awareness efforts are not aligned with the epidemiology. There are no effective vascular public awareness efforts underway. It is true for most vascular diseases that "What you don't know can kill you." At a time when the public is actively informed about Ebola, West Nile Virus, or Lyme disease, it would seem appropriate for the public to be informed about more common and potentially life-threatening vascular disorders.

ADVOCACY

In 2006, the American Heart Association hosted an Atherosclerotic Vascular Disease Conference that defined the areas in critical need of further work to advance the care of patients with atherosclerosis. These topic areas ranged from pathophysiology to imaging and revascularization6. Notably absent from the six areas of concentration at that conference was advocacy. Although not stated explicitly, the need for advocacy for these topics may not have been as compelling, since coronary heart disease and stroke already enjoyed broad support and public awareness. There are many origins of the disparity, which may include the historically artificial separation of systemic atherosclerosis into component complications, the adoption of constituents of venous thromboembolism by different specialties, and the relative infrequency of aortic aneurysm. No matter the cause, these vascular diseases affect millions of patients and have yet to garner the sustained attention needed to reduce mortality and extend a high quality of life. To accomplish these larger goals, a program of advocacy is needed to educate decision-makers, healthcare providers, and the public, with the goal of implementing evidence-based therapies.

The objectives of advocacy for vascular disease include raising awareness among the public, policy makers, and private sector leaders to create an environment favorable to advance the goals developed as part of this summit. Advocacy is a process that begins with summits such as this, takes months and years of work to fully realize, and includes the process of defining the goals of the effort, understanding the power structure in care delivery, targeting audience identification, and the creation of messages. By leveraging resources inherent to the AHA, the ultimate success of this program will be facilitated by its communication to the public and policymakers.

OPPORTUNITIES TO IMPACT PREVENTION, DIAGNOSIS AND TREATMENT OF VASCULAR DISEASE

PREVENTION

Prevention of vascular disease begins by providing clear, accurate information, at an appropriate reading level in various educational formats. It must also be culturally and linguistically tailored. Many patients and caregivers do not understand the basics, such as the differences between arteries and veins. This leads to misunderstanding about these diseases and thwarts prevention strategies.

For PAD, VTE and AAA, the key to prevention is increased public and healthcare provider awareness of the risk factors such as obesity, diabetes, smoking and lack of physical activity. The public would benefit from understanding the symptoms of each disease and the long-term consequences of foregoing treatment. Early detection from patient physical examination, including the ankle-brachial index (ABI) where indicated, may help prevent adverse PAD outcomes. Information must be provided to patients and caregivers to help them understand why they are participating in vascular examinations. Highly visible displays about VTE risk and prevention strategies in airports and on travel websites would improve prevention of VTE. Additionally, hospitals need to provide educational programs about VTE prophylaxis to their healthcare providers and conduct outreach programs for the public. AAA prevention can be improved by informing the public and educating providers about indications for screening.

DIAGNOSIS

Diagnosis of PAD can be improved by ensuring increased utilization of the foot examination during routine physical examinations. Following the 2005, 2010, and 2013 AHA-ACCF PAD guidelines, the detection of abnormal pulses should consistently lead to the use of the ABI as a critical diagnostic tool. Detection of VTE would be improved by wider use of accepted diagnostic algorithms in hospital and emergency care settings. Provider awareness is essential also for timely diagnosis of pulmonary embolism, the symptoms of which are often misdiagnosed

as myocardial ischemia, asthma or chronic obstructive pulmonary disease.

AAA screening should be provided at age 65-75 for men who have ever smoked, as well as first degree relatives of patients with AAA. Thoracic aortic aneurysm (TAA) screening can be guided by syndromic features (e.g., Marfan syndrome), the presence of a bicuspid aortic valve, or family history of TAA.

TREATMENT

Physician education and dissemination of treatment guidelines, including risk factor modification such as smoking cessation, lowering high cholesterol, treating diabetes, as well as institution of antiplatelet therapy, will reduce the risk of adverse cardiovascular outcomes in patients with PAD. Both patients and providers should be aware that exercise therapy improves symptoms in PAD patients with intermittent claudication. Also, physicians should know when to refer patients with severe claudication or critical limb ischemia to a vascular specialist for consideration of revascularization. Creation of a Get with the Guidelines vascular program is one potential avenue to motivate providers to focus on cardiovascular prevention and adherence to guidelines and create toolkits for care providers.

Public and clinician understanding of high-risk situations for VTE can be improved. Once VTE is diagnosed, providing patients with information about their anticoagulant medications is likely to improve compliance, reduce the risk of recurrent VTE, and decrease potential for bleeding. Moreover, it is important that physicians are knowledgeable about indications for prophylactic and therapeutic anticoagulation, properties of anticoagulant drugs, monitoring of patients, and optimal duration of therapy.

Physicians should be educated about recommendations for monitoring AAAs once diagnosed, and about indications for referral for endovascular or open surgical repair when an AAA expands rapidly or reaches a critical size. More research is needed to identify genetic markers and risk factors that might predict aneurysm growth and the risk for rupture, and for discovery of drugs that can limit aneurysm growth.

GAP AREAS THAT NEED TO BE ADDRESSED FOR THESE CONDITIONS INCLUDE:

- Examination of individuals at high risk for PAD according to evidence-based guidelines
- Promotion of health behaviors and treatments to reduce risk of PAD and VTE
- Improved public awareness and physician recognition of symptoms of PAD
- Availability of and access to programs that provide exercise training for PAD
- Public awareness and physician education about risk factors and symptoms of VTE
- Education of patients and physicians about VTE management
- Physician education about AAA screening and guideline recommendations for surveillance and referral for AAA repair
- Quality outcome initiatives based on performance measures for PAD, VTE, and AAA
- Research in each of these areas to develop more effective methods for diagnosis and treatment

INTEGRATION WITH AHA STRATEGIC BUSINESS PLAN AND IMPACT GOAL

OVERVIEW OF 2020 IMPACT GOAL/METRICS; UPDATE ON 2017 PROCESS

Everything the AHA does is in support of the mission: Building healthier lives, free of cardiovascular diseases and stroke. The AHA sets a 10-year health impact goal and has a three-year planning cycle to develop shorter-term plans. The current plan is for 2014-17. A 2017-2020 plan will be developed by October 2016 to cover the remainder of the decade. Also, the AHA will begin a process in 2016 to develop the 2030 goal, to be approved in 2018. The 2020 health impact goal is: "By 2020, to improve the cardiovascular health of All Americans by 20%, while reducing deaths from cardiovascular diseases and stroke by 20%". For the health portion of the goal, progress is tracked using National Health and Nutrition Examination Survey (NHANES) data, baseline year 2007-2008, by assessing average population improvement on the Life's Simple 7[29] factors (smoking, BMI, physical activity, diet, cholesterol, blood pressure, and blood glucose). The last internal progress report, using data from 2011-12 showed[28]:

- Improvements for both adults and children in smoking and physical activity;
- Improvements in children but worsening in adults in glucose and blood pressure;
- Improvements in adults but worsening in children in blood cholesterol;
- Worsening in both children and adults in BMI;
- A slight improvement in diet in adults with no change in children.

The overall average improvement across the seven factors for children was 5 percent, and 2.9 percent for adults. As this is a 10-year goal and the data availability lag by two to three years, the numbers should be interpreted with caution, as they do not represent the total years AHA has executed against the goal.

Mortality rates for total cerebrovascular disease, coronary heart disease, and stroke are decreasing and the expectation is that the 20 percent target will be reached. This holds true

across the racial and ethnic subgroups tracked in response to the "All Americans" portion of the goal.

HOW DOES VASCULAR DISEASE RELATE TO THE AHA 2020 IMPACT GOAL AND STRATEGIC PLAN?

According to the 2015 AHA Statistical Update, cardiovascular diseases caused 1,361,165 deaths in 2012; of these 62,183 (4.6 percent) were attributed to PAD, 43,579 (3.2 percent) to VTE, and 16,417 (1.2 percent) to aortic aneurysms[19]. These vascular diseases are often not the proximate cause of death in patients who are affected. For example, those with PAD often die of heart disease or stroke, and cancer is an underlying disease in 20 to 30 percent of those with VTE. Among those with both cancer and thrombosis, mortality is very high. Vascular disease has a negative impact on morbidity and quality of life, and treatment can have adverse side effects. For example, patients with PAD often suffer from impaired mobility, and those with deep vein thrombosis are at risk of disabling post-thrombotic syndrome or bleeding complications due to medical treatment.

The AHA's current focus to reduce these vascular disorders in the context of the 2020 impact goal centers around efforts to prevent and control risk factors for atherosclerosis and thrombosis, as embodied in the concept of improving cardiovascular health through Life's Simple 7[29]. Diabetes, smoking, hypertension and hyperlipidemia explain 75 percent of the incidence of PAD[30], and obesity and physical inactivity, as expressed in the AHA's Life's Simple 7, are major risk factors for VTE[31]. The AHA's efforts to build a culture of health by improving the population status of these key health factors will ultimately reduce these diseases. Examples include policy initiatives for tobacco control and prevention[19], obesity prevention in children (Voices for Healthy Kids), and educational programs and clinical tools for risk factor control (Check. Change. Control.; Power to End Stroke; Heart360).

THE AMERICAN STROKE ASSOCIATION EXPERIENCE

The American Stroke Association programs can be used as templates to guide AHA initiatives in Vascular Diseases. Indeed, stroke has a long-standing history in the AHA. Patient materials addressing stroke can be tracked as far back as the mid-1950s. By the 1970s the AHA was publishing the journal Stroke, considered today the leading stroke journal in the world, and in 1976 the AHA began hosting the annual International Stroke Conference, arguably the most substantial stroke meeting in the world. In response to this strong professional presence established in the 1970s, in June 1985, the AHA Delegate Assemble voted to amend the AHA's mission statement to include stroke, reemphasizing the commitment to decreasing stroke-related death and disability.

The AHA's visibility and dedication to stroke had another substantial resurgence in the late 1990s when tPA was approved for the acute treatment of stroke. The AHA responded in real time with the Acute Stroke Treatment Program (soon transformed into the community-based program "Metro Stroke Task Force" and ultimately "Operation Stroke"). This product/effort eventually developed into a nationwide initiative to concurrently address:

- Professional education regarding diagnosis and utilization of tPA
- Public education campaigns to grow recognition of stroke symptoms and the knowledge necessary to activate the emergency medical system (EMS)
- Training within the EMS for appropriate diagnosis and patient transportation
- Regulation regarding hospital bypass to ensure patient delivery to hospitals prepared to offer best care vs closest care
- Development and implementation of GWTG – Stroke for hospital benchmarking and continued quality improvement
- Access to appropriate rehabilitation post discharge

This effort transformed stroke recognition and care in the United States and positioned the AHA as the most vested, and invested, voluntary health organization dedicated to stroke in this country. With that came an evolution of naming conventions and stroke efforts now branded under The American Stroke Association (ASA), a division of the American Heart Association.

The AHA/ASA's commitment to stroke continues to grow and emerge to this day through an infrastructure driven by a small, dedicated group of staff who work through influence and integration in the AHA's full portfolio. The ASA also tackles those things determined as most important to the stroke effort that cannot be integrated or represented by the larger "Heart" activities. While this approach has been unquestionably

successful in improving stroke recognition and care, it does come with increased costs, some duplication of effort driven by desire for brand recognition vs. health outcome, and some public and professional confusion surrounding the use and intent of the ASA name itself.

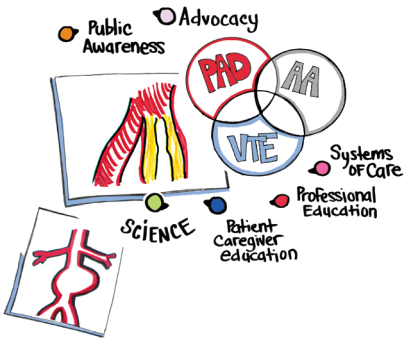
AHA BUSINESS ASPECTS

In keeping with the AHA's mission to "Build Healthier Lives, Free of Cardiovascular Disease and Stroke," it is essential to provide life-saving and life-serving health information to patients, their caregivers and their families. The AHA is a trusted and credible source of health information and education in an increasingly fragmented, and often overwhelming, health information marketplace. It garners over 20 billion media impressions annually and has over 90 percent consumer name recognition.

From a health education perspective, there is a strong belief in individual decision-making and patient-consumer empowerment. As an information provider, a goal of the AHA is to deliver information (and decision support) at the right time, and in the right way, to patients, caregivers and their families, such that improved health decisions will be made.

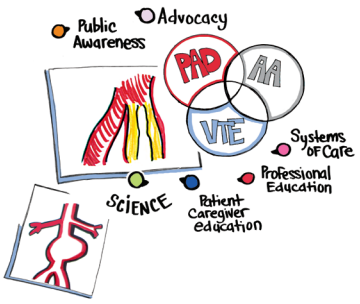
The AHA's health education products and programs cover the full spectrum of cardiovascular and stroke care and are designed to meet the needs of the specific channel and setting. Health education is provided through a line of about 90 patient brochures, patient magazines, patient TV, and literally thousands of articles, videos, tools and interactive applications delivered through the AHA web and social media sites. It is the intent of the AHA to drive health education initiatives, tools and content into the forefront so that we move directly into the flow of care and life. It will be essential to do this in sustainable ways, continuously identifying new business models and relationships to meet our goals.

WHAT ARE WE DOING WELL? WHERE ARE THE GAPS?



PERIPHERAL ARTERY DISEASE

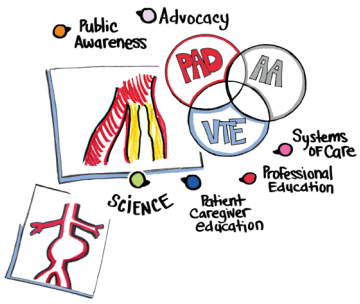
More than 200 million people suffer from peripheral artery disease across the globe[32]. Moreover, with population aging, there has been a rising prevalence of PAD worldwide. Patients with PAD experience functional disability and high rates of cardiovascular events that exceed those of patients with coronary artery disease. Several key challenges are important in advancing prevention, diagnosis and treatment of PAD. There is limited public awareness of PAD, and knowledge of PAD among healthcare professionals is inadequate. Therefore, a considerable gap exists in PAD detection and delivery of optimal medical therapies to patients with PAD. Systems based approaches using care teams and incentives to adhere to guideline-based treatments have potential to reduce cardiovascular risk in PAD. Collaborative approaches using novel technologies hold promise to achieve implementation of medical and exercise-based treatments in PAD. More research is necessary to establish the long-term efficacy of preventive and therapeutic interventions. Also, patient-centered outcomes focusing on durable treatments that improve function are needed. Partnerships are critical to advance translational science with the goal of developing novel medical therapies to treat PAD. By improving access to care, defining research priorities, and focusing on outcomes important to patient health, we can develop bold new programs to achieve a goal of reducing death and disability from PAD.



AORTIC & PERIPHERAL ANEURYSMS

Aneurysms, including aortic and peripheral artery aneurysms, are commonly encountered vascular conditions. Management decisions are typically predicated on aneurysm diameter in order to reduce the risk of rupture of aortic aneurysms or thromboembolic complications of peripheral artery aneurysms. Oftentimes, however, patients are unaware that they have an aortic aneurysm and present with catastrophic rupture; or those with popliteal artery aneurysm develop limb threatening ischemia. Screening programs for abdominal aortic aneurysms in males who have ever smoked have been supported through the Welcome to Medicare Physical Examination. These programs are relatively new and relatively few patients have undergone screening. Once detected, surveillance of aortic aneurysms for expansion in size is important to determine when a critical diameter is reached that merits placement of an endovascular graft or surgical repair. Indeed, significant progress has been made in terms of lowering mortality from a high-risk open surgical procedure to less invasive endovascular therapy. Unfortunately, there are no current medical therapies aimed specifically at retarding aneurysm growth. Also, little natural history data is available regarding growth patterns outside of clinical trials. Therefore, there is no consensus regarding follow-up interval with ultrasound once a small aneurysm is found.

Gaps exist in public and physician knowledge of AAA and peripheral artery aneurysms. There is little effort to increase public awareness or physician-directed education about aneurysm disease. Poor public and physician awareness reduces detection and timely life-saving intervention for aortic aneurysms. Peripheral artery aneurysms, such as popliteal artery aneurysms in particular, are usually asymptomatic, and if undetected and untreated, may thrombose and cause limb loss. Therefore educational efforts, primarily for healthcare professionals, may improve the likelihood of early diagnosis and provision of appropriate intervention. Importantly, increased basic and clinical research is needed to increase our understanding of the pathogenesis and mechanisms of aneurysm growth and facilitate discovery of medical therapies that prevent and treat aneurysmal disease.



VENOUS THROMBOEMBOLISM

Venous thromboembolism, which includes deep vein thrombosis and pulmonary embolism, is a major cardiovascular disease that affects adults of all ages and ethnicities, yet has received far less attention than heart attack and stroke. Diagnosed in one to two per 1,000 persons per year[33, 34], VTE is the second most common cardiovascular disorder after acute coronary syndrome[35]. Pulmonary embolism, the most serious form of VTE, is the 3rd-leading cause of cardiovascular death overall and of sudden death in hospitalized patients[36]. Approximately 10 percent of patients with acute pulmonary embolism die rapidly prior to diagnosis[37], emphasizing the importance of preventing VTE.

Twenty percent of symptomatic VTE is provoked (e.g. limb fracture or plaster cast, hospitalization with bedrest, or use of general anesthesia, each within the previous three months), and 30 percent is associated with cancer[38], highlighting the importance of efforts to prevent VTE in high-risk settings and patient education to ensure early diagnosis. The remaining 50 percent of patients have unprovoked VTE, for which the optimal duration of treatment is uncertain.

VTE imposes lifelong burden for many patients because of chronic sequelae, which include: recurrent episodes of VTE (recurrence rate off anticoagulants is about 5 to 10 percent per year)[39]; the post-thrombotic syndrome (PTS) (occurring in 20 to 40 percent of DVT patients); and chronic thrombo-embolic pulmonary hypertension (occurring in 3 to 4 percent of PE patients)[40]. Hence, health care costs of VTE are substantial[41, 42], and indirect costs such as loss of productivity are also considerable[43,44]. The annual cost of VTE and its complications has been estimated to be between $15.4 billion and $34.4 billion[45].

Anticoagulants, the mainstay of VTE treatment, are very effective at preventing VTE extension and VTE recurrence. Anticoagulants are also the leading drug class linked to drug-related adverse events (e.g. life-threatening

bleeding)[46]. The need for injections, frequent laboratory monitoring, and lifestyle or dietary modifications impose patient burdens. Several new oral anticoagulants to prevent and treat VTE have been approved in the last few years, and others are in the development or testing phases[47].

Patients with suspected VTE present in a wide variety of settings including primary care offices, emergency rooms, inpatient medical and surgical wards, and intensive care units. Hence, all healthcare providers require basic knowledge of VTE prevention, VTE diagnosis and principles of VTE treatment.

There are a number of VTE areas in which we are doing well. These include a strong record of discoveries in basic science, important findings in translational and clinical research, and high impact randomized controlled trials addressing prevention and treatment of VTE; development of evidence-based guidelines and AHA scientific statements[48,42,43]; creation of a national VTE research network in Canada (CanVECTOR Network); and selected offerings of thrombosis fellowships (e.g. in Canada at McMaster, Ottawa, and McGill universities).

Yet, there remain considerable gaps. There is a need for real-world, population-based VTE research. There is limited use of large-scale healthcare administrative databases to conduct population-based quality of care and effectiveness studies. Registries and novel randomized clinical trials must be designed to evaluate the impacts and outcomes resulting from real-world use of VTE prevention strategies. The long-term efficacy, safety, cost effectiveness, and comparative effectiveness of new oral anticoagulants are unknown, and many hospital and community physicians have limited experience with their use.

There is a need for research on management of VTE in subgroups and "orphan" populations. Only selected patients were included in the trials that led to regulatory approval of anticoagulant drugs, leaving key knowledge gaps about the role of new therapies in many important subgroups (elderly patients, obese patients, those with renal dysfunction, extremes of body weight, pregnant or lactating women, pediatric patients, cancer patients, and those with antiphospholipid antibody syndrome). The optimal duration of anticoagulation for unprovoked VTE is not yet established. In addition, there are other important knowledge gaps, which include inadequately understood causal factors/biomarkers for first and recurrent VTE; inconsistent use of proven measures to prevent VTE; and inconsistent use of validated clinical decision rules to diagnose deep vein thrombosis and pulmonary embolism.

There are also gaps in knowledge transfer and translation as reflected by limited community expertise in diagnosing and managing VTE and its complications among front-line practitioners, and by limited knowledge of VTE among the general public. Educational initiatives that are targeted to the general public (promoting early diagnosis), patients (promoting prevention, early diagnosis, compliance with therapy), and general healthcare providers (promoting prevention, diagnosis and initial treatment) are needed. There needs to be greater engagement with patients and their caregivers. Patients should be involved in the planning, implementation and translation of VTE research to optimize priority setting and patient centeredness. Patient-important outcomes should be measured with involvement of patient advocacy and support groups.

It is vital to invest in training and mentoring of scientists and clinicians in order to develop future leaders in the field. This requires resources and a financial commitment from universities to support salary and start-up funds for early career investigators. True partnerships among academic institutions, not-for-profit organizations, and industry can help close these gaps.

GUIDANCE ON PRIORITIZATION OF AHA RESOURCES

WHAT POSSIBLE ROLES MIGHT THE AHA PLAY IN THE SCIENTIFIC RESEARCH AND DISSEMINATION DOMAIN?

There are important research opportunities in each of these three areas of vascular disease (PAD, aortic/peripheral aneurysms, VTE). For PAD, there is a need for better risk prediction tools for both primary and secondary prevention. Such risk prediction tools would help both individuals and clinicians know when an ABI should be obtained[49]. While measurement of the ankle-brachial index can detect PAD (i.e., evidence of atherosclerosis), and is thereby a potent predictor of overall cardiovascular event risk, data are not currently available as to whether this or other risk-markers select patients who might benefit from more aggressive treatment. In addition, there are few tools to guide more intensive treatment for the prevention of limb ischemic events. There is a significant unmet need with regard to defining limb vascular events and disseminating information about the risk and outcomes to clinicians, patients and families. Clinical trials have used variable definitions, and treatments largely focus on reducing the risk of major adverse cardiovascular events as a primary endpoint. Further research is needed to define limb vascular events in a way that is broadly understood, similar to that of myocardial infarction and stroke. For VTE, better risk predictors that could identify patients (e.g. those with high-risk malignancies) as candidates for VTE prophylaxis would be useful, as would algorithms based on relative benefit and risk, which could help guide the duration of anticoagulation for patients with a history of VTE. In the area of aortic aneurysm, there is significant unmet need in describing the natural history in the era of modern medical therapy. More data are needed to define who is at risk, the pathogenesis and determinants of growth of abdominal and thoracic aortic aneurysms, the impact of medical therapy, and long-term outcomes.

The AHA provides great resources for research and knowledge dissemination in its Council on Peripheral Vascular Disease and its engagement of vascular specialists and scientists across different disciplines. An AHA research

program focused on vascular disease holds the promise of discoveries that would improve diagnosis and treatment of peripheral vascular diseases and favorably impact disease outcomes. Translation of science to programs that implement vascular care would also improve detection and disease management. The AHA is positioned to convene vascular specialists and scientists to identify gaps and develop a list of priorities and mechanisms that the AHA could use to guide further research. Also, the AHA can leverage tools and resources already utilized or under development (e.g. big data initiatives, registries) for discovery in vascular medicine. Finally, a strategically focused research network, as has been developed for other areas of need, could be exploited to further knowledge in the area of vascular medicine. In terms of knowledge dissemination, the AHA might convene a group of vascular specialists, scientists, patients, payers, policy experts and others to review knowledge gaps that affect current guidelines and develop practical approaches to patient care.

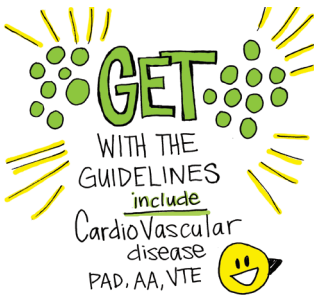
WHAT POSSIBLE ROLES MIGHT THE AHA PLAY IN THE PROFESSIONAL EDUCATION DOMAIN?

The AHA can utilize its existing strengths and infrastructure as a trusted professional education source with a proven track record in order to address unmet needs in vascular disease. The AHA has an opportunity to provide education to primary care providers, cardiovascular physicians, and other healthcare professionals. There is an opportunity to construct a library of uniform curriculum elements covering prevention, diagnosis and treatment of PAD, aortic and peripheral aneurysms, and VTE, potentially in collaboration with other professional organizations. Education also could be directed at residents, fellows in training or vascular specialists and include more advanced materials such as guideline-based steps in determining the best medical or surgical path to follow in treating individual patients.

WHAT POSSIBLE ROLES MIGHT THE AHA PLAY IN THE PATIENT AND CAREGIVER EDUCATION DOMAIN?

As an organization committed to patient health, the AHA has opportunities to utilize its existing resources and brand recognition to reach the public directly with tools to help patients and caregivers and to facilitate other outreach programs. Registries and surveys are needed to define patients' demographics, characteristics and outcomes, and to support strategies for decision-making tools that can help design treatment programs for patients. Awareness campaigns similar to Go Red for Women would help inform the public about the risks, signs and symptoms of vascular disease. The AHA can provide materials to patients on its website, develop support networks for patients, and educate physicians to discuss the risks with their patients.

WHAT POSSIBLE ROLES MIGHT THE AHA PLAY IN THE SYSTEMS OF CARE DOMAIN?

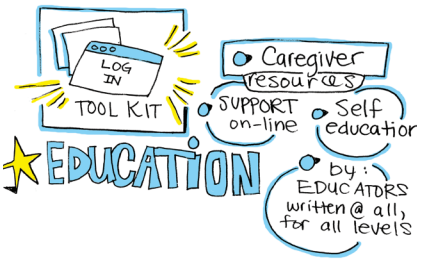


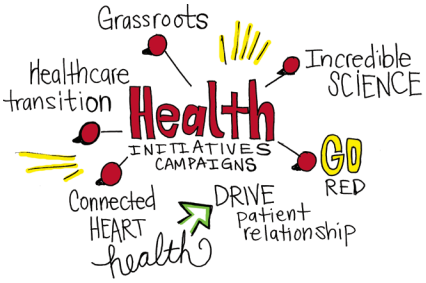
The AHA can capitalize on its existing strengths in the Get-With-the Guidelines program (GWTG) and Guideline Advantage program to expand into the vascular disease domain to promote guideline awareness and adherence in clinical settings. This would have the dual effect of improving patient care and secondary prevention, as well as providing a framework for public reporting and pay-for-performance programs. Coordinating with other stakeholders by way of a national registry would also advance public awareness of and standards of care for PAD, VTE, and AAA.

WHAT POSSIBLE ROLES MIGHT THE AHA PLAY IN THE PUBLIC AWARENESS DOMAIN?

The American Heart Association is positioned to lead future vascular disease awareness initiatives. A strategic approach would include a series of steps designed to maximize the efficacy of such a campaign. A future vascular public awareness campaign would leverage lessons learned from past heart disease and stroke awareness efforts. First, public knowledge would be measured to define current PAD, VTE and AAA risk awareness and knowledge. The public sample would be derived to include all relevant age, sex, and ethnic/cultural risk groups. This effort would also seek to identify "action motivators" that would lead to behavior changes. Second, this information would be used to inform a pilot national vascular awareness campaign designed to engage all stakeholders; as with heart disease campaigns, it is critical

that public awareness effort not be split by specialties. This can be achieved via engagement of key AHA Council leaders and their members, including the Councils on Peripheral Vascular Disease, Epidemiology and Prevention, Lifestyle and Cardiometabolic Health, Quality of Care and Outcomes Research, Clinical Cardiology, Cardiovascular and Stroke Nursing, and others. Other health professional societies, government agencies (NHLBI, PCORI, others), and industry (pharmaceutical and device companies) should also be engaged to ensure that all dissemination platforms are used and that financial resources are leveraged to maximal effectiveness. Based on the information obtained by a pilot (regional) campaign, national dissemination would be associated with efficacy measures. Creating a "vascular health literate" American public would support both the AHA mission and its 2020 Impact Goal.





WHAT POSSIBLE ROLES MIGHT THE AHA PLAY IN THE ADVOCACY DOMAIN?

As the public health burden of vascular diseases such as PAD, VTE and AAA continues to grow, there is an urgent and unmet need for advocacy to improve the vascular health of the population in the United States and around the world. The AHA has a strong public brand based on its longstanding promulgation of high quality science, disease awareness, and healthy lifestyle, as well as an active volunteer workforce. It has a solid track record of success in advocacy for heart disease and stroke and a professional infrastructure to go with it. Thus the AHA is well positioned to play a leading role in advocacy for vascular health and may serve as the organizer to bring together professional societies, nonprofits, private industry, and other stakeholders with shared goals and interests.

Several key priority areas for advocacy are identified. Lack of reimbursement for supervised exercise rehabilitation in PAD is a major unmet need. Programs to improve the utilization of VTE prevention modalities in at-risk populations would also have great potential impact. In the area of AAA, a high priority is to increase the availability of ultrasound screening within Medicare for both men and women with defined risk factors. Advocacy for increased research funding for vascular diseases, particularly in clinical, translational, and population science, remains a critical need. Major gaps in epidemiology, comparative effectiveness of different medications and treatments, disparities in care based on socioeconomic status, and emerging therapies for vascular diseases currently exist. The magnitude of need in these areas requires collective investment from federal agencies (NIH, AHRQ, PCORI, CMS), the private sector (payers, drug, device and biological companies), and other non-profit health agencies. The AHA should take a leadership role in this arena to convene stakeholders from all sectors, inform key decision-makers, and influence policy and systems of care to improve vascular health and favorably affect outcomes of patients with vascular disease.

THE AMERICAN HEART ASSOCIATION'S ROLE

Based on the discussion of strengths and gaps in key areas driving vascular disease awareness and care, prioritized opportunities for AHA were identified at the conclusion of the summit (Table 1). These recommendations will enable the AHA to prioritize where to concentrate its activities in vascular diseases.

STAKEHOLDER	EXPERT SUGGESTIONS TO THE AHA
Science	Consider creating a Strategically Focused Research Network for Vascular Disease. Explore convening leading vascular specialists and scientists to develop a list of ongoing research priorities. Consider reviewing AHA's research infrastructure to identify segments that can quickly align with potential research priorities.
Professional Education	Investigate the possibility of promoting the recognition of Vascular Medicine as an ABMS accredited specialty. Consider developing a standardized entry-level professional education portfolio. Explore strategies whereby 'vascular diseases' also become part of AHA's recognized brand. Align internal AHA resources to allow for coordination of vascular disease assets. Investigate the expansion of vascular disease programming at Scientific Sessions and becoming a leader in vascular meetings. Explore developing a stand-alone publication segment emphasizing vascular focus across specialties.
Patient and Caregiver Education	Suggest initiating a campaign similar to Go Red for Women aimed at increasing public awareness of PAD signs and symptoms, especially in at-risk populations (e.g. smokers over 65 years of age). Consider a campaign to promote AAA screening in vulnerable populations (e.g. male smokers over age 65). Investigate development and implementation of a patient education toolkit to prepare patients for healthcare encounters. This might include tools for recognition of signs and symptoms, creation of a risk score including interpretation and next steps, and creation of support groups. Consider creating a tool to identify the risk of VTE for cancer patients and subsequent patient education tools.
Systems of Care	Examine the potential to expand Get With The Guidelines to include vascular disease such as PAD, VTE and AAA. Consider creating Centers of Excellence for PAD that would improve patient, physician and public awareness of the disease. Explore creating a National Registry for Vascular Disease to uniformly track patients.
Public Awareness	Suggest that the AHA consider creating a major public awareness campaign or initiative for vascular disease. Consider initiating a wide-reaching surveillance system to measure public awareness of vascular disease and provide timely, population-focused information. Explore creating and regularly convening a coalition of expert thought leaders to drive a broad vascular disease segment within a fully integrated CV Health initiative. Consider creation of unifying large simple trials around vascular diseases. Examine the potential of aligning AHA resources in the financial, volunteer, and staff segments to drive integrated vascular health programs. Investigate advancing awareness of vascular disease in diverse racial and ethnic populations. Explore enhancing the AHA website content for vascular disease.
Advocacy	Consider advocating for supervised exercise reimbursement in PAD treatment. Explore expanding marketing of vascular disease patient information. Examine expanding vascular disease programming at Scientific Sessions. Explore opportunities to increase the implementation of clinical research results by healthcare providers. Consider identifying and setting targets for advancing advocacy goals in vascular disease issues. Suggest improving community-level messaging about vascular disease risks, signs and symptoms, and ultimate consequences if untreated.

SUMMARY & CONCLUSION

The discussion among participants at the summit identified a wealth of potentially fruitful opportunities for the AHA to advance the field of vascular disease awareness, education and care. These include: engage the public and develop awareness campaigns for PAD, VTE and AAA; create quality initiatives for PAD and VTE such as Get with the Guidelines and Guideline Advantage programs; implement professional education programs in vascular diseases and develop standardized vascular content for practitioners; enhance formal training by promoting the recognition of vascular medicine as an ABMS specialty; fund a Strategically Focused Research Network for Vascular Disease; advocate for PAD screening using the ankle-brachial index (ABI) and for a payment scheme for supervised exercise training for PAD.

American Heart Association
American Stroke Association
life is why.

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American Heart Association Vascular Disease Thought Leaders Summit, **August 20, 2015**

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