



American
Heart
Association.



PAD Roundtable REPORT

A VASCULAR DISEASE THOUGHT LEADERS SUMMIT REPORT 2019



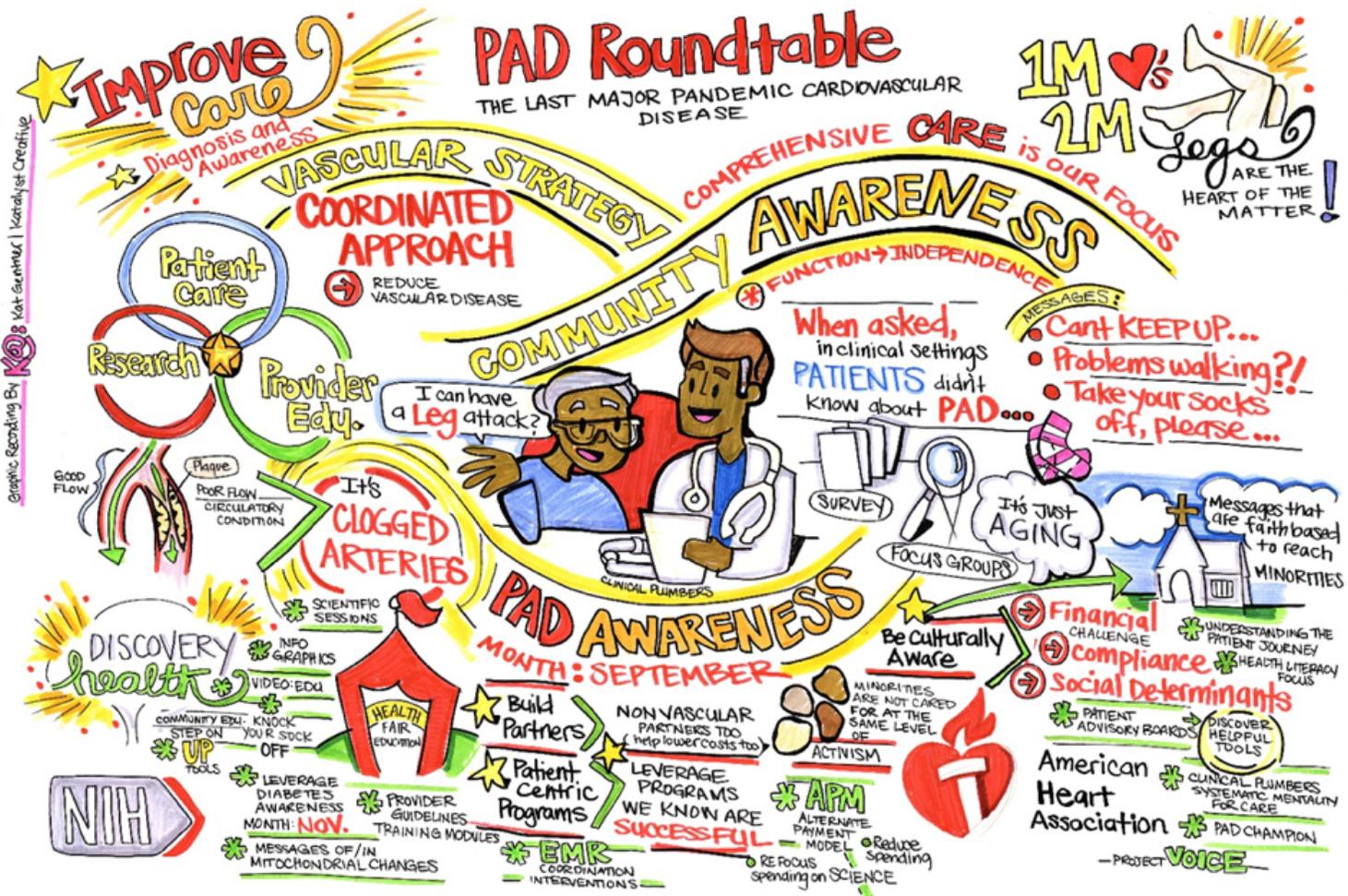


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Improving Awareness of Peripheral Artery Disease: The Peripheral Artery Disease Awareness Roundtable, Dec. 10, 2018

"PAD is a major pandemic in cardiovascular disease."

– Alan T. Hirsch, MD

Peripheral Artery Disease: Focusing on Vascular in Cardiovascular Health

Peripheral artery disease (PAD) is a progressive atherosclerotic disease in which one or more peripheral arteries, typically in the lower limbs, are partially or completely obstructed, reducing blood perfusion to the limb.¹

Overall, PAD affects approximately 8.5 million Americans, most of them age 65 and older.² A recent analysis of Medicare³ inpatient and outpatient claims estimated a mean annual incidence of 26.8 per 1,000 and an overall mean annual prevalence of 12.4% for diagnosed PAD. The prevalence is significantly higher in black women and men (16.9% and 13.2%, respectively) compared to white men and women (12.1%, and 10.9%, respectively).³ These estimates do not account for cases of PAD that remain undetected due to low patient and provider awareness of the disorder. Given the growing elderly population, by 2050 an estimated 19 million Americans will have PAD.⁴

Patients with PAD are at a significant risk of cardiovascular events. In the EUCLID study, the risk of cardiovascular death, myocardial infarction (heart attack) and stroke at 30 months was between 9.9% and 11.4%. The condition is associated with reduced mobility, limb function, quality of life, high cost of care and increased rates of hospitalization and amputation.^{5,6}

Many of the same conditions that contribute to coronary artery disease are also implicated in PAD, including cigarette smoking, diabetes, hypercholesterolemia and hypertension⁷

Despite its relatively high prevalence, there is a significant gap in the public's understanding of PAD, its symptoms and complications compared to other similarly prevalent atherosclerotic conditions, such as heart attack. In one telephone survey of 2,500 adults ≥ 50 years, just 26% were familiar with PAD compared to more than 65% for coronary heart disease, stroke and heart failure. Only 14% knew that PAD could lead to amputation, and merely 25% were aware that the condition was associated with a higher risk of heart attack and stroke.⁸

The knowledge gap among physicians is significant, resulting in a large number of patients with PAD going undiagnosed.⁹⁻¹² This gap represents a significant unmet need in education, as proper diagnosis and treatment reduce morbidity and mortality in this population.¹³

Even among patients correctly diagnosed, there is evidence these patients often do not receive appropriate treatment. The variance may partially be reflective of a knowledge gap among patients, clinicians and health systems about the value of prevention, early detection and management of the condition.^{4,9,11,14-16}

Getting to the Heart of Vascular Health



The American Heart Association (AHA) is a global leader in the fields of cardiovascular disease and stroke and has a long history in the discovery, dissemination and application of scientific knowledge. Recognizing the importance of prevention, diagnosis and treatment of PAD and the broad range of individuals working on the science, professional education, patient care and health education aspects of the disease, the AHA partnered with the National Heart, Lung, and Blood Institute (NHLBI) to hold an expert roundtable on Dec. 10, 2018, to identify and address gaps in PAD awareness and management. The participants included a multi-disciplinary group of leaders from key collaborating medical organizations, federal health agencies and patient advocacy groups as well as patient advocates (Table 1, page 28).

The meeting's goal was to develop the roadmap for a National PAD Awareness Initiative that (Figure 1):

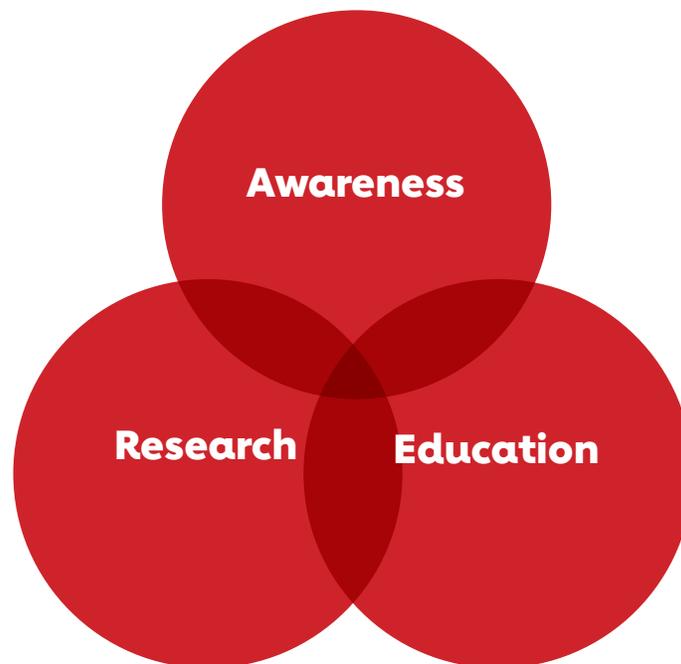
- Improves patient and clinician awareness;
- Uses clinician education about evidence-based management to improve outcomes and quality of life; and
- Identifies research gaps.

As Amy Pollak, MD, chair of the AHA's Task Force for PAD Awareness, noted: *"We need to have all three legs of the stool addressed to be able to make a significant impact on PAD awareness and future outcomes for patients with PAD."*

This conference report summarizes the topics discussed and priorities identified at the roundtable and provides a roadmap for a national action plan. Additionally, the appendix includes highlighted PAD related activities discussed by representative members of the collaborating organizations (Appendix).

The PAD Task Force presented their findings from preliminary community-based PAD awareness surveys and focus groups. The roundtable participants then shared their current efforts in increasing clinician PAD awareness, community activation and professional education. This was followed by breakout group discussions on key topics. Each group presented their recommendations to all.

Figure 1: Key Goals of a PAD National Initiative



Awareness of PAD: Community Surveys, Messaging and Focus Groups

The AHA's PAD Task Force conducted a survey in April and May 2018 to gauge public awareness of the disease. Survey goals included measuring the baseline knowledge of PAD risk factors and symptoms; assessing understanding of risk for cardiovascular events and the connection between PAD and cardiovascular disease and stroke; testing awareness messaging; and providing insights for marketing and communications planning. Dr. Aruna Pradhan, the Chair of AHA's Council on Peripheral Artery Disease, reviewed the results and presented this section at the Roundtable meeting.

The pilot survey was conducted among 1,645 adults across four audiences: members of the AHA's Go Red for Women and EmPowered to Serve groups; attendees at the Church of God in Christ (COGIC) conference; and women from black and Hispanic senior communities in underserved areas of downtown Chicago. Most of the participants were women between the ages 50 and 70, and 80% were white.

The survey results revealed a low overall Awareness individual cardiovascular risk among respondents, particularly those who had no affiliation with AHA. There was also less awareness of PAD compared to other cardiovascular conditions among all groups (Figure 2). Fewer than half of community participants were aware of the condition. Black and Hispanic participants across all groups demonstrated lower awareness than whites.

Less than half (47% and 23%) of AHA program respondents knew the clinical symptoms associated with PAD. Only 5% and 6% of the COGIC and Chicago respondents, respectively, were aware of PAD symptoms (Figure 3). This lack of awareness is all the more remarkable as it occurred on a background of an estimated 20% to 25% of respondents having experienced at least one potential PAD symptom in the past 12 months, primarily unexplained leg pain or cramping during exercise or walking.

Chicago and COGIC respondents were also significantly less knowledgeable about PAD overall compared to other surveyed groups.

Figure 2: Awareness of PAD

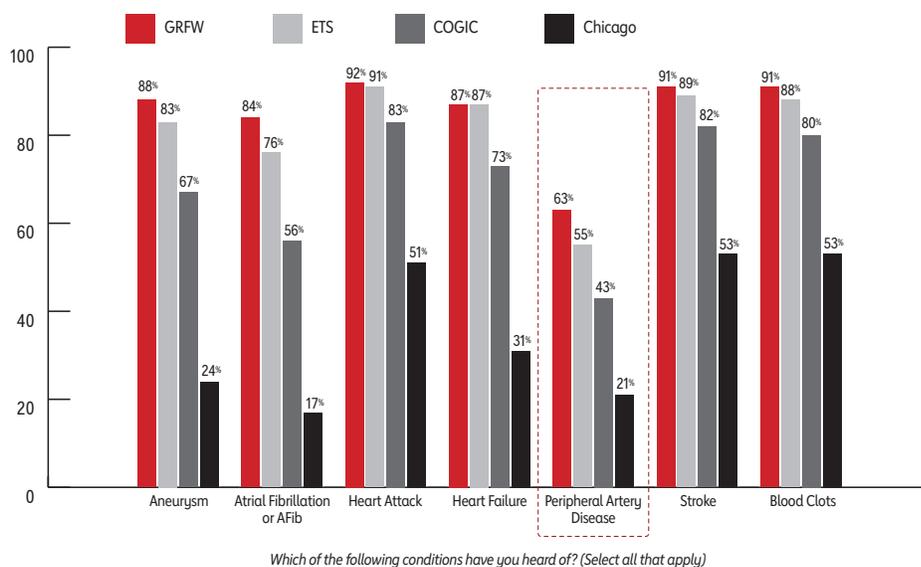
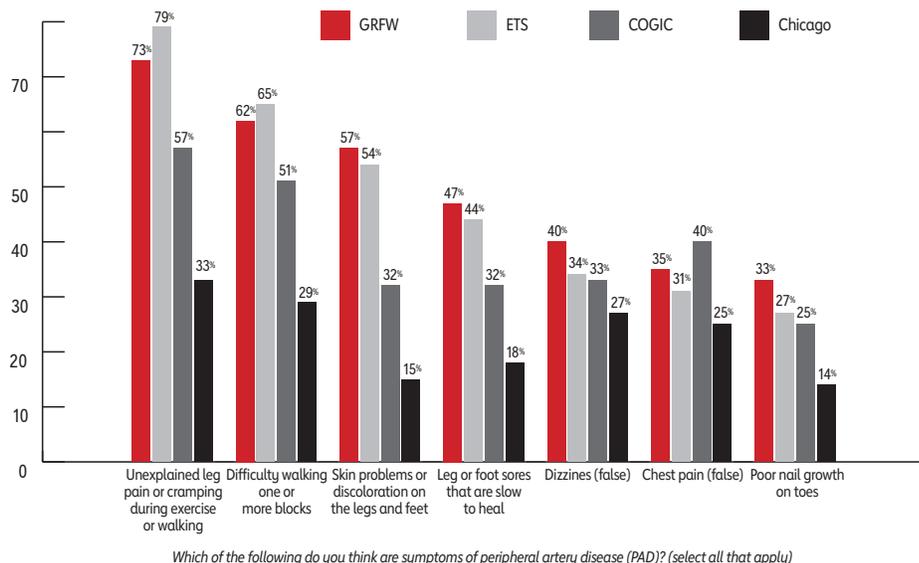


Figure 3: Knowledge of PAD Symptoms



The PAD Task Force is implementing the survey with a broader segment of the population, with a higher representation of males.

Surveyors also tested five messages about PAD (Table 2). There were differences in the types of messaging that participant groups identified as most motivating.

Table 2

Messaging About PAD
<ul style="list-style-type: none"> • Can't keep up? Maybe clogged leg arteries are slowing you down. Talk to your doctor to find out about peripheral artery disease. • Take off your socks at your next checkup. It could save more than your legs: It could save your life. • Problems walking? Your legs may be at the heart of the matter. Get checked for peripheral artery disease. • Your legs and feet could hold clues to your heart and brain health. Learn about peripheral artery disease. • Don't ignore your legs. They may be telling you about your risk for a heart attack or stroke. If you have leg pain, ask your doctor about peripheral artery disease.

Chicago Focus Group Data

“Wait a minute. I can have a leg attack the same way that I can have a heart attack or a brain attack?”
– focus group participant

The PAD Task Force engaged 124 Hispanic and African American individuals in education and focus group sessions at four senior centers in downtown Chicago. The objective was to identify their knowledge levels of PAD and test Potential PAD messages to understand how they resonate with people from diverse communities. All attendees completed the PAD awareness survey and received PAD education. Approximately 50 participants then participated in one of five focus groups (average of 10 participants per group).

In one focus group of 10 individuals, just three had ever been asked to take their socks off to have their feet checked in a physician’s office. Although one participant’s mother had a limb amputated, the daughter was unaware that it may have been related to vascular disease. In this same group, four people had leg symptoms with exertion and noted they had been slowing down, not able to walk as far as in the past. Although they tried talking with their health care providers about this, they were told it was “normal aging.” Others said that rushed office visits prevented them from reporting their leg discomfort and limited mobilization.

Other findings from the focus groups around messaging are highlighted in **Table 3**.

Table 3

Key Takeaways about PAD Messaging from the Focus Groups

- “Leg attack” resonated with focus group members.
- Connecting PAD with losing a leg provides a powerful message.
- There is no one perfect message for everyone, even within the same community; thus, personalized messaging is required.
- “Just can’t keep up” is confusing and also would not translate well into Spanish.
- The term “peripheral” implies that PAD is not central to health.
- Messaging must highlight that PAD involves clogged arteries/blood vessels.
- Messaging must include concrete actions, such as “talk to your doctor.”
- Messaging must be specific that PAD involves the legs.

Community Activation: PAD Awareness Month

Figure 4: PAD Survivor - Frank Diaz



Activating the community requires getting out into the community. J. Antonio Gutierrez, MD, interventional cardiologist and Assistant Professor of Medicine at Duke University Medical School, described an AHA awareness/activation event tied to PAD Awareness Month. The goal, he said, was to build a unified public health approach using top-down and bottom-up approaches. The key theme connected “slowing down” to a clogged artery in the leg.

The initiative involved outreach efforts during Heart Walks in September 2018 in Dallas, Jacksonville and Cleveland. During the events, volunteers distributed more than 400 PAD T-shirts, red socks, stickers and educational resources. In addition, PAD patient advocate Frank Diaz shared his story in the AHA’s consumer publication, Heart Insight, which reaches over 400,000 readers nationwide. “One of the most important things for outreach is having the patients lead the awareness initiative,” said Dr. Gutierrez. “We feel that was probably one of the most impactful approaches.”

“Living with PAD: Patient Advocacy”

Figure 5: PAD Survivor - Elizabeth Beard



Patient volunteer Elizabeth Beard is a member of the AHA’s PAD Task Force. She was the first Go Red for Women advocate with a history of PAD. She has worked to share her story of PAD diagnosis and treatment and her experience of living with PAD. Elizabeth spearheaded the Dallas Heart Walk efforts for PAD awareness in 2018, which was supported by her vascular surgeon, Dr. Russell Lam of Lam Vascular.

After being a smoker for 35 years, Beard quit. She started a walking program so she wouldn’t gain weight. Around that time, she began experiencing tight calf muscles and numbness in her feet.

At first, she thought it was because she was overweight. What she thought was a simple leg problem turned out to be something much more serious — peripheral artery disease. Despite having a family history of cardiovascular disease, she never made the connection between her own health risk factors and heart disease.

Read Elizabeth’s story in the **Fall 2017 Issue of Heart Insight**

Provider Education Outreach Efforts

"I dream of a world in which patients who realize that they're at risk for PAD are inundating their doctor's office trying to ask what should be done."

– Scott Damrauer, MD, Vascular Surgeon, University of Pennsylvania

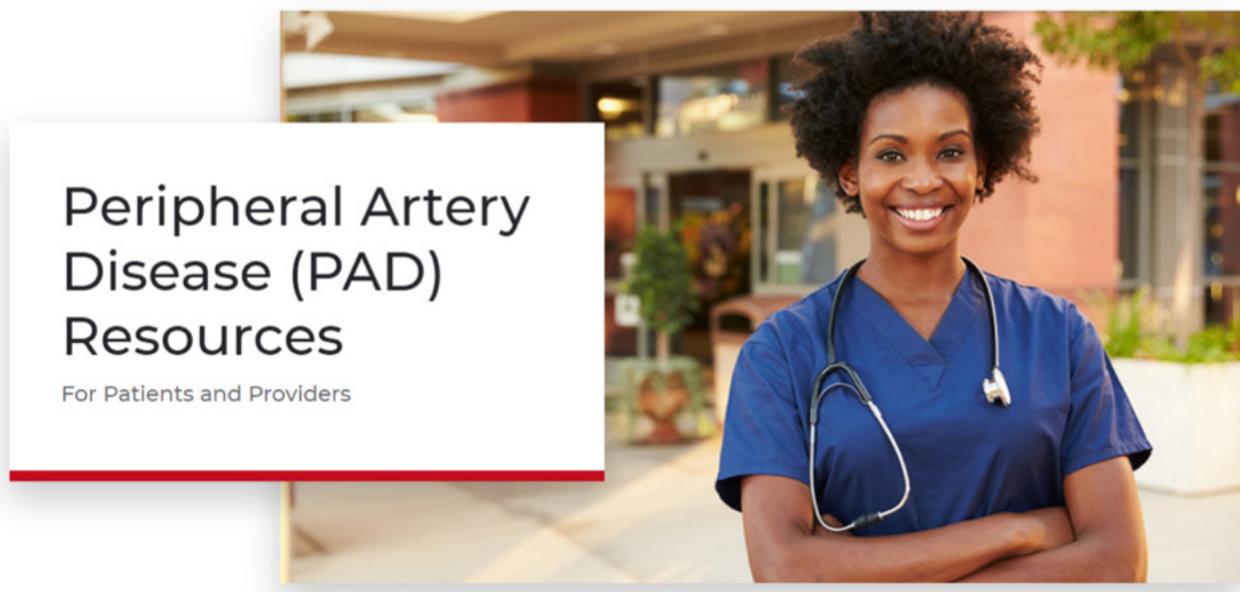
"Building PAD awareness among clinicians requires collaboration with non-vascular specialties," said Scott Damrauer, MD, vascular surgeon and Assistant Professor of Surgery at University of Pennsylvania Medical School. That includes internists, family practitioners, orthopedic surgeons, podiatrists, endocrinologists, rheumatologists, advance practice providers, community health workers and home health nurses.

"We are looking to develop a strong collaborative interdisciplinary and inter-society approach to raising provider awareness," he said.

A key question is how to engage large numbers of busy clinicians. Potential points of engagement include professional societies, health systems, payers and regulators. Dr. Damrauer highlighted the many digital resources the AHA has online for health care professionals, including the PAD Go-to-Guide, a webinar and fact sheets (Figure 6).

This report includes a listing of provider education efforts from collaborating societies and organizations also doing work in this area. In one such effort, Deborah Kohlman-Trigoboff, a nurse practitioner at Duke University Medical School, led an educational session at the National Black Nurses Association conference to increase engagement across disciplines. The need to coordinate efforts among the organizations was discussed and had broad appeal.

Figure 6. AHA Online Resources for Health Care Professionals





Building a National PAD Initiative



Building a National PAD Initiative: Elements of Successful Programs

The following were deemed essential requirements for a national PAD initiative:

- Build a unified approach to increase PAD awareness, detection and treatment
- Improve patient-centered outcomes
- Target community health leaders and stakeholders

Several organizations described their PAD efforts and national initiatives to begin the process of creating cross-organization strategic approaches. The discussion focused on lessons from the Association of Black Cardiologists' recent PAD roundtable, the ASA's Stroke Awareness Campaign and the NHLBI's National COPD Action Plan and Million Hearts Initiative.

A. Lessons from the Association of Black Cardiologists Roundtable on PAD

Lee Kirksey, MD, vice chair of the department of vascular surgery at the Cleveland Clinic, and a member of the Association of Black Cardiologists (ABC) described efforts by the ABC to identify and address disparities in PAD in blacks. As he noted:

- PAD disproportionately affects blacks.
- Blacks with PAD have worse outcomes than other racial groups.
- Blacks are less likely to receive aggressive treatment.
- Blacks have higher rates of amputation
- Blacks are less likely to undergo imaging prior to amputation.

"Prior to amputation, blacks are less likely to be offered a revascularization attempt," he said, "so they undergo a primary amputation without an attempt to salvage the limb." In addition, they are less likely to see a board-certified revascularization specialist and less likely to be treated in a high-volume hospital.

Tackling a growing call to address these inequities, the ABC held a PAD roundtable in 2017 with interventional cardiologists, podiatrists, cardiologists, vascular surgeons and researchers. The group identified several issues around PAD and minorities, including:

- Implicit bias by the health care system;
- Low minority enrollment in clinical trials;
- Poor reimbursement for clinicians, because most patients are covered by Medicare or Medicaid;
- Poor smoking-cessation compliance; and
- Challenges related to the determinants of health, most of which are outside the control of the vascular specialist

With the movement towards value-based reimbursement in health care, Dr. Kirksey said, improving outcomes among patients with PAD has become a greater focus. "That represents an opportunity for funding both at the healthcare system and the national level," he said.

Building a National PAD Initiative: Elements of Successful Programs (continued)

Like several speakers at the AHA/NHLBI roundtable, Dr. Kirksey reiterated that patients are often unaware of PAD. “There is a lack of awareness from both the health care provider and the patient perspective,” he said. “Every patient with diabetes fears the loss of a limb but there is a lack of understanding that diabetes can be associated with PAD and that this population is at the highest risk of amputation.” There is also confusion over who is the most appropriate specialist to manage PAD. “Patients don’t understand they could seek a second opinion when someone tells them they need an amputation.”

One approach, he said, is to work with faith leaders to improve awareness and provide a medium for messaging. The ABC is also active in lobbying for public reporting of outcomes at the provider and the hospital level. “Public reporting systems will elevate community awareness and increase transparency of the outcomes related to PAD.”

B. Lessons from a Stroke Awareness Campaign

Hank Wasiak, MBA a volunteer with the AHA/ASA, highlighted the ASA’s Together to End Stroke awareness campaign as a best strategy that can be replicated to elevate PAD awareness. “We emphasized that 80% of strokes are largely preventable,” he said. “Our vision was to empower people to live longer, healthier lives free of stroke and cardiovascular disease.” An important lesson from that campaign, he said, is that the message has to be personal, emotional and positive.

Strategic approaches include:

- Make it important, big and emotional.
- Set specific, realistic objectives and direction.
- Compartmentalize if possible; one campaign may not do it all.
- Leverage internal and external resources.
- Seek out champions.
- Partner whenever possible with like-minded organizations/groups.
- Be nimble.
- Elevate awareness internally before going outside the organization.
- Have an awesome creative brief.
- Use simple language to bring science to life.
- Tell stories.
- Recognize that fear alone is not a good motivator.
- Amplify digital and mobile strategies.
- Communicate through several channels.

C. Lessons Learned from National Heart, Lung, and Blood Institute (NHLBI)-Led Initiatives

Lenora Johnson, DrPH, the NHLBI's Director of Science Policy, Engagement, Education and Communications, shared lessons learned on the challenges of reaching large audiences through an awareness campaign. Such campaigns, she said, can be extremely resource-intensive and difficult to evaluate. She outlined key components of the process:

- Assess gaps through a robust needs-assessment.
- Identify priorities through a defined theoretical framework, which answers the question: "What is it that impedes people's knowledge or understanding around the issue?"
- Set goals and objectives.
- Develop a cohesive framework.
- Implement the strategy.
- Monitor and evaluate progress.

D. Lessons Learned from the Centers for Disease Control and Prevention: The Million Hearts Initiative

When developing an awareness campaign, think about creating a movement, said former Million Hearts Executive Director Janet Wright, MD. "People want to belong to something bigger than themselves."

Strategic advice:

- Create an open framework so participants and organizations can visualize how their work contributes to the overall mission.
- Narrow the message down to the essentials.
- Match missions with other partners.
- Showcase stories of high performers.
- Create a set of messages that other organizations can adopt or adapt.
- Tell people's stories.



Small Group Breakout Sessions



Small Group Breakout Sessions: Six Key Areas for a National PAD Initiative



During the second half of the roundtable, participants broke into six small groups to develop a set of recommendations around a specific goal.

1) Key Messaging to Broaden Understanding of PAD

Goal: Develop a broad public health campaign to increase awareness of PAD. The campaign should be relevant to diverse audiences, provide education about symptoms and consequences and identify actions required to diagnose and treat PAD.

The group consisted of communications professionals and specialists from organizations dedicated to fighting PAD. It was agreed that no existing program cohesively or compellingly informs and educates the public and patients about PAD and that a consistent, sustainable effort is urgently needed.

The objective is to create a comprehensive communications program that will establish PAD as serious potential public health risk. The program should address a range of issues, from awareness of the disease, relevancy to specific audiences, education about symptoms and consequences and actions needed to prompt diagnosis and treatment.

Summary of Current Landscape and Critical Gaps:

The public is virtually unaware of the existence of PAD, much less its symptoms, health risks or treatment. The name “peripheral artery disease” is difficult for consumers to understand, and the abbreviation, PAD, needs explanation.

The first step is to connect with and educate the general public about the disease and treatment. It is also important that public communications be coordinated with medical professionals.

Recommendations

- 1) Scope:** Approach the problem as a broad public awareness campaign, with the primary focus being highest at-risk audiences and their family/friends.
- 2) Awareness and symptoms:** The focus for generating awareness could be get people to pay attention to their legs. For example, “Listen to Your Legs. They’re telling you something vital to your health and well-being.”
- 3) Create a sense of urgency:** Consider emphasizing quality-of-life symptoms and links to increased risk for heart disease and stroke. *“PAD is impeding my life/lifestyle and silently bringing me closer to a heart attack or stroke”*. Call to action e.g.: “Get more information and speak to your doctor.”
- 4) Nomenclature:** It was felt that using the full medical description of the disease could be an impediment and that PAD should be used as the shorthand. However, it will require consumer-friendly approaches to bring it to life. Once nomenclature and descriptions are agreed to, they should be used across all general audience communications as well medical professional audiences. Ideas discussed included:
- 5) Messaging: “Limb Loss”:** While this was felt to be an important consequence of PAD, it would be too extreme an outcome to include as a primary top-line motivator in initial communications. *“Leg Attack”:* This was felt to be too acute and sudden as a description which ignores the chronic and often progressive nature of the disease.

Next Steps:

1. Conduct a communications audit: i.e., an audit of consumer communications materials from all the participating organizations should be conducted. Determine the range of messaging currently being delivered as well as curate possible concepts and goals.
2. Finalize objectives and goals
3. Develop a creative brief
4. Identify a creative platform for dissemination

2) Community Activation and Public Health Engagement for PAD Awareness

Goal: Develop and implement initiatives designed to increase the capacity and skills of individuals, community health leaders and stakeholders to build and sustain coalitions and partnerships that support vascular health. Given the low awareness of PAD, in order to have a long-term effect on vascular health, we need to focus on community and public health engagement. The goal of the group was to identify initiatives that would serve as a vehicle to accomplish this aim. The group identified four initiatives:

1. We determined that community and public health activation could be advanced by fostering an environment where the public is encouraged to ask basic questions regarding PAD: What is it? Why is diagnosis so important? How do you treat it? This would have to be linked with an accessible platform or forum where health care professionals could provide answers. This initiative would hopefully establish clarity to what the community is dealing with in terms of PAD and its consequences.
2. We determined that the best way for medical professionals to get the message across would be through existing campaigns (such as AHA's Go Red for Women or barbershop/beauty salon HTN intervention model), large organizations (such as the YMCA) and other well-known approaches (public transportation and trusted elders).
3. To improve chances of initial success, the communication process should be tied into technology that had a "Wow Factor" (such as social media or apps). This would allow for rapid mass dissemination of knowledge.
4. PAD needs to gain spotlight at the national level. A perfect opportunity for this would be a National PAD Action Plan in collaboration with key stakeholders and integration into AHA's Healthy People 2030. National attention would be useful for the sustainability of initiatives 1-3.

Recommendations:

- Focus on public, patient and health care professional understanding.
- Leverage existing initiatives to amplify PAD, such as smoking cessation, diabetes prevention and management, and coronary artery disease and stroke prevention.
- Leverage digital/social media platforms.
- Include PAD as a topic/objective in the AHA's "Healthy People 2030."
- Launch PAD initiatives throughout communities, including YMCA, faith-based organizations, barbershops/nail shops and community centers.

3) Improving Support for Patients Diagnosed with PAD

When diagnosed with a medical ailment, patients often turn to both medical professionals and peers for support. This may take the form of concrete medical interventions, lifestyle changes, and development of an emotional support network. The ultimate goal is to provide the individual with the tools to take charge of their medical care as they manage this chronic disease. Furthermore, patients who engage in self-management have better health outcomes and increased self-efficacy (confidence in ability to accomplish a specific goal).

Although PAD is common, it remains underrecognized by both patients and clinicians. As such, there is not a pre-existing framework to help patients achieve self-management. This is a critical gap, particularly given the prevalence, morbidity, and mortality of PAD.

Goal: Develop initiatives to increase patient self-sufficiency and engage them in the management of their condition. Our objectives were to suggest three initiatives to support PAD patients as they transition from the initial diagnosis to living with a chronic disease.

Summary of Current Landscape and Critical Gaps

Educational resources for PAD patients are sparse in comparison to other major cardiovascular diseases like heart attack and stroke. For instance, one PAD patient said that when she was hospitalized for major aortofemoral surgery, she received educational content related to heart attack and stroke but nothing regarding PAD. Some resources exist online through sources such as the AHA, professional societies and hospital systems, but patients must seek out such content. No framework, such as cardiac rehabilitation following heart attack, exists for PAD.

Chronic disease management programs and workshops are aimed at helping patients build skills in self-management of such conditions as diabetes and chronic pain. There is a gap in chronic disease management specifically for PAD.

Overall Recommendations

This group saw several areas for potential intervention. Given the lack of self-management tools for PAD patients, the group highlighted the creation of a chronic disease management program modeled after existing programs, such as those from the Self-Management Resource Center. Many AHA resources exist for atherosclerotic cardiovascular disease. As PAD shares risk factors with heart attack and stroke, many of these resources could be adapted and expanded upon to educate PAD patients. Hospitalization for PAD events is a time when the patient audience is “captive.” Health systems and payers should be encouraged, or even incentivized, to create pilot PAD programs for patients at the time of hospital discharge.

Patients obtain and process health education differently depending on education level, socioeconomic status and other factors. Supporting patients diagnosed with PAD may occur in many different venues. It is important to develop local networks that sync with the AHA’s patient support network but also meet patients where they are most comfortable receiving medical information, whether that is in community centers, churches or the doctor’s office.

Furthermore, multispecialty support of PAD patients is critical, including in the areas of primary care, women’s health and obstetrics/gynecology, podiatry, cardiology, vascular medicine and vascular surgery and endocrinology.

Recommendations:

- Create a PAD chronic disease management program based on existing models.
- Build a PAD component into existing education and support resources from AHA and other groups.
- Encourage payers and health networks to pilot PAD programs for patients at time of hospital discharge.
- Encourage local support groups.
- Encourage shared decision-making between clinicians and patients.
- Provide multispecialty support.

4) Research Gaps for PAD Awareness

Goal: Increase PAD awareness across the industry, foundations and federal funding agencies.

Many participants in the roundtable and the working group acknowledged that more research is necessary to better understand the biology, epidemiology, prevention and treatment of PAD. Lack of funds is a major barrier to furthering scientific discovery about the disease. One reason for the money shortage is that potential funders aren't aware of the prevalence, morbidity and lack of effective treatments for PAD.

The purpose of this working group was to focus on knowledge gaps of funding sources for research in PAD. Relative to coronary disease and stroke, there is much less public and private funding for PAD research. This lack of money slows the understanding of the biological mechanisms specific to PAD and limb ischemic events. This results in fewer efficacious therapies.

Summary of Current Landscape and Critical Gaps

- Lack of public awareness. While many people understand what heart attacks and strokes are, relatively few understand what PAD and limb ischemic events are. Fewer understand they are at risk. This lack of public awareness manifests in many ways, including a lack of advocacy to Congress to support funding for PAD research.
- Lack of awareness in Congress regarding the burden of PAD and the importance of driving more funds toward PAD research.
- Lack of high-profile spokespeople for PAD.
- Belief that PAD is just a risk factor among patients with atherosclerosis and not a unique disease state. This has led indications for treatment in PAD to be driven by small subgroups (5-20%) of large trials where consistency of effect for major adverse cardiovascular events is enough to gain an indication. Examples include CAPRIE, the Heart Protection Study and the HOPE trial. None of these trials included adjudicated PAD-specific endpoints, and little is known about limb outcomes.
- Poor translation of trials to practice. The PAD treatment landscape in the United States is fragmented and difficult to penetrate. Although there are data and Class I guideline indications for medical therapies, data sets show that these are underused compared to other atherosclerotic diseases. The reasons are complex, including a diverse practitioner group, a focus on limb patency and intervention, and a heterogenous understanding of data and evidence.

Overall Recommendations and Potential Solutions

1. AHA activities to raise awareness and advocate for greater public funding for PAD research.
Specific Initiatives:
 - a. Have an AHA Lobby Day focused on PAD.
 - b. Conduct ABI screening on members of Congress to diagnose and raise PAD awareness.
 - c. Identify high-profile people with PAD willing to act as spokespeople and call for greater funding for research.
 - d. Call for public-private partnerships in funding PAD research.
 - e. Identify PAD as a unique disease state with specific risks such as limb ischemic events and amputation, which differentiates it from other coronary disease. It also has more diverse and complex biology, including medial artery calcification, as well as more traditional atherosclerosis.
2. Lead a multi-society statement and engage with the Food and Drug Administration (FDA) around a call for trials that are powered for PAD endpoints using consensus definitions.
 - a. Lead a collaborative discussion with the FDA.
 - b. Identify the risk of trials focused only on MACE where there may be adverse limb outcomes (e.g. CANVAS program).
3. Produce dedicated PAD research issues in journals to raise awareness and highlight all phases of research in PAD.
 - a. September may be a good month since its PAD Awareness month.
4. Call for and support implementation science in PAD.
 - a. Fund, support and publish research focused on the reasons for the under-utilization of therapies in PAD and how to increase use.
 - b. Highlight to public and private funders that trials of effective novel therapies can be successfully translated into practice.

5) Health System Activation and Clinician Education

Goal: Improve provider education, raise awareness and increase adoption of best practices in vascular care within health care systems.

Recommendations:

- Advocate for more education on PAD in medical, nursing and advanced practitioner curriculums.
- Create consumer demand for PAD education and empower patients to encourage provider education.
- Develop a multidisciplinary consensus statement and appropriate-use criterion that targets primary care providers.
- Develop an educational toolkit to disseminate at national meetings for primary care providers.
- Create a certification for PAD-aware health systems/clinics through CME. We could create a PAD CME program, including a certificate upon successful completion.

- Encourage a multidisciplinary, team-based treatment approach with clearly defined core competencies for each team member.
- Disseminate current guidelines and highlight the fact that PAD is an expression of the effects of atherosclerosis and is a warning sign of other potential cardiovascular symptoms.

6) Advocacy for PAD

Goal: The objective is to find and use traditional and novel mechanisms to raise awareness of PAD to increase the patient recognition, physician diagnosis and treatment, and medical system focus on this problem. In this way, amplify our voices through access to established channels that would introduce our concerns into the sphere of decision-makers.

Advocacy provides a voice for those who cannot speak for themselves or who need amplification to be heard. Advocacy is fundamental to the safeguarding of rights; permits the expression of concerns and fosters discussion with decision-makers for the exploration of opportunities, choices and options on important issues. Many of the participants at this roundtable have participated in government advocacy and public health awareness to advance the cause of patients with PAD. The American Heart Association have already achieved an important advocacy goal of Medicare coverage of supervised exercise therapy for patients with symptomatic PAD.

Summary of Current Landscape and Critical Gaps

Peripheral artery disease remains the least- understood, diagnosed and treated manifestation of atherosclerosis, for several reasons. First, the legacy of initial limb-specific approach. Before it was understood that atherosclerosis was systemic and that the diagnosis of PAD was associated with increased rates of heart attack and death, vascular surgeons focused on saving patients' limbs. This focus slows medical physician investigation for patients before the onset of severe symptoms. The downgrading in importance of PAD is amplified by the United States Preventive Services Task Force (USPSTF) decision not to recommend screening for PAD due to insufficient evidence and the lack of Medicare coverage in many areas of the country for diagnostic ankle brachial index (ABI) testing for patients with abnormal physical exams.

The group also recognized that physician and regulatory interest in a disease process mirrors, in part, interest by the population. Public awareness of PAD significantly lags that for heart attack and stroke, despite similar long-term outcomes.

Recommendations

1. Public Awareness Opportunities
 - a. Public reporting of amputation.
 - b. Advocacy for a Surgeon General's Report on PAD.
 - c. Create a PAD Action Plan to parallel the COPD Action Plan.
2. Health Care Professional Awareness/Diagnostic Opportunities
 - a. Standardized Medicare coverage for ABI diagnostic testing across Medicare Administrative Contractors in response to an abnormal physical exam.
 - b. Create a program to mirror the VA's Amputation Prevention Program through the Center for Medicare and Medicaid Innovation.

3. Research

- a. Advocate for more NIH funds for PAD-related outcomes.
- b. Further support the BEST-CLI trial.

4. Patient Empowerment

- a. Work with local authorities to expand the availability of safe walkable places.
- b. Create programs that focus on older patients to foster physical activity and exercise.

Follow-Up Plan/Call to Action

Action items developed in the small-group breakout sessions were presented to the larger group and voted on. There was unanimous agreement about the need to develop a National PAD Action Plan to unify the organizations committed to working in PAD awareness, detection and treatment. The top six recommendations from the PAD roundtable are:

1. Broaden the **appropriate use of diagnostic ABI testing** for patients with exertional leg symptoms and lower extremity wounds. Ensure reimbursement for a diagnostic ABI when ordered for abnormal lower extremity pulses.
2. Write a set of **multidisciplinary guidelines for primary care providers**, endocrinologists, podiatrists, gynecologists for PAD education about risk factors, symptoms and diagnosis.
3. Advocacy effort for **public reporting of amputations**.
4. Create a **PAD Action Plan** (like the COPD Action Plan), which will be the basis for a unified, enduring national PAD movement.
5. Have a **Lobby Day to advocate for PAD** in Washington DC.
6. Build **PAD information into existing resources/systems** (MI, Stroke, Diabetes, Tobacco Cessation).

The next steps will be to draft a National PAD Action Plan, organize a PAD Summit to further discuss elements and implementation of a coordinated and enduring national approach to PAD awareness, detection and treatment.

APPENDIX:

Stronger Together: Collaborative Efforts in PAD Awareness and Education

Roundtable participants included representatives from collaborating medical organizations and patient advocacy groups, who described their own outreach efforts.

The American Podiatric Medical Association (APMA)

The APMA is a national nonprofit organization representing over 12,000 podiatrists. Using innovative approaches, several recently completed or ongoing programs highlight PAD. Its current campaign, “Knock Your Socks Off,” focuses on diabetes awareness but has been successful in generating awareness that people with PAD or diabetes or any other cardiovascular risk factors need to take their socks off during an exam.

Another campaign, “A Path to Poor Circulation,” conducted during Diabetes Awareness Month in November 2016, also tied the risk of vascular disease to diabetes. A third campaign, “Podiatrists: First Responders for Vascular Disease,” had such a strong reaction from the public that the same concept was used for a foot health awareness campaign, said Dr. Dyane Tower, DPM, MPH. “This was really trying to let folks know that the podiatrist might be the person who would diagnose their vascular disease,” she said. The campaign generated more than 80 million social media hits and 123 million media impressions. The APMA strives to use a mix of materials and channels for its campaigns, including advertising on the streaming music service Pandora and promoting heavily on social media with paid and organic content.

Society for Vascular Medicine (SVM)

The Society for Vascular Medicine began with 13 members in 1989 and is celebrating its 30th Anniversary with approximately 500 members. SVM is a diverse organization of vascular clinicians and investigators and prides itself on its diversity and multi-specialty membership. Among its clinicians, SVM membership includes vascular medicine internists, cardiologists, endovascular specialists of different specialty pathways, surgeons, podiatrists, vascular nurses, wound care specialists, advanced practice providers, and vascular technologists.

The SVM mission is to *promote and advance the discipline of vascular medicine and the care of patients with vascular disease.*

Past SVM activities related to PAD include:

- Partnership in development of multi-societal PAD guidelines
- Leadership of the PAD Coalition and NHLBI “Stay in Circulation” by Dr. Alan T. Hirsch (past SVM President) and many other SVM members
- Participation in PAD-related advocacy issues, including recent presentation at the CMS MEDCAC Panel on PAD

APPENDIX: (continued)

SVM current PAD-related activities include:

- SVM Scientific Sessions – reach in PAD-related educational and scientific content
- SVM Fellows course and new Advanced Practice Provider Course
- Journal *Vascular Medicine* which publishes clinical, basic, and translational research on PAD and review articles
- Vascular Medicine patient education pages (Edited by Drs. Natalie Evans and Elizabeth Ratchford) which have covered topics such as PAD, smoking cessation, ABI, statins, and advanced image. These pages are available at: www.vascularmed.org
- In partnership with Janssen Pharmaceuticals, a PAD toolkit which includes information on epidemiology, diagnosis, and treatment of PAD for both health care professionals and patients. Materials are available for free at <http://myperipheralarterydisease.com/>

According to Heather Gornik, MD, FSVM, SVM President, “We are a small but mighty society...PAD has been an important part of our fabric since our founding in 1989. You can count on SVM in as a partner in your PAD awareness efforts.”

The American College of Cardiology (ACC)

The ACC’s outreach to its members around PAD includes:

- Disseminating lower-extremity PAD guidelines through CME and MOC credit-eligible modules.
- Collections of articles and opinion pieces on PAD available on its website.
- CardioSmart PAD educational tools for patients and consumer-facing infographics for physician offices.

A recent ACC roundtable meeting on the use of antithrombotic medications in PAD and CAD began a discussion about how to integrate newer therapeutics into practice, said Gregory Piazza, MD, who chairs ACC’s Peripheral Vascular Disease Member Section. The goal is to develop a strategy to identify patients most likely to benefit from the use of these therapies.

National Institute of Aging (NIA)

NIA, one of the 27 Institutes and Centers of NIH, leads the federal government in conducting and supporting research on aging and the health and well-being of older people. The Institute seeks to understand the nature of aging and the aging process, and diseases and conditions associated with growing older, in order to extend the healthy, active years of life. NIA has identified numerous goals to accomplish its mission in its strategic plan (<https://www.nia.nih.gov/about/aging-well-21st-century-strategic-directions-research-aging>) relevant to the PAD research community. The broad overarching goals of the strategic plan are to understand the dynamics of the aging process; to develop effective interventions to maintain health, well-being and function; and to prevent or reduce the burden of age-related disease, disorders, and disabilities by supporting research, and supporting the research enterprise.

“Some of the areas of research that NIA strives to support with respect to PAD include improving or maintaining mobility, activities of daily living, physical function, quality of life, and independence,” said Lyndon Joseph, PhD, program officer at the NIA. Dr. Susan Ziemann, medical officer at the NIA, also commented that “the NIA is interested in interventions that improve these outcomes and can be easily translated to the community. The NIA is interested in therapies that may address the

underlying mechanisms of aging, such as age-related changes in muscle structure and function, mitochondrial function, and delivery of oxygen and nutrients from the blood to the peripheral skeletal muscle. If we can find compounds that improve muscle strength and function, older adults might be better able to maintain mobility, and perhaps may be more able to engage safely in supervised exercise therapy. We do know that even moderate exercise can improve some of these age-related changes in peripheral skeletal muscle.”

OptumHealth

OptumCare

OptumCare provides health services for more than 14 million people across over 90 payers, 40,000 providers, and more than 1,000 clinics in 40 states, said Kevin Heath MD, National Medical Director for Education Solutions, OptumCare. The goal, he said, is to bring care-delivery organizations together across the country with a commitment to research and patient outcomes.

OptumCare began screening for PAD in 2011. Subsequently, some clinics have integrated screening guidelines for PAD into the electronic health record as part of annual visits among high risk seniors. Preliminary retrospective data suggests screening led to improved patient outcomes.

Preventative Cardiovascular Nursing Association (PCNA)

The PCNA's mission is to provide culturally sensitive, literacy-level appropriate educational materials for providers and patients in the primary, secondary, and interventional cardiovascular care space, said board member Lola Coke, PhD. It also plays a key advocacy role, most recently working with congressional representatives to bring about greater PAD awareness.

The PCNA also developed a PAD toolkit, called Step on Health PAD, which includes information on conducting community screenings. Another tool is a behavior change certificate to incentivize patients to change their behavior and reduce their risk of PAD.

Portrait Study

The PORTRAIT study is a multi-center observational registry designed to document the treatments and health-status outcomes (symptoms, function, and quality of life) of 840 US patients with PAD over one year. Supported by the Patient Centered Outcomes Research Institute (PCORI), the registry focuses on quality of life and health outcomes. Patients play a major role in the study, said study investigator Kim Smolderen, PhD, an associate professor at the University of Missouri-Kansas City School of Medicine, where she leads on a patient advisory board that prioritizes topics for outcomes assessment in PAD. To date, the registry has resulted in the design of a patient education tool.

“Patients worked with us to tell us what materials they need to be better informed about how this disease is treated, what outcomes they can expect, and what preferences matter in their treatment decision,” she said. “We learned that there was still a lot of unawareness, even among patients who are diagnosed. Patients often don't realize that there are multiple options for treatment.” For instance, less than 2% of patients in the registry were referred for supervised exercise therapy, which most patients weren't aware was an option.

The patient education tool, which is being piloted, is designed to inform patients about treatment pathways. “The primary outcomes we focused on were PAD knowledge and satisfaction with the treatment decision conversation with health care providers,” she said. Once the testing is complete, they plan to roll out the tool to a larger population.

APPENDIX: (continued)

The results of the second phase of the PORTRAIT study are being tallied, and investigators have developed a two-year dissemination plan. The focus will be the urban core of Kansas City, a predominantly African American, underserved community with the city's lowest life expectancies and worst health outcomes. "We want to synergize our efforts (with other organizations) on the health side and find ways to engage the community, making them more aware of health issues such as PAD," Dr. Smolderen said.

The PORTRAIT study was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (IP2 PI000753-01; CE-1304-6677), the Netherlands Organization for Scientific Research (VENI Grant No. 916.11.179), and an unrestricted grant from W. L. Gore & Associates, Inc (Flagstaff, AZ). The PORTRAIT engagement work is supported by a Eugene Washington PCORI Engagement Award (EA #14505). The statements in this manuscript are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

Society for Vascular Surgery (SVS)

Peripheral artery disease is at the heart of the SVS, said Yazan Duwayri, MD, a vascular surgeon and member of the SVS quality committee. Its members provide interventional as well as primary vascular medical care.

The SVS works closely with the AHA and other medical societies to increase awareness of PAD through science and research, he said, as well as quality improvement. For instance, the organization is working with the European Society for Vascular Surgery and the World Federation of Vascular Societies on a global vascular guideline, with the first set of guidelines focused on chronic limb-threatening ischemia.

The organization is also advocating for an alternative payment method (APM) for PAD management to address significant cost and quality disparities. Such models typically provide bonuses for clinicians who participate, as well as additional incentives for those who provide high-quality, high-value care, while penalizing poor performers.

The goals of the proposed APM are to:

- Reward PAD providers for participation in quality initiatives that improve the outcome.
- Protect patient access to advanced treatment options.
- Ensure fair and stable payment for PAD providers.
- Incentivize the appropriate use of medical and surgical treatments.

The bundled payment model is being developed in partnership with the Centers for Medicare & Medicaid Services (CMS) and clinicians. By incorporating services such as phone calls, return office visits, wound care and podiatry care into the overall medical care, "we can also reduce spending and change the unnecessary spending to potential savings that can be utilized for technology and discovery, screening, patient awareness and maintaining patient access to care," Dr. Duwayri said.

Society of Cardiovascular Angiography and Intervention (SCAI)

An interventional cardiologist and past president of SCAI, Chris White, MD, described the value of a “heart team” in managing structural heart disease. Such a team includes not only the surgeon and interventionist, but other general providers who are involved in the care of the patient. “We think it’s time to call for that similar sort of collaboration among the various members who care for people with vascular disease,” he said. “The silos that have been created are not conducive for the best outcomes. Collaborative practice with a patient-centered approach is something we should seriously consider for PAD patients.”

Vascular Cures

Vascular Cures has a national network and focuses on patient-centered research and patient engagement in vascular diseases outside the heart. “Our focus is on generating and implementing novel collaborations that can move fast and flexibly change patient outcomes,” said Wendy Hitchcock, the organization’s former CEO and current Board member. Vascular Cures works with AHA to provide PAD education, fund research, and advance multi-sector stakeholder collaboration which include patients.

Two of the organization’s programs are: Project Voice, which focuses on vascular outcomes improvement through community engagement, and a multi-sector Working Group to develop patient-reported outcomes measures in PAD and chronic limb ischemia. A recent grant funded a project on engaging patients in shared decision-making and developing new tools to support shared decision making.

WomenHeart

WomenHeart has developed numerous educational outreach materials around PAD, including an infographic and animated video targeting women. “We are interested in understanding more about women’s journey from diagnosis into treatment,” said the director of public policy Amy Friedrich-Karnik, MPP. “What does that look like? Who are they seeing first? How are they being responded to? Are they being heard and what happens after that?”

The organization also conducted focus groups among women with PAD about their experiences. “To better understand how we reach women,” Ms. Friedrich-Karnik said, “requires taking their experiences into consideration. What is going to be the most effective way of reaching out to women from diverse communities? What kind of policy and resource needs should we ask for?”

Peripheral Artery Disease (PAD) Roundtable Participants

PARTICIPANTS	ORGANIZATION	ROLE/SPECIALTY
Aaron Aday, MD	American Heart Association	AHA PVD council member/ Cardiologist
Amy Friedrich-Karnik, MPP	WomenHeart	Director of Public Policy
Amy Pollak, MD	American Heart Association	AHA PVD council member/ Cardiologist
Aruna Pradhan, MD, MPH	American Heart Association	AHA PVD council chair/ Cardiologist
Cassandra McCullough, MBA	Association of Black Cardiologists	Chief Executive Officer
Cheryl Sadowski	Society of Interventional Radiology	Senior Director, Communications, Publications and Marketing
Christopher J. White, MD	Society for Cardiovascular Angiography and Interventions	Cardiologist
Danielle Haney, PhD,	NHLBI - Office of Science Policy, Engagement, Education and Communications	Science Policy Advisor
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Dyane Tower, DPM	American Podiatric Medical Association	Director, Clinical Affairs
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Heather Gornik, MD	Society for Vascular Medicine	SVM President/Cardiologist
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Josh Beckman, MD	American Heart Association	AHA PVD council member/Cardiologist
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Lee Kirksey, MD	Association of Black Cardiologists	Cardiologist

PARTICIPANTS	ORGANIZATION	ROLE/SPECIALTY
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Lucinda "Cindy" Miner, PhD	NHLBI OSPEEC (Office of Science Policy, Engagement, Education and Communications)	Director, Division of Health, Scientific and Regulatory Communications
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Natalie Evans, MD	American Heart Association	AHA PVD council chair-elect/ Internist and Vascular Medicine Specialist
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Yazan Duwayri, MD	Society for Vascular Surgery	SVS Member/ Vascular Surgeon
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Kathryn Genter	American Heart Association Vendor	Graphic Designer

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