

AHA SCIENTIFIC STATEMENT

# Advancing Peripheral Artery Disease Quality of Care and Outcomes Through Patient-Reported Health Status Assessment: A Scientific Statement From the American Heart Association

Kim G. Smolderen, PhD, Vice Chair; Olamide Alabi, MD; Tracie C. Collins, MD, MPH, MHCDS; Bernard Dennis, BA; Philip P. Goodney, MD; Carlos Mena-Hurtado, MD; John A. Spertus, MD, MPH, Carole Decker, PhD, RN, Chair; on behalf of the American Heart Association Council on Peripheral Vascular Disease and Council on Lifestyle and Cardiometabolic Health

**ABSTRACT:** Peripheral artery disease (PAD) is chronic in nature, and individualized chronic disease management is a central focus of care. To accommodate this reality, tools to measure the impact and quality of the PAD care delivered are necessary. Patient-reported outcomes (PROs) and instruments to measure them, that is, PRO measures, have been well studied in the research and clinical trial context, but a shift toward integrating them into clinical practice has yet to take place. A framework to use PRO measures as indicators of the quality of PAD care delivered, that is, PRO performance measures (PRO-PMs), is provided in this scientific statement. Measurement goals to consider by PAD clinical phenotypes are provided, as well as an overview of potential benefits of adopting PRO-PMs in the clinical practice of PAD care, including reducing unwanted variability and promoting health equity. A central discussion with considerations for risk adjustment of PRO-PMs, individualized PAD care, and the need for patient engagement strategies is offered. Furthermore, necessary conditions in terms of required competencies and training to handle PRO-PM data are discussed because the interpretation and handling of these data come with great responsibility and consequences for designing care that adopts a broader framework of risk that goes beyond the inclusion of biomedical variables. To conclude, health system perspectives and an agenda to reach the next steps in the implementation of PRO-PMs in PAD care are offered.

**Key Words:** AHA Scientific Statements ■ health equity ■ patient reported outcome measures ■ peripheral arterial disease ■ quality of health care

Peripheral artery disease (PAD) is a spectrum of disorders, ranging from asymptomatic disease to critical limb ischemia (CLI). PAD remains one of the most impactful cardiovascular conditions in terms of both the number of affected individuals and its impact on the individual's survival and health status (their symptoms, function, and quality of life). Accordingly, its impact on society is profound. With >8.5 million affected Americans, the need to improve treatment is imperative and growing.<sup>1</sup> Patients with PAD, even with optimal medical management, are known to have a substantial risk of major adverse cardiovascular and adverse limb events that ranges between 5%/y and 10%/y.<sup>2,3</sup> Among patients with CLI, 1 in 3 experiences an amputation in their remain-

ing lifetime, and 1 in 3 dies within a year of diagnosis.<sup>4</sup> Younger patients <65 years of age now constitute the fastest growing group of patients with CLI.<sup>5</sup> The most prominent risk factors observed for PAD are smoking, age, diabetes, obesity, hypertension, and dyslipidemia, but PAD rarely presents with a single risk factor.<sup>6-8</sup> Most often, risk factors are clustered with several other comorbidities such as renal disease, coronary artery disease, addiction disorders, and depression.<sup>6</sup> Despite guidelines to guide the care of patients with PAD,<sup>6</sup> there is great variability in practice,<sup>9</sup> and new methods are needed to quantify the quality of health care so as to increase accountability for health care professionals to develop holistic strategies for improving the treatment of patients with PAD.

Concept	Definition	Example
Patient-Reported Outcome (PRO)	Any information on the outcomes of health care obtained directly from patients without modification by clinicians or other health care professions	Symptom: depression Symptom: self-reported walking impairment
Patient-Reported Outcome Measure (PROM)	Any standardized or structured questionnaire regarding the status of a patient's health condition, health behavior, or experience with healthcare that comes directly from the patient (i.e., a PRO). The use of a structured, standardized tool, such as a PROM, will yield quantitative data that enables comparison of patient groups or providers.	Patient Health Questionnaire-9 (PHQ-9), a standardized tool to assess depression  Walking Impairment Questionnaire (WIQ), a standardized tool to assess walking impairment
PRO-Based Performance Measure (PRO-PM)	A performance measure that is based on patient-reported outcomes assessed through data often collected through a PROM and then aggregated for an accountable healthcare entity	Percentage of patients with a diagnosis of major depression or dysthymia and initial PHQ-9 score with a follow-up PHQ-9 score <5 at 6 months (NQF #0711)  eg, Percentage of patients with WIQ at initial assessment, and percentage of patients with a follow-up WIQ reaching MCID threshold for improvement

**Figure 1. Distinctions among PROs, PROMs, and PRO-PMs.**

MCID indicates minimal clinically important difference; and NQF, National Quality Forum. Adapted with permission from "Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures: Final Technical Guidance Report."<sup>14</sup> Copyright © 2021, The National Quality Forum.

## STATE OF THE FIELD IN HEALTH STATUS ASSESSMENT FOR PERIPHERAL ARTERY DISEASE

To document the impact of PAD on patients' lives as seen from their perspective, multiple patient-reported outcome (PRO) measures (PROMs; eg, the Walking Impairment Questionnaire) have been newly developed and used to capture PROs (eg, self-reported leg pain) through a range of dimensions that are relevant to the patient.<sup>10</sup> The measurement of health status across chronic conditions like PAD has originated largely as science-based or methodological efforts, but this is rapidly changing. Original efforts focused on developing methodological frameworks to quantify the impacts of disease on patients' functioning and to assess treatment effects in comparative effectiveness research. Other US medical specialties have also been on the forefront of another more recent development: using PROMs in routine clinical care as a metric of performance for the quality of care that is being delivered to patients.<sup>11–13</sup> Leveraging PROMs for performance evaluation is referred to as PRO-based performance measures (PRO-PMs; eg, percentage of patients with initial Walking Impairment Questionnaire assessments on presentation). Key organizations that have worked together with multidisciplinary stakeholders to develop quality criteria for PRO-PMs include the National Quality Forum (NQF), the National Committee for Quality Assurance, and several US medical professional societies<sup>14</sup> (Figure 1 provides definitions of PROs, PROMs, and PRO-PMs). Moreover, the American College of Cardiology/American Heart Association Task Force on Performance Measures has recently proposed a PRO-PM as a quality metric, although not a performance measure, for heart failure.<sup>15</sup>

These trends portend a future in which health care will increasingly focus on patients' health status, which is particularly relevant in PAD.

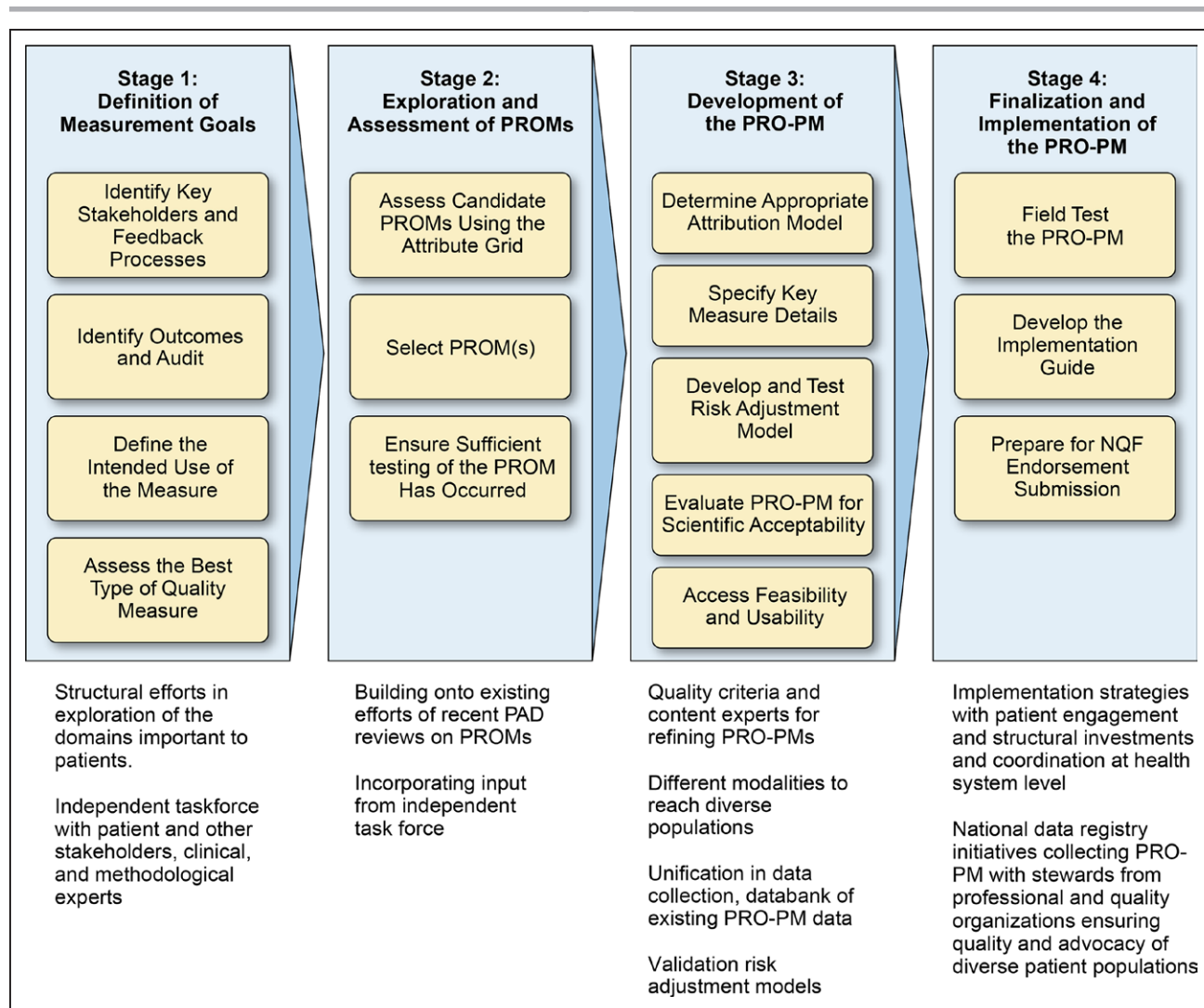
This new development of measurement-based care is rapidly evolving, and benchmarks are being defined for several medical specialties, including psychiatry, psychology, and oncology.<sup>16–18</sup> The goal is to implement these metrics across health systems in a scalable fashion. Furthermore, the Centers for Medicare & Medicaid Services will then incorporate performance targets into payment models. Efforts are underway to develop pilot programs and to gain more experience with measurement-based care. Current NQF quality criteria for PRO include PROs of relevance to the patient, scientific acceptability, feasibility, usability, and comparisons made to evaluate competing measures in an effort to harmonize or select the best measure.

This scientific statement aims to provide a multidisciplinary evaluation of critical questions to be considered as one prepares for the design of PRO-PMs for PAD. The scientific statement will serve as a road map for measurement-based care for PAD. Areas to evaluate are (1) which candidate PROMs to use for which PAD clinical phenotypes, (2) when to administer PROMs, (3) targets for performance, (4) considerations for risk adjustment, and (5) practical considerations for implementation.

## MAKING THE CASE FOR HEALTH STATUS ASSESSMENT TO ADVANCE THE FIELD OF PAD

Under a contract from the Centers for Medicare & Medicaid Services, the NQF has begun a multistakeholder process to build a framework for creating PRO-PMs. The program, Building a Roadmap From Patient-Reported





**Figure 2. A road map for developing PRO-PMs in PAD.**

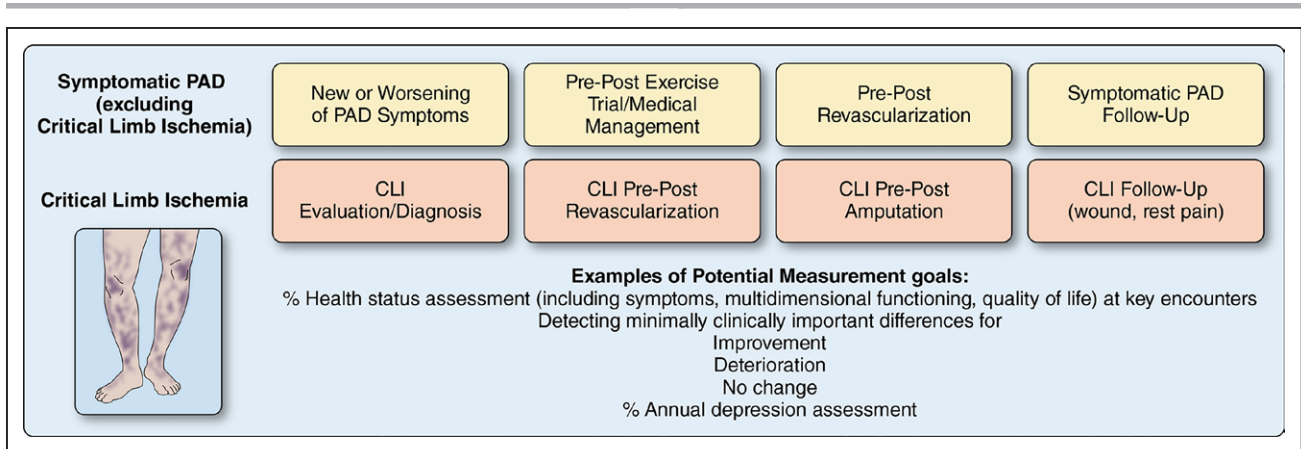
NQF indicates National Quality Forum; PAD, peripheral artery disease; PROM, patient-reported outcome measure; PRO-PM, patient-reported outcome measure–based performance measure. Adapted with permission from “Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures: Final Technical Guidance Report.”<sup>14</sup> Copyright © 2021, The National Quality Forum.

Outcome Measures to Patient-Reported Outcome Performance Measures,<sup>14</sup> began with efforts to define good PROs and to select PROs for clinical use and, potentially, performance measure development. In 2020, the NQF launched its latest effort to develop PRO-PMs from suitable PROs. This effort has defined 4 key steps with which to build a PRO-PM: (1) definition of the measurement goals, (2) exploration and assessment of PROMs, (3) development of the PRO-PM, and (4) finalization and implementation. Fifteen steps were identified as part of these 4 stages, and the order of completing these steps was intentionally designed to be flexible. An outline of the process is provided in Figure 2.

This report reflects on these steps by summarizing efforts completed thus far to cover stages 1 and 2, defining the measurement goals and selecting candidate PROMs, and laying out next steps to prepare for the development of the PRO-PM (stage 3) and implementa-

tion and testing of the PRO-PM (stage 4). By including patients, health care professionals, and researchers, this report highlights the intended use of a PRO-PM, which is to elevate the experience of patients into a basis for defining the quality of care being provided to patients.

Although the NQF’s effort to define the methodology for PRO-PMs is important, it requires clear articulation of the need for such a measure. Patients with symptomatic PAD seek care to reduce their symptoms, to improve their function, and to optimize their quality of life. Although clinician-oriented scales such as the Rutherford stages or ankle-brachial index have traditionally been used to classify symptoms and disease severity, they are coarse and are physicians’ interpretations of patients’ limitations or indirect assessments of disease burden, rather than coming from patients themselves. In PAD, we know that these clinical metrics do not correlate well with patients’ experienced burden.<sup>19,20</sup> Thus, from



**Figure 3. Clinical PAD phenotypes for patient-reported outcome measures as benchmarks for quality of PAD care.**

CLI indicates critical limb ischemia; and PAD, peripheral artery disease.

the patients' perspectives, the use of a PRO to rigorously define the symptoms, function, and quality of life is an important means of recognizing the severity of patients' condition and identifying the need for more direct therapy to optimize their health status.

### Defining the Measurement Goals

Patients with PAD can present with a spectrum of leg symptoms ranging from asymptomatic disease to exertional leg discomfort to CLI. The negative impact of a diagnosis of PAD on a patient's daily life cannot be overstated. Assessing outcomes in patients with PAD is important to drive health care delivery and to optimize disease management. Outcome measures that include the perspectives of patients can guide not only patients and their families as they make decisions about their health and treatment but also health care professionals and health systems, as well as health policymakers, as to what constitutes quality of PAD care.

Just as one defines clinical metrics for quality for the management of medical conditions, there is a shift toward including more patient-sensitive measures as benchmarks of quality. It is timely to also reflect on the state of the field as to how we might be able to start defining the quality of PAD care using the patient's perspective as part of a portfolio of quality metrics for quality PAD care. As patients with PAD seek care, with acknowledgment of the uniqueness of each patient's trajectories, several broad clinical phenotypes can be discerned that may define critical evaluation points from a treatment goal perspective from the standpoint of the clinician but also the patient (activation, improve lower-extremity functioning, improve symptoms and quality of life, manage pain, salvage the limb, etc). Depending on the disease and treatment process, because patients can cycle in or out of these stages, and depending on the Rutherford stage, these goals may look vastly different. Regardless, they all share in common that patients

care about attaining improved health status (their symptoms, functioning, and quality of life) as an important treatment goal in and of itself.<sup>21</sup> Figure 3 summarizes phenotypes in the clinical trajectories of those with Rutherford stages 1 to 3 (mild-severe claudication) and those with Rutherford stages 4 to 6 (CLI, also referred to as chronic limb-threatening ischemia) as critical evaluation points at which significant changes in patients' health status may be discerned, making them important measurement goals to consider for PAD.<sup>22</sup>

As for selecting candidates of PROMs for PAD, 2 recently completed reviews<sup>10,23</sup> have thoroughly looked into the different attributes that need to be evaluated when selecting candidate PROMs for chronic conditions. Instruments that emerged as meeting quality standards for these attributes were the Walking Impairment Questionnaire,<sup>24,25</sup> an instrument focused on the disability related to the lower-extremity functioning as a single-domain measure. PROMs accommodating multidimensional frameworks of functioning, including the Vascular Quality of Life Questionnaire<sup>26</sup> and the Peripheral Artery Questionnaire,<sup>27</sup> were considered as candidates meeting quality standards for validation, availability of data, and readiness of use in the clinical setting.<sup>10,23</sup> Most available PAD health status instruments are multidimensional instruments that capture patients' PAD symptoms; their emotional, physical, and social functioning; and their quality of life but are in various stages of development.<sup>10,23</sup> For patients with CLI, a disease-specific instrument capturing salient aspects of their disease, including pain experience, body image, and dependence on care givers, is currently lacking,<sup>10,23</sup> which defines this as an important need for future development. As a generic tool to assess health status, the short EQ-5D tool offers opportunities to measure functioning across populations, with the downside being that it does not measure aspects specific to the disease and treatment process of PAD.<sup>28</sup>

Complementary measures that are not specific to PAD have frequently been used to capture patients'



**Table. Suggested Pilot Test PRO-PMs for Patients With Symptomatic PAD (Without CLI)**

	PRO	PROM	PRO-PM
1.	Self-reported leg pain and functioning (unidimensional health status)	WIQ	Percent of WIQ scores obtained Percent of individuals reaching MCID (0.11 for improvement) <sup>24</sup> after PAD treatment at 6 and 12 mo
2.	PAD-specific health status	PAQ	Percent of PAQ scores obtained Percent of individuals reaching MCID (10-point improvement) <sup>34</sup> for improvement after PAD treatment at 6 mo
		VascuQoL	Percent of VascuQoL scores obtained Percent of individuals reaching MCID (0.87 for improvement) <sup>24,35</sup> after PAD treatment at 6 mo
3.	Generic health status	EQ-5D	Percent of EQ-5D index scores obtained Percent of individuals reaching MCID (0.18 for improvement) <sup>36</sup> after PAD treatment at 6 mo
4.	Depressive symptoms	PHQ-9	Percentage of patients with a positive screen on PHQ-9 score ( $\geq 10$ ) <sup>37</sup> who have a follow-up PHQ-9 score $< 5$ at 6 mo

CLI indicates critical limb ischemia; MCID, minimal clinically important difference; PAD, peripheral artery disease; PAQ, Peripheral Artery Questionnaire; PHQ-9, 9-item Patient Health Questionnaire; PRO, patient-reported outcome; PRO-PM, patient-reported outcomes–based performance measure; PROM, patient-reported outcome measure; VascuQoL, Vascular Quality of Life Questionnaire; and WIQ, Walking Impairment Questionnaire.

Denominator: all with symptomatic PAD excluding those unable to complete for cognitive or other reasons.

broader level of functioning especially resulting from related impactful conditions that frequently co-occur in PAD such as depression, as measured by the Patient Health Questionnaire 9-item,<sup>29</sup> for example. Depressive symptoms are one of the strongest predictors of patients' health status, and depression occurs more frequently in patients with PAD. Thus, in terms of candidate measures, depression screening may be one to consider.<sup>30–33</sup>

On the basis of these prior reviews,<sup>10</sup> this scientific statement also formulated candidate test PRO-PMs that could be trialed in the clinical setting for feasibility and benchmarking, pending final identification of PRO-PMs for the field of PAD. These measures are focused on patients with symptomatic PAD (excluding CLI because no validated CLI-specific measures have been identified)<sup>10,23</sup> and include single-domain disease-specific measures related to walking disability, disease-specific measures, and complementary measures that affect patients' health status (Table). Metrics of feasibility consist of percent completed in one's population, percent of patients for which one obtained follow-up scores, and percent achieving thresholds for improvement. Eligible patients would be all patients in one's PAD practice except for those unable to complete for cognitive or other reasons.

## Important Considerations for the Development of the PRO-PMs in PAD

### Reproducible and Accountable Framework for Quality of PAD Care

Designating a PRO-PM creates an external mandate for routinely collecting these measures in clinical practice. Once available and once physicians become familiar with their interpretation, they offer a reproducible frame-

work for evaluating the impact of escalating therapies (exercise, smoking cessation, medications, and revascularization) and enabling changes in strategies if the PROs do not improve by the thresholds set for minimally clinically important differences.<sup>10</sup> They also provide feedback to patients to understand the importance and benefits of adhering to recommended therapies and monitoring their progress. These benefits need to be considered against the tradeoffs of data collection burden, patient privacy, and variation in measurement skills across treatment settings.

### Reduced Variability in Quality of Care and Enhanced Coordination of PAD Care Needs

From a health system–level perspective, the routine use of PRO-PMs for PAD will contribute to the infrastructure of a data-driven population health management approach. Care of patients with PAD can be rendered by numerous specialties such as primary care, cardiology, interventional radiology, surgery, and vascular medicine and, depending on the complex care needs, may extend to nephrologists, podiatrists, physical therapists, behavioral health specialists, and other specialists. Successfully coordinating the complex care needs for patients with PAD requires alignment of multidisciplinary care. A health care system that has insight into the health status of its patients with PAD and the multidimensional factors that play into it can build protocols and disease management programs to better recognize, tailor, and intensify treatments for those who are not doing well. Evidence that health status outcomes are largely explained by and vary by how health systems organize their care comes from coronary disease.<sup>38</sup> For example, in a large prospective registry of patients with heart failure treated at 150 practices, there was marked variability in the control of patients'

health status across sites. With the use of the Kansas City Cardiomyopathy Questionnaire, the proportion of each clinic's patients with a score  $\geq 75$  (indicating good to excellent health status) varied from 0% to 80%. The median odds that a statistically identical patient would have good health status was 70% greater at 1 random clinic compared with another.<sup>38</sup> Although the potential to investigate this in PAD exists today, it would require implementing PRO-PMs to start acting on these insights and to translate them to the field of PAD.

### **Reduced Health Disparities in PAD Care and Promotion of Equity in PAD Care**

The systematic quantification of patients' health status also represents an important opportunity to reduce disparities and to achieve better equity in health care. PROs offer an opportunity to reproducibly quantify the health status of different patients, including communities of color, tribal communities, cisgender men and women, LGBTQIA (lesbian, gay, bisexual, transgender/transsexual, queer/questioning, intersex, and allied/asexual/aromantic/agender) individuals, rural residents, and veterans. As we learn from patients, we anticipate that outcomes of interest will extend beyond leg (pain-free and total walking distance, need for invasive intervention) and systemic (ie, myocardial infarction, stroke) concerns to mental and behavioral health, as well as the social determinants of health, including patients' ability to afford evidence-based PAD care.<sup>39</sup> Specific to social determinants of health, the measurement of PROMs enables systems to consider upstream factors that drive access to care and outcomes for patients with PAD (eg, food deserts, housing, and income) so that novel strategies to address these determinants can be considered and that there could be incentives (the desire to demonstrate higher quality) to address blind spots of access to care and the ability to attain improved outcomes, including groups who are most vulnerable.

Creating incentives to address these blind spots and disparities for PAD care is important because patients with PAD come from diverse backgrounds and ages and their health status trajectories may be different,<sup>40</sup> and this diversity may not always be adequately captured in specialty care or in contemporary trials testing PAD treatment regimens.<sup>41</sup> Women can present with more severe leg symptoms but with the same level of disease severity, as captured by the ankle-brachial index, compared with their male counterparts. Black women and men have a higher prevalence of PAD compared with non-Hispanic White men and women. Furthermore, Black individuals with PAD have greater walking impairment (defined as a reduction in walking distance, walking speed, or stair climbing) and more severe disease compared with non-Hispanic White individuals.<sup>42</sup> Black and Latino individuals with PAD are more likely to undergo nontraumatic lower-extremity amputation

versus revascularization compared with non-Hispanic White individuals. Members of tribal communities are at greater risk for nontraumatic lower-extremity amputations than non-Hispanic White individuals.<sup>43</sup> Veterans have a tremendous burden of PAD, which increases their risk for adverse events and poor outcomes.<sup>44</sup> However, their health status trajectories have not been captured in dedicated efforts that help increase representation in and design of culturally sensitive metrics to capture the richness of their perspectives. In addition to limb and systemic health for patients with PAD, mental health and health status outcomes warrant further exploration with the development of valid measures. We know from prior work that poor mental health, including increased stress,<sup>45,46</sup> is highly prevalent among patients with PAD, especially on presenting with new or worsening symptoms. Thus, the creation of an ideal PRO-PM measurement set should include not only disease-specific measures of PAD health status but also assessments of mental health such as depressive symptoms, anxiety, and stress.

To move us to the next level in PAD management, we must tailor PROMs to each of these important demographic and social constructs.



## **ADDITIONAL CONSIDERATIONS FOR THE DEVELOPMENT OF PRO-PMs IN PAD FOR THE ADVANCEMENT OF QUALITY OF PAD CARE AND OUTCOMES**

There are several other considerations for the use of PRO-PMs in addition to their potential as a metric for the performance of the clinical care. They offer a more sensitive way of risk-stratifying the patient; they may provide an actionable framework for tailoring the care of the patient to his or her current needs; and they add a dimension that allows further strengthening of patient engagement.

### **Risk Stratification and Risk Adjustment**

PRO-PMs not only can be used as an outcome and benchmark for the quality of care but also are sensitive ways to further risk-stratify PAD populations because PROMs—generic or disease specific—have been shown to predict clinical outcomes of relevance to clinicians and their patients. Both the generic EQ-5D and the disease-specific PAD predict long-term outcomes (including mortality) in PAD, and showing the benefit of recurrent assessment as changes in health status may be more prognostic than patients' initial state of presentation.<sup>47–49</sup> These metrics may further need to be tested as risk stratification tools for other outcomes relevant to PAD care and for defining value-based care such as PAD readmission rates, repeat

revascularizations, and cardiovascular and limb events. Because there are no widely accepted risk stratification tools for PAD that are used across disciplines treating patients with PAD, undertaking efforts to design and implement PRO-PMs may also offer opportunities for risk-stratifying patient populations.

Because changes in health status in the context of PAD management may be more meaningful to patients and clinicians, both in terms of outcomes and as ways to risk-stratify,<sup>49</sup> it becomes important to understand what the drivers of those changes might be and to construct longitudinal trajectories of patients' health status. Proper risk stratification requires us to develop risk prediction models, including readily available patient characteristics, information on comorbidities, and social determinants of health. This can help us to understand how PRO-PMs need to risk-adjust for severity of case mix when quality metrics are compared across practices through the use of PRO-PMs and to understand which modifiable factors are present in patients that need further evaluation and provide information for further action plans. Naturally, PAD treatments would be expected to have an impact on health status outcomes,<sup>50</sup> and thresholds for meaningful change have been set.<sup>24,35,51</sup> Besides PAD treatment effects, factors that are the most robust predictors of future health status outcomes include depression and other psychosocial factors,<sup>33,52</sup> in addition to common comorbidities such as diabetes or sleep apnea.<sup>53,54</sup> Further expansion and replication of risk adjustment models in PAD across different PAD databases so as to include other considerations of risk stratification—socioeconomic, cognitive, and frailty metrics—are an important future area of development to enable the implementation and interpretation of information derived from PRO-PMs.

### PRO-PMs as an Actionable Framework for Tailoring Patient Care

Health status measures such as PRO-PMs offer an actionable framework for tailored and patient-centered care. Using established benchmarks of minimally clinically important differences, one can use the information for treatment selection and escalation. Holistic frameworks of functioning include a focus on multidimensional health status metrics and complementary PRO-PMs such as mental health or cognitive function screening, receipt of specialized wound care, and smoking cessation support. This multidimensional framework can highlight areas that may greatly affect patients' health status and require further targeted evaluation and treatment. These approaches can direct PAD care toward more integrated, multidisciplinary PAD care approaches that can address the complex care needs of patients with PAD and enhance the quality of care.<sup>55</sup>

Collecting PRO-PMs not only should be an exercise to inform patients, clinicians, and health systems about the quality of PAD care and outcomes but also is a powerful and actionable tool to enhance self-management and increased engagement of patients. The information collected can also inform shared decision-making approaches. Sharing this information in a tailored way with patients is another urgent area of action in that few options exist for patients with PAD to access these types of information in a patient-friendly format.<sup>56,57</sup>

It is recognized that the use of health status measures in PAD as PRO-PMs may see an evolution through the development of these as quality measures first. The use of these as quality measures may happen concurrently with the collection of high-quality scientific evidence, that can elevate the practice to standards that are currently being used to establish Class I PAD guidelines,<sup>6</sup> that directly demonstrate that the usage of PRO-PMs results in improved PAD outcomes.

### Strengthening Patient Engagement

The patient-clinician relationship and, by extension, the relationship with the care team are unique, with both parties bringing their own frames of reference and different expectations for respective roles and responsibilities. Patients and clinicians bring their own uniqueness and backgrounds as a function of their knowledge, competing priorities, socioeconomic and cultural backgrounds, communication skills, and many other variables. Interactions with clinicians and health care systems also occur in a context of available resources that may support or limit the delivery of the medical treatment (resources, time, material, staff). Despite a daunting list of differences, in a perfect world, all should agree on the objective to resolve, as much as possible, the life-impacting issues of PAD, including reducing pain and increasing mobility, and to provide a common understanding of the recommended treatment plan. From a patient's perspective, the objective is to return to as normal a life as possible. From the health care professional's perspective, the objective is to recommend actions that can reach that goal. A starting point for a common understanding and for enhancing the quality of the communication between patients and their clinicians could also be the use of standardized health status assessments (PROs/PROMs), which enable both the patient and the health care professional to interact on critical topics essential to developing and evaluating their treatment plan.

As we move toward implementation of PRO-PMs, structures to facilitate patient engagement will need to be developed. Better understanding patient perspectives is the first step in shifting the paradigm toward the inclusion of continuous health status monitoring in the management of the patient with PAD. These efforts would need to go beyond the delivery of information in a passive way but find ways to

actively involve the patient and work with them as a collaborator in the design and implementation of the PRO-PM assessment process.<sup>58</sup> Several tasks lie ahead in successfully undertaking this process of engaging patients: (1) ensuring that patients understand the benefits of use of PROs and PRO-PMs to them, requiring training tools to deliver that information in digestible and culturally sensitive formats, and accommodating patients' (technological) literacy levels; (2) selecting measures that are clearly understood and relevant to the patients; and (3) ensuring ease of use and minimizing the patient burden.

These tasks will have to be continuously evaluated; pilot projects should be designed to test the implementation and interpretation of PRO-PMs in partnership with patients. Structures to support these processes could be adding patient experts, patient scientists, and patient navigators to the team; setting up partnerships with community organizations; or engaging a patient and family advisory board to embark on this process.

## OPERATIONALIZING HEALTH STATUS ASSESSMENT FOR THE IMPROVEMENT OF OUTCOMES IN CLINICAL PRACTICE

Patient engagement strategies also extend to the operationalization of the health status assessment. Realizing that not one size fits all, especially in terms of patients' various levels of technology literacy, can help foster independent engagement in electronic health assessments. Many patients will require additional human support, and being prepared to offer alternative modalities to collect the PRO-PM information will better fit a diverse audience of patients' needs.

Operationalizing health status assessments as part of the routine clinical practice requires additional support once data are collected. Setting up database management, ensuring adequate response rates, monitoring missingness data, analyzing and interpreting health status data, and linking with clinical information require data-driven, integrated, multidisciplinary teams that can leverage their expertise in a standardized way specific to the underlying problems that need to be addressed and in a synchronized fashion with ongoing measurement-based initiatives at the health system and national levels. All these levels of expertise and experience may not be present at this time in all institutions. Therefore, quality partnerships and teams in measurement-based care specialized in PAD care need to be formed, as well as certification programs that ensure a minimum level of training requirements and expertise to handle patient-level data derived from PROMs.

Future implementation of results from continuous health status monitoring should include integration

with the electronic health record. Ideally, these results are being reported and used in real time supporting the patient with PAD and their care team as part of the disease management process by the multidisciplinary team of health care professionals who are caring for patients with PAD. This can assist care teams in the future creation of algorithms of care that incorporate health status scores. It will, however, be important to clearly define who will manage the data, who can access these data, and how the data will be used. Along a similar vein, data sharing and ownership for patients are areas that need to be worked out.

Although it is clear that increases in resources beget increased costs upfront, the continuous monitoring of health status in patients with PAD can optimize value. Demonstrating this improvement in value can help engage the health care system in understanding how these upfront resources are justified. Clear delineation, reporting of results, and consensus building at the leadership level within each organization should be prioritized with clear plans for dissemination and coordination across the health care system.

Last, because PAD care is not delivered by a single specialty, national data registry initiatives collecting PRO-PMs will need to be instituted with stewards from professional and quality organizations that can ensure quality and advocacy reflecting this diversity. A special effort needs to be made to represent diverse patient populations, including hard-to-reach populations, regardless of the management strategy that patients are undergoing, and to ensure representation of different PAD care specialties and allied health professionals who take care of patients with PAD.

## CURRENT CHALLENGES AND FUTURE DIRECTIONS

PAD has long been underdetected and undertreated, partially because of the lack of awareness and fragmented care.<sup>59,60</sup> Currently, there is an understanding that multidisciplinary teams are the way forward, but many of those approaches are still focused on treating the disease, not the patient with the disease.<sup>55</sup> Meeting the care needs of patients with PAD goes beyond treating the lesion but benefits from a more holistic approach incorporating the broader range of functioning and quality of life affected by PAD. Integrating PRO-PMs would mean an important paradigm shift in the way that quality PAD care is defined, starting from the patient's perspective and not defined by the discipline treating it or by the latest technological advance.

There is a groundswell of enthusiasm to unify and improve PROs for PAD among major societies such as the American Heart Association, the Society for Vascular Surgery, and a number of other organizations.<sup>10,61</sup> These



groups and the authors of this scientific statement also recognize the challenges that lie ahead. Four main challenges describe the next steps ahead.

1. Developing structural efforts to explore the domains important to patients with PAD is likely to be a key next step in sharpening focus on PROs for patients with PAD. The NQF framework discussed in this scientific statement provides a structure and agenda that the PAD community can follow, with some of the work done by prior groups that needs to be taken to the next level.<sup>10,23</sup> An independent task force with the patient, other stakeholders, and clinical and methodological experts will need to be convened to realize this agenda.
2. Compiling existing evidence and unification of data collection will be a key near-term goal. Evidence for patients with PAD and their perspectives arrives in different shapes, sizes, and labels, depending on its origin. Prior collected PROM evidence, the risk prediction models, and longitudinal outcome data are all collected in fragmented ways. A range of PRO collection tools have increasingly been used in research and clinical care, but generating the true message from a noisy conglomeration of data emanating from different formats and from different smaller studies and trials is a clear challenge that lies ahead.
3. Understanding differences in populations needs to be a priority for PAD PROs. Different speeds of development of PRO-PMs may be likely as it relates to the stage of PAD, with more data and experience available in the realm of mild-severe claudication and glaring gaps in understanding the patient's perspective for patients with CLI, as well as our ability to reach diverse populations with PAD. Reaching these populations requires dedicated funding agendas to build patient and stakeholder capacity and engagement approaches to serve these populations.
4. Stakeholder engagement and pilot testing will help lead us toward better measures. Once a set of core PRO-PMs have been constructed, payers, societies, and stakeholders will need to consider the usability, practicality, and impact on patients and their processes of care, as well as how the measure is recorded and communicated in the electronic health record and in research communications.
5. PRO-PMs will need to be developed in concert with other key clinical PAD performance measures that address evidence-based components of PAD care because, again, no formal metrics

or public reporting measures been instituted that affect reimbursement or rankings of quality of PAD care delivered. Related to this last step, PRO-PMs must be held against the same standards of evidence as these other PAD performance measures and Class I PAD recommendations.<sup>6</sup> While the field develops this rigorous evidence, testing health status measures as quality measures and collecting supporting data are necessary.

These are several important considerations to lead to success when embarking on this paradigm shift of integrating PRO-PMs as indicators of quality PAD care. Myriad professional organizations and stakeholders, however, would benefit from the development of a systematic PRO for patients with PAD. Patient-facing organizations, clinical research organizations, federal and foundation-based research entities, patients, clinicians, health care professionals, and industry partners would all have a common mechanism to better understand the effects of PAD on patients and the effects of treatment on patients with PAD.

## ARTICLE INFORMATION



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## Disclosures

## Writing Group Disclosures

Writing group member	Employment	Research grant	Other research support	Speakers' bureau/honoraria	Expert witness	Ownership interest	Consultant/advisory board	Other
Carole Decker	University of Missouri–Kansas City	None	None	None	None	None	None	None
Kim G. Smolderen	Yale University School of Medicine	Johnson & Johnson (research grant critical limb ischemia registry)†; Shockwave (research grant real-world registry common femoral disease)†; Philips (research grant secondary data analysis)†	None	None	None	None	Optum†; Abbott†; Cook Medical*; Happify Inct; Tegus*	None
Olamide Alabi	Emory University School of Medicine	None	None	None	None	None	None	None
Tracie C. Collins	University of New Mexico College of Population Health	None	None	None	None	None	None	None
Bernard Dennis	Retired	None	None	None	None	None	None	None
Philip P. Goodney	Dartmouth Hitchcock Medical Center	None	None	None	None	None	None	None
Carlos Mena-Hurtado	Yale University School of Medicine	None	None	None	None	None	Cook*; Optum†; Abbott†	None
John A. Spertus	University of Missouri–Kansas City	Janssen (grant to do analyses from CHIEF-HF)†; Bristol Meyers Squibb (grant to analyze EXPLORER-HCM)†; Abbott Vascular (support for ABSORB III and IV)†	None	None	None	Copyright to Peripheral Artery Questionnaire*	Janssent†; Bristol Meyers Squibb†	None

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\*Modest.

†Significant.

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Reviewer	Employment	Research grant	Other research support	Speakers' bureau/honoraria	Expert witness	Ownership interest	Consultant/advisory board	Other
Amr E. Abbas	Beaumont Health	None	None	None	None	None	None	None
J. Dawn Abbott	Brown University	None	None	None	None	None	None	None
Andrew W. Gardner	Penn State Hershey College of Medicine	None	None	None	None	None	None	None
Beau M. Hawkins	University of Oklahoma	NIH/NHLBI (site principal investigator for BEST-CLI RCT, BEST registry)*; Hemostemix (site principal)*	None	None	None	None	Baim Research*	None
Amy Pollak	Mayo Clinic	None	None	None	None	None	None	None

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\*Modest.

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