

## Treatment Decisions for Patients with Mild to Severe Claudication

### Development Process of the SHOW-ME-PAD© Decision-Aid

Smolderen – PAD Decision Aid

Kim G. Smolderen, PhD<sup>1,2</sup>; Christina Pacheco, JD, MPH<sup>1</sup>; Jeremy Provance, MS<sup>1</sup>; Nancy Stone, MEd<sup>1</sup>, Christine Fuss, RN<sup>1</sup>; Carole Decker, RN, PhD, FAHA<sup>1,2</sup>; David Safley, MD<sup>1</sup>; John A. Spertus, MD MPH<sup>1,2</sup>

<sup>1</sup>Saint Luke's Mid America Heart Institute, Kansas City, MO; <sup>2</sup>University of Missouri-Kansas City, Kansas City, MO

#### Address for Correspondence:

Kim G. Smolderen, PhD  
Assistant Professor – Implementation Science  
UMKC School of Medicine – Biomedical & Health Informatics  
Kansas City, MO 64108

Outcomes Research Scientist  
Saint Luke's Mid America Heart Institute  
4401 Wornall Rd  
Kansas City, MO 64111  
Office: 816-932-5846  
Fax: 816-932-5130  
E-mail: [smolderenk@umkc.edu](mailto:smolderenk@umkc.edu)

**Word Count:** X,XXX words

**ABSTRACT**

**BACKGROUND:** The overall aim of this study was to make the existing evidence-base on treatment options and outcomes for mild to severe claudication – ischemic pain due to arterial blockages in the legs – more transparently available in a patient-centered way to patients and providers to enable informed, evidence-based, shared treatment decisions.

**METHODS:** We used a mixed model design and applied the International Patient Decision Aids Standards (IPDAS) criteria. In the first phase, we reviewed existing literature and collected qualitative input from patients (n=28) through focus groups and patient and physician (+allied health) expert panel meetings (n=34) about decisional needs, barriers, outcomes, knowledge and preferences related to claudication treatment. We also collected input on implementation and dissemination logistics from 59 patients and 27 providers. A prototype was developed and tested in the Alpha testing phase through a survey administered to 20 patients with peripheral artery disease (PAD) and to 18 providers.

**RESULTS:** The treatment decision that was identified for patients with new or worsening symptoms of claudication included pursuing an invasive (endovascular or surgical revascularization options) or a non-invasive (supervised exercise therapy, claudication medications) treatment pathway or combinations thereof. The prototype decision aid materials that were created included a patient brochure with discussion cards and a website. Patient vignettes were also created with video recordings as supportive materials to the decision aid. A total of 61.1% of providers thought the brochure would be useful for medical decision making, an additional 33.3% thought the brochure would be useful, with suggested improvements. For patients those percentages were 75% and 25%, respectively. For the website, 73.3% of providers, and 85.7% of patients thought it would be useful for decision-making, an additional 20% of

providers, and 14.3% of patients thought it would be useful, provided suggested improvements would be made.

**CONCLUSION:** A decision aid for patients with new or worsening symptoms of claudication was co-created with PAD patients and providers. The first prototype was well received among patients and providers. A next step will be the implementation of the revised prototype in a PAD specialty care setting and evaluate its efficacy for improving patient knowledge, engagement, and decisional quality.

## INTRODUCTION

Peripheral arterial disease (PAD) is a very prevalent and burdensome condition that affects 10% of the population and increases to 15-20% among those  $\geq 70$  years.<sup>1-3</sup> Patients with PAD have arterial blockages in their leg arteries due to atherosclerosis. PAD can cause patients to experience excruciating pain in their legs while walking. In PAD, the underlying pathophysiologic process, atherosclerosis, presents itself as blockages in patients' leg arteries that prevent adequate blood flow and can result in burning calf (or buttock) pain while walking and that is relieved upon rest ("intermittent claudication"). In extreme cases, PAD can progress to critical limb ischemia characterized by ulceration, gangrene, and threatened limb viability.<sup>4</sup> While the onset of PAD tends not to be as abrupt as for other cardiovascular conditions, such as stroke or myocardial infarction, leg symptoms can severely affect patients' health status (their symptoms, functional status, and quality of life).<sup>5-7</sup> In addition, one-year cardiovascular event rates – including cardiovascular death, myocardial infarction, or stroke, or other hospitalizations for atherothrombotic events – are estimated to be over 21% in patients with PAD, and mortality rates of 15-30% 5 years after diagnosis have been observed.<sup>4,8,9</sup>

Patients with PAD have significant atherosclerotic risk factors and impaired health status and thus creating therapeutic goals, including the prevention of cardiovascular events and improved symptom control and quality of life are of key importance.<sup>10</sup> For symptom relief, several treatment options are available for PAD, ranging from invasive revascularization procedures, including peripheral percutaneous intervention (PPI) and surgical revascularization to non-invasive options, including supervised and home-based exercise therapy, and PAD-specific medications. All patients are recommended to receive cardiovascular risk management.<sup>11</sup> While there is no "gold-standard" PAD treatment for symptomatic relief, less invasive options are recommended as a first-choice treatment.<sup>11</sup> Despite these recommendations, invasive procedures are often first offered to patients in the US, with no alternative options being

discussed.<sup>12</sup> In treatment scenarios with a lot of clinical equipoise (i.e. uncertainty about what treatment would be best) there is a high risk of unwanted variation in treatment practices, misallocation of treatments, and unnecessary costs.

A very promising strategy to avoid such unwanted variations is the use of evidence-based, decision support tools. For patients with new or worsening symptoms of claudication, it is currently unknown whether patient-centered PAD decision-tools can be designed to improve the alignment of patients' values with respect to their treatment choice and whether these tools can improve patients' knowledge and access to the evidence-base related to PAD treatment and outcomes. In the study we present, we aimed to create such tools and evaluate its acceptance as a foundation for broader integration of shared decision-making in the clinical care for PAD.

## **METHODS**

The development process of the decision aid followed the International Patient Decision Aids Standards.<sup>13</sup> Qualitative input was collected from patient and provider stakeholders in 3 waves, each leading to a steering session to integrate the feedback of the stakeholders and design the decision aid (Figure 1).

**Waive I** was organized in parallel with the preparation of the Patient-centered Outcomes Related to Treatment practices in peripheral Arterial disease” Investigating Trajectories (PORTRAIT) study.<sup>14</sup> As part of the PORTRAIT study, a series of patient focus groups (a total of 28 patients with a diagnosis of PAD were included, details of patient characteristics provided in Supplemental Table 1) were conducted and a patient expert panel was instituted to give us input on their decision needs, perceived barriers to PAD decision-making, preferred outcomes, PAD knowledge, and preferences for PAD decision-making. The detailed methods of PORTRAIT, the recruitment strategy of the enrolled population as well as the stakeholders that we engaged have been described elsewhere.<sup>14</sup> Briefly, PORTRAIT enrolled patients with new or an exacerbation of

PAD symptoms (Rutherford category 1-3 including mild, moderate, severe claudication) from 16 PAD specialty centers in the US, the Netherlands and Australia. The PAD diagnosis was confirmed by an abnormal ankle-brachial index (ABI) with the goal to follow them for 1 year after diagnosis and document their PAD-specific health status as a function of their patient characteristics and the PAD treatments received. Similar input was obtained from providers, allied health professionals, and a standing 3-member PAD provider expert panel (a cardiologist, vascular surgeon, a vascular medicine specialist) as well as a shared decision-making expert (n=34). Following the stakeholder meetings, a steering (1a) was organized with key research personnel (KS, JS, KS, CD, DS) and expert panel members to integrate the collected feedback and make decisions for further study design and decision-aid development.

In **Wave II** (from 9/12/2016 until 03/31/2018), the same stakeholder groups were invited to provide input on implementation logistics for the decision aid and dissemination and planning priorities. In addition to the stakeholder settings we recruited from in Wave I, we also recruited patient stakeholders (individuals with chronic diseases including diabetes, coronary artery disease, and peripheral arterial disease) from the Second Baptist Church in Kansas City Missouri, and from the Diabetes Prevention Program in Kansas City, Kansas. Following this round of input, another steering meeting (1b) was convened with key research personnel and experts to review the input and design the prototype decision-aid with a graphic design and videographer team.

For the alpha testing phase, the **prototype decision-aid** was sent out to a convenience sample of 20 patients with an established diagnosis of PAD (Rutherford categories 1-6) who were recruited from the Saint Luke's Health System vascular clinics (vascular surgery and interventional cardiology) in Kansas City, Missouri and to a convenience sample of 18 providers and allied health professionals from Saint Luke's Health System Kansas City MO, Yale University, New Haven CT, University of Missouri, Columbia MO, University Hospitals Cleveland OH,

University of Missouri Kansas City MO, Hackensack University Medical Center Hackensack NJ, and Kansas University Medical Center, Kansas City KS between 04/01/2018 and 08/31/2018. Both patients and providers filled out a 44-item survey on the user friendliness of the decision aid materials (both website and printed brochure and discussion cards). The survey items were derived from previous work frameworks for decision-aids.<sup>15,16</sup> The provider survey was sent out electronically through RedCap.<sup>17</sup> The patient version of the survey was sent out in the mail with a prepaid return envelope.

The evidence-base used to guide the development process were the latest American Heart Association and the American College of Cardiology guidelines for PAD.<sup>18</sup> Their weighting system for the level of evidence was transferred over as we summarized the treatment information in the decision-aid.<sup>18</sup>

The research protocol for PORTRAIT and supporting qualitative research work was approved by the Institutional Review Board (IRB) of the Saint Luke's Health system Kansas City Missouri and the 15 other participating centers, as applicable. All enrolled patients provided informed consent. Focus group discussions were recorded and transcribed. The transcribed text was then coded by a team of nurses, psychologist, an interventional cardiologist, and a community-based participatory health researcher. Coding was done according to the prescribed methodology by Hahn<sup>19</sup> using Microsoft Word (Microsoft Corporation, Redmond, WA). For each wave of focus groups, we kept interviewing patients until we reached saturation with our coding. The descriptive data obtained from the alpha testing survey, was analyzed using IBM SPSS statistics (IBM Corporation, Armonk, New York).

## Results

For **Wave I** (Figure 1), an overview of provider and allied health characteristics are provided in Supplemental Tables 1-2. A complete overview of the stakeholder interactions is

provided in Supplemental Table 3. The decision needs for patients with mild to moderate claudication that we identified based on the stakeholder interactions focused on obtaining symptom relief for their PAD and finding the information that would fit their needs. They were looking for high quality information about treatment options and their recovery time but did not feel that they were always presented with options. Perceived barriers were a lack of information, the quality of the patient-physician relationship, and variable information.

Following the Wave I interactions, the following outcomes were identified as important PAD treatment outcomes: quick pain relief, living longer, improved quality of life, cost of treatment, avoid loss of toes or legs, timeline to return to normal activities, decreased risk of heart attack and stroke, long-lasting treatment benefit, avoiding a procedure or surgery. In the Steering 1a meeting, it was then decided that the treatment decision support would focus on highlighting the evidence<sup>18</sup> of 2 treatment pathways for PAD symptom relief: a non-invasive pathway that included medications and supervised exercise therapy (SET) and an invasive treatment pathway that included endovascular and surgical options. The option of “do nothing” was also chosen to be highlighted. Per the guidelines, lifestyle management for PAD was highlighted as recommended for everyone, regardless of the treatment path(s) were chosen to relieve the PAD symptoms (Figure 2, left panel). Based on the list of important PAD treatment outcomes derived from the Wave I interactions, the following consolidated treatment outcomes were highlighted in the decision aid concept: (1) symptom relief and quality of life; (2) cost; (3) decreased risk of heart attack and stroke; (4) avoid loss of toes or legs; and (5) timeline of return (Figure 2, middle panel).

For **Wave II** of stakeholder interactions (Figure 1), patient stakeholders indicated they wanted a variety of educational materials through different media (video, paper, website) to assist them in their PAD treatment decision needs (Supplemental Table 3). The provider stakeholders' priority was that the decision aid materials would work well with the clinical flow of the diagnostic work up process. A typical clinical pathway is described in Figure 3. The decision aid was



designed to be provided to patients for whom a diagnostic work-up for PAD is ordered based on the symptom presentation. In a typical scenario, the patient would receive a vascular diagnostic test, following which they are being sent the materials or can review the materials in the clinic before they see their provider where they discuss diagnostic test results and PAD treatment plan. By designing the process in this way, the patient would come in prepared and would have their prioritized their preferences and questions they want to discuss with the provider. A website and brochure were designed with a creative development team following the Steering 1b meeting. The prototype decision aid resulted in a website with patient and physician videos where outcomes were discussed for the different treatment pathways in easy-to-review discussion cards. A paper version of the decision aid materials was mirrored after the website materials (Figure 2, right panel). The website can be reviewed at: <http://showme-pad.org> A parallel Spanish version of the website is also available through this link.

For the **alpha testing**, the characteristics of the patients and providers who participated in this testing are presented in Tables 1 and 2. All patients and physicians thought the information of the brochure was relevant, and that the brochure was easy to use (100% and 94.4%, respectively). The different treatments were presented in a balanced manner is what both patients and providers agreed upon for both the brochure (87.5% and 83.3%, respectively) and the website (85.7% and 86.7%, respectively). The brochure looks visually attractive is what 84.2% of the patients, and 94.1% of the providers indicated. Patients and providers also liked the visual presentation of the website (92.9% and 86.7%, respectively). Both patients and providers thought that the language for both the brochure (94.4% and 100%, respectively) and the website (100% and 93.3%, respectively) was easy to understand. Risks of treatments were thought to be presented in a realistic way for all the treatments (range 83.3-92.3% for patients; range 88.9-100% for providers). Patients and providers agreed that the brochure (75% and 61.1%, respectively) and the website (85.7% and 73.3%, respectively) would be useful instruments for

decision-making in PAD. Of all the providers surveyed, 94% would recommend the decision aid in their own practice. Further reporting and details of the survey results are presented in Table 3. In Supplemental Table 3, an overview of all suggestions provided by patient and provider stakeholders that completed the alpha testing, as well as the steering 3 action items that were derived from these.

## Discussion

We designed and alpha tested an evidence-based shared decision tool to assist patients and providers to make a more informed and shared decision with regards to their PAD treatment. We worked intensely with patient and provider stakeholders to design a platform that would support patients with new or worsening of symptoms of PAD in understanding and considering different treatment options for PAD symptom relief. Patients expressed interest in learning more about 5 different PAD treatment outcomes: (1) symptom relief and quality of life; (2) cost of treatment; (3) decreased risk of heart attack and stroke; (4) avoid loss of toes or legs; and (5) timeline of return to normal activities. These outcomes defined the framework for presenting levels of evidence for non-invasive and invasive treatment options for PAD symptom relief. Stakeholders indicated that they wanted the materials presented in a variety of modalities (website, videos, and printed materials) and that they would serve to facilitate the treatment discussion with the provider, but could be used independently by patients in preparation of their visit. The prototype decision aid was tested among a group of patients with PAD and a group of providers. Overall, the tool was well received and next steps for an update of the tool for implementation testing (beta testing) were formulated.

The current SHOW-ME PAD© decision aid is a patient-friendly shared decision aid that co-developed by both patients and providers and it is ready for testing in routine clinical practice (PAD specialty setting). Limited experience has been built up with shared decision making in PAD. A first decision aid<sup>20</sup> was developed by Healthwise, but the focus on the patient experience has never been that central to a tool that facilitates decision making in PAD as the one adopted in the SHOW-ME PAD© tool. With patients and providers, we co-created a platform that takes into account the latest evidence about all available treatment options and their outcomes for PAD symptom relief,<sup>18</sup> as well as patients' preferences with regards to treatment and potential outcomes that matter to *them*.<sup>21</sup> Shared decision-making is extremely useful in treatment

situations where there is great clinical equipoise (i.e. different potential treatment options and associated benefits and risks) and where the choice of treatment is greatly based on patients' preferences.<sup>21</sup>

Decision aids that facilitate this process of shared decision-making, have proven to have the potential to be cost saving due to less invasive options being preferred by patients, to provide higher treatment satisfaction and knowledge, and less decision conflict<sup>21,22</sup> PAD is a disease for which several treatment options are available; invasive revascularization procedures, including peripheral transluminal angioplasty with or without arterial stenting or surgical approaches [peripheral arterial bypass grafting, endarterectomy]) and non-invasive options, including supervised and home-based exercise therapy, PAD-specific medications, and cardiovascular risk management.<sup>11</sup> While there is no real “gold-standard” treatment for PAD, least invasive options are generally recommended as a first-choice treatment, however, personal preferences, quality of life considerations, or anatomical factors may also weigh into a treatment decision.<sup>11</sup> Each of the treatment options also have their own specific treatment risks and benefits. Patients may not always know what risks and benefits are associated with each treatment, they may not realize that they have a choice when treatment decisions are being made, and their treatment preferences and goals may not always be in line with the treatment that they receive. In treatment scenarios with a lot of *clinical equipoise* (i.e. uncertainty about what treatment would be best) and a rapid growing market with new technologies being introduced, including medical devices for invasive PAD procedures (e.g. arterial stents), with limited performance measurement and accountability criteria, there is a high risk for unwanted variation in treatment practices, misallocation of treatments, and unnecessary costs. Patient-centric tools like the SHOW-ME PAD© decision aid could be used to align decision-making better with patients' preferences and reduce unwanted variations.

Next steps for evaluation of the SHOW-ME PAD© decision aid is implementing and evaluating it in the PAD specialty care setting. The tool is underway to be tested in a pre-post design study<sup>23</sup> in patients with new or worsening of PAD symptoms consulting a PAD specialty care clinic in the US. The study goals are to demonstrate lower decisional conflict scores on the decisional conflict scale<sup>24</sup> and higher knowledge scores on PAD knowledge and treatment options items. Upon demonstration of its performance, further testing in a randomized design are anticipated as well as the construction of individualized modules that are data driven (based on clinical trial and registry data) such that personalized risk estimates for key PAD treatment outcomes can be consulted during the decision-making process.

While the study has rigorously adhered to the IPDAS development criteria and was conceptualized to be very patient-centric, it has the following limitations. The study was mainly designed in the PAD specialty care setting, and it is unclear whether the tool's benefit will extend to the primary care setting or to patients who have difficulties accessing or affording PAD care. Dedicated validation work and/or updates would be warranted to ensure wider generalizability of its use. The same holds for its geographic generalizability. While we have recruited patients and providers from different areas of the US, it is unclear whether the tool will have the same use and benefit outside of these contexts.

In conclusion, the overall goal of SHOWME-PAD© is to make the existing evidence-base on treatment outcomes –focusing on health status outcomes that reflect the *patients' perspective* – more transparently available to patients and providers, such that more informed, evidence-based shared treatment decisions occur. This study served as the foundation for future research to more definitely document the impact of precision medicine on PAD care and outcomes. As such, we demonstrated the feasibility of this vision and gained important insights into the barriers and facilitators of personalized shared decision-making tools in routine clinical care. SHOWME-

PAD© has the potential to radically reorganize care delivery to patients with PAD such that more value for the patient and society will be created.

**REFERENCES**

1. Criqui MH, Fronek A, Barrett-Connor E, Klauber MR, Gabriel S, Goodman D. The prevalence of peripheral arterial disease in a defined population. *Circulation*. 1985;71(3):510-515.
2. Hiatt WR, Hoag S, Hamman RF. Effect of diagnostic criteria on the prevalence of peripheral arterial disease. The San Luis Valley Diabetes Study. *Circulation*. 1995;91(5):1472-1479.
3. Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000. *Circulation*. 2004;110(6):738-743.
4. Hirsch AT, Haskal ZJ, Hertzner NR, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation*. 2006;113(11):e463-654.
5. Smolderen KG, Pelle AJ, Kupper N, Mols F, Denollet J. Impact of peripheral arterial disease on health status: a comparison with chronic heart failure. *J Vasc Surg*. 2009;50(6):1391-1398.

6. deGraaf JC, Ubbink DT, Kools EJC, Chamuleau SAJ, Jacobs MJHM. The impact of peripheral and coronary artery disease on health-related quality of life. *Annals of vascular surgery*. 2002;16:495-500.
7. Hallin A, Bergqvist D, Fugl-Meyer K, Holmberg L. Areas of concern, quality of life and life satisfaction in patients with peripheral vascular disease. *Eur J Vasc Endovasc Surg*. 2002;24(3):255-263.
8. Steg PG, Bhatt DL, Wilson PW, et al. One-year cardiovascular event rates in outpatients with atherothrombosis. *JAMA*. 2007;297(11):1197-1206.
9. Weitz JI, Byrne J, Clagett GP, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. *Circulation*. 1996;94(11):3026-3049.
10. McDermott MM, Fried L, Simonsick E, Ling S, Guralnik JM. Asymptomatic peripheral arterial disease is independently associated with impaired lower extremity functioning: the women's health and aging study. *Circulation*. 2000;101(9):1007-1012.
11. Rooke TW, Hirsch AT, Misra S, et al. 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Peripheral Artery Disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2011;58(19):2020-2045.
12. van Zitteren M, Denollet J, Heyligers JM, et al. One-Year Health Status Benefits Following Invasive Treatment for Lower-Extremity Peripheral Arterial Disease: The Importance of Patients' Baseline Health Status. *EJVES*. In Press.
13. Coulter A, Kryworuchko J, Mullen P, Ng C, Stilwell D, van der Weijden T. Using a systematic development process. In Volk R & Llewellyn-Thomas H (editors). 2012



- Update of the International Patient Decision Aids Standards (IPDAS) Collaboration's Background Document. Chapter A. . 2012. Accessed April 7, 2013.
14. Smolderen KG, Gosch K, Patel M, et al. PORTRAIT (Patient-Centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories): Overview of Design and Rationale of an International Prospective Peripheral Arterial Disease Study. *Circ Cardiovasc Qual Outcomes*. 2018;11(2):e003860.
  15. Harmsen MG, Steenbeek MP, Hoogerbrugge N, et al. A patient decision aid for risk-reducing surgery in premenopausal BRCA1/2 mutation carriers: Development process and pilot testing. *Health Expect*. 2018;21(3):659-667.
  16. Garvelink MM, ter Kuile MM, Fischer MJ, et al. Development of a Decision Aid about fertility preservation for women with breast cancer in The Netherlands. *J Psychosom Obstet Gynaecol*. 2013;34(4):170-178.
  17. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics*. 2009;42(2):377-381.
  18. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2016.
  19. Hahn C. *Doing Qualitative Research Using Your Computer: A Practical Guide*. SAGE Publications Ltd; 2008.

20. Healthwise. Peripheral Arterial Disease: Should I Have Surgery?  
<https://www.healthwise.net/cochrane4756/Content/StdDocument.aspx?DOCHWID=ue4756>.
21. O'Connor AM, Wennberg JE, Legare F, et al. Toward the 'tipping point': decision aids and informed patient choice. *Health Aff (Millwood)*. 2007;26(3):716-725.
22. Arterburn D, Wellman R, Westbrook E, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. *Health Aff (Millwood)*. 2012;31(9):2094-2104.
23. SHOWME-PAD.  
<https://clinicaltrials.gov/ct2/show/NCT03190382?term=smolderen&rank=3>.
24. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15(1):25-30.

## **Funding Sources**

Research reported in this manuscript was partially 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)
- Unrestricted grant from W. L. Gore & Associates, Inc (Flagstaff, AZ)
- Unrestricted grant from Merck Merck & Company, Inc (Kenilworth, NJ)

## **Disclosures**

- “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.”
- All manuscripts for the PORTRAIT study are prepared by independent authors who are not governed by the funding sponsors and are reviewed by an academic publications committee before submission.
- The funding organizations and sponsors of the study had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.
- The authors report no other disclosures or conflicts of interest.
- Copyright for SHOW-ME PAD© held by Kim Smolderen, PhD

## **Data Access and Responsibility**

Dr. Smolderen had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Table 1. Overview of Patient Characteristics**

<b>Patient Characteristic</b>	<b>N=20</b>
Age (Mean±SD)	69.8±12.4
Female	12 (60.0)
Race	
American Indian/Alaska Native	0 (0.0)
Black/African American	7 (35.0)
Native Hawaiian/Pacific Islander	0 (0.0)
White	12 (60.0)
Other	0 (0.0)
Hispanic Ethnicity	0 (0.0)
Greater than High School Education	13 (65.0)
Married	12 (60.0)
Full Time or Part-Time Employed	4 (20.0)
Living Location	
Urban	11 (55.0)
Suburban	
How long have you had PAD?	
Less than 1 Year	1 (0.05)
1-2 Years	4 (20.0)
2-3 Years	2 (10.0)
≥3 Years	12 (60.0)
Table 1 (continued)	
PAD stage	
Claudication	10 (50.0)

---

<b>Patient Characteristic</b>	<b>N=20</b>
Non-healing wounds	6 (30.0)
Amputation	4 (20.0)

---

Data are presented as numbers (percentages), unless otherwise stated. Abbreviations: SD, standard deviation; PAD, peripheral artery disease.

**Table 2. Overview of PAD Provider Characteristics**

<b>Provider Characteristic</b>	<b>N=18</b>
<b>Specialist Type</b>	
Cardiologist	9 (42.9)
Vascular Surgeon	2 (9.5)
Wound Care Specialist	0 (0.0)
Internal Medicine	2 (9.5)
Other	7 (33.3)
<b>Years Practicing</b>	
0-5	8 (38.1)
6-10	4 (19.0)
11-15	2 (9.5)
16-20	0 (0.0)
21+	7 (33.3)
<b>Practice Facility Type</b>	
Academic	18 (85.7)
Non-Academic	3 (14.3)

Data are presented as numbers (percentages), unless otherwise stated. Abbreviations: SD, standard deviation; PAD, peripheral artery disease.

<b>Table 3. Alpha Testing Results</b>		
Evaluation Criteria	Patients (N=20)	Providers (N=18)
For the paper brochure, I think the amount of information is too much		
Agree	3 (15.0)	6 (33.3)
Disagree	17 (85.0)	10 (55.6)
Do not know	0 (0.0)	2 (11.1)
For the paper brochure, I think the brochure will do more harm than good		
Agree	1 (5.0)	3 (16.7)
Disagree	18 (90.0)	14 (77.8)
Do not know	1 (5.0)	1 (5.6)
For the paper brochure, I think the brochure contains information that can help a patient decide about PAD treatment		
Agree	20 (100.0)	16 (88.9)
Disagree	0 (0.0)	1 (5.6)
Do not know	0 (0.0)	1 (5.6)
For the paper brochure, I think the information is relevant		
Agree	20 (100.0)	18 (100.0)
Disagree	0 (0.0)	0 (0.0)
Do not know	0 (0.0)	0 (0.0)
I think the paper brochure is easy to use		
Agree	20 (100.0)	17 (94.4)
Disagree	0 (0.0)	0 (0.0)
Do not know	0 (0.0)	1 (5.6)
For the paper brochure, I think the different sections are presented in a clear manner		
Agree	20 (100.0)	16 (88.9)
Disagree	0 (0.0)	1 (5.6)
Do not know	0 (0.0)	1 (5.6)

For the paper brochure, I think the information is easy to understand

Agree	19 (95.0)	15 (83.3)
Disagree	1 (5.0)	0 (0.0)
Do not know	0 (0.0)	3 (16.7)

For the paper brochure, I think the different PAD treatments are explained in a clear manner

Agree	18 (94.7)	14 (77.8)
Disagree	0 (0.0)	3 (16.7)
Do not know	1 (5.3)	1 (5.6)

For the paper brochure, I think the pros and cons of PAD treatments are presented in a clear manner

Agree	19 (95.0)	14 (82.4)
Disagree	0 (0.0)	2 (11.8)
Do not know	1 (5.0)	1 (5.9)

For the paper brochure, the invasive treatment information is easy to understand

Yes	17 (89.5)	15 (83.3)
No	2 (10.5)	3 (16.7)

The risks of invasive treatments in the paper brochure seem

Underestimated	3 (16.7)	2 (11.1)
Overestimated	0 (0.0)	0 (0.0)
Realistic	15 (83.3)	16 (88.9)

For the paper brochure, the non-invasive treatment information is easy to understand

Yes	18 (94.7)	18 (100.0)
No	1 (5.3)	0 (0.0)

The risks of non-invasive treatments in the paper brochure seem

Underestimated	3 (15.8)	0 (0.0)
----------------	----------	---------



Overestimated	0 (0.0)	0 (0.0)
Realistic	16 (84.2)	18 (100.0)
Do you feel the information in the paper brochure and decision cards is balanced between invasive and non-invasive PAD treatment options?		
Yes	14 (87.5)	15 (83.3)
No, slanted towards invasive	1 (6.3)	1 (5.6)
No, slanted towards non-invasive	1 (6.3)	2 (11.1)
I think the brochure looks visually attractive		
Agree	16 (84.2)	16 (94.1)
Disagree	1 (5.3)	0 (0.0)
Do not know	2 (10.5)	1 (5.9)
For the paper brochure, I think the font and font size are easy to read		
Agree	15 (78.9)	12 (66.7)
Disagree	4 (21.1)	5 (27.8)
Do not know	0 (0.0)	1 (5.6)
How would you rate the paper brochure length?		
Too long	5 (26.3)	3 (16.7)
Too short	1 (5.3)	1 (5.6)
Just right	13 (68.4)	14 (77.8)
How would you rate the amount of information shared in the paper brochure?		
Too much	4 (23.5)	5 (27.8)
Too little	1 (5.9)	0 (0.0)
Just right	12 (70.6)	13 (72.2)
Overall, the paper brochure is easy to understand		
Yes	17 (94.4)	18 (100.0)
No	1 (5.6)	0 (0.0)

The paper brochure is useful in decision making

Yes	12 (75.0)	11 (61.1)
Yes, with recommended improvements	4 (25.0)	6 (33.3)
No	0 (0.0)	1 (5.6)

For the website, I think the amount of information is too much

Agree	4 (25.0)	4 (23.5)
Disagree	9 (56.3)	7 (41.2)
Do not know	3 (18.8)	6 (35.3)

For the website, I think it will do more harm than good

Agree	3 (18.8)	2 (11.8)
Disagree	10 (62.5)	10 (58.8)
Do not know	3 (18.8)	5 (29.4)

For the website, I think it contains information that can help a patient decide about PAD treatment

Agree	14 (87.5)	12 (70.6)
Disagree	0 (0.0)	2 (11.8)
Do not know	2 (12.5)	3 (17.6)
Missing	4	4

For the website, I think the information is relevant

Agree	14 (87.5)	13 (76.5)
Disagree	0 (0.0)	0 (0.0)
Do not know	2 (12.5)	4 (23.5)

I think the website is easy to navigate

Agree	13 (81.3)	12 (70.6)
Disagree	1 (6.3)	2 (11.8)
Do not know	2 (12.5)	3 (17.6)

For the website, I think the sections are presented in a clear manner

Agree	13 (81.3)	12 (70.6)
Disagree	1 (6.3)	2 (11.8)
Do not know	2 (12.5)	3 (17.6)
For the website, I think the information is easy to understand		
Agree	13 (81.3)	12 (70.6)
Disagree	1 (6.3)	1 (5.9)
Do not know	2 (12.5)	4 (23.5)
For the website, I think the different PAD treatments are explained in a clear manner		
Agree	13 (81.3)	10 (62.5)
Disagree	1 (6.3)	3 (18.8)
Do not know	2 (12.5)	3 (18.8)
For the website, I think the pros and cons of PAD treatment are presented in a clear manner		
Agree	13 (81.3)	10 (58.8)
Disagree	0 (0.0)	3 (17.6)
Do not know	3 (18.8)	4 (23.5)
For the website, the invasive treatment information is easy to understand		
Yes	11 (100.0)	12 (80.0)
No	0 (0.0)	3 (20.0)
The risks of invasive treatment on the website seem		
Underestimated	1 (7.7)	1 (6.7)
Overestimated	0 (0.0)	0 (0.0)
Realistic	12 (92.3)	14 (93.3)
For the website, the non-invasive treatment information is easy to understand		
Yes	13 (92.9)	15 (100.0)
No	1 (7.1)	0 (0.0)

The risks of non-invasive treatments on the website seem

Underestimated	1 (7.7)	1 (6.7)
Overestimated	0 (0.0)	0 (0.0)
Realistic	12 (92.3)	14 (93.3)

Do you feel the information on the website is balanced between invasive and non-invasive PAD treatment options?

Yes	12 (85.7)	13 (86.7)
No, slanted towards invasive	1 (7.1)	1 (6.7)
No, slanted towards non-invasive	1 (7.1)	1 (6.7)

I think the website looks visually attractive

Agree	13 (92.9)	13 (86.7)
Disagree	1 (7.1)	0 (0.0)
Do not know	0 (0.0)	2 (13.3)

For the website, I think the font and font size are easy to read

Agree	14 (100.0)	11 (78.6)
Disagree	0 (0.0)	1 (7.1)
Do not know	0 (0.0)	2 (14.3)

How would you rate the amount of information shared on the website?

Too much	3 (21.4)	1 (6.7)
Too little	0 (0.0)	3 (20.0)
Just right	11 (78.6)	11 (73.3)

Overall, the website is easy to understand

Yes	11 (100.0)	14 (93.3)
No	0 (0.0)	1 (6.7)

The website tool is useful in decision making

Yes	12 (85.7)	11 (73.3)
Yes, with recommended improvements	2 (14.3)	3 (20.0)
No	0 (0.0)	1 (6.7)

The decision aid provides enough information  
for a PAD patient to decide on a treatment

Yes, for both versions	15 (93.8)	13 (81.3)
Yes, for only the paper brochure	1 (6.3)	0 (0.0)
Yes, for only the website	0 (0.0)	0 (0.0)
No	0 (0.0)	3 (18.8)

For both versions, the decision card topics are

Well chosen	14 (93.3)	15 (93.8)
At least one needs to be removed	1 (6.7)	1 (6.3)
At least one needs to be added	0 (0.0)	0 (0.0)

Do you feel the content of the brochure and  
website are consistent?

Yes	15 (100.0)	14 (100.0)
No	0 (0.0)	0 (0.0)

Do you find the PAD Quiz and Your  
Preferences Matter helpful in PAD decision  
making

Yes, for both versions	12 (80.0)	14 (87.5)
Yes, for only the paper brochure	0 (0.0)	1 (6.3)
Yes, for only the website	0 (0.0)	0 (0.0)
No	3 (20.0)	1 (6.3)

I would recommend the Show-Me PAD  
decision aid for PAD patients

Yes, for both versions	15 (93.8)
Yes, for only the paper brochure	0 (0.0)
Yes, for only the website	0 (0.0)
No, I would not recommend either	0 (0.0)
No, I do not recommend decision aids in general	1 (6.3)

---

Data are presented as numbers (percentages).

Figure 1 – Timeline of Development Process SHOW-ME PAD© Decision Aid

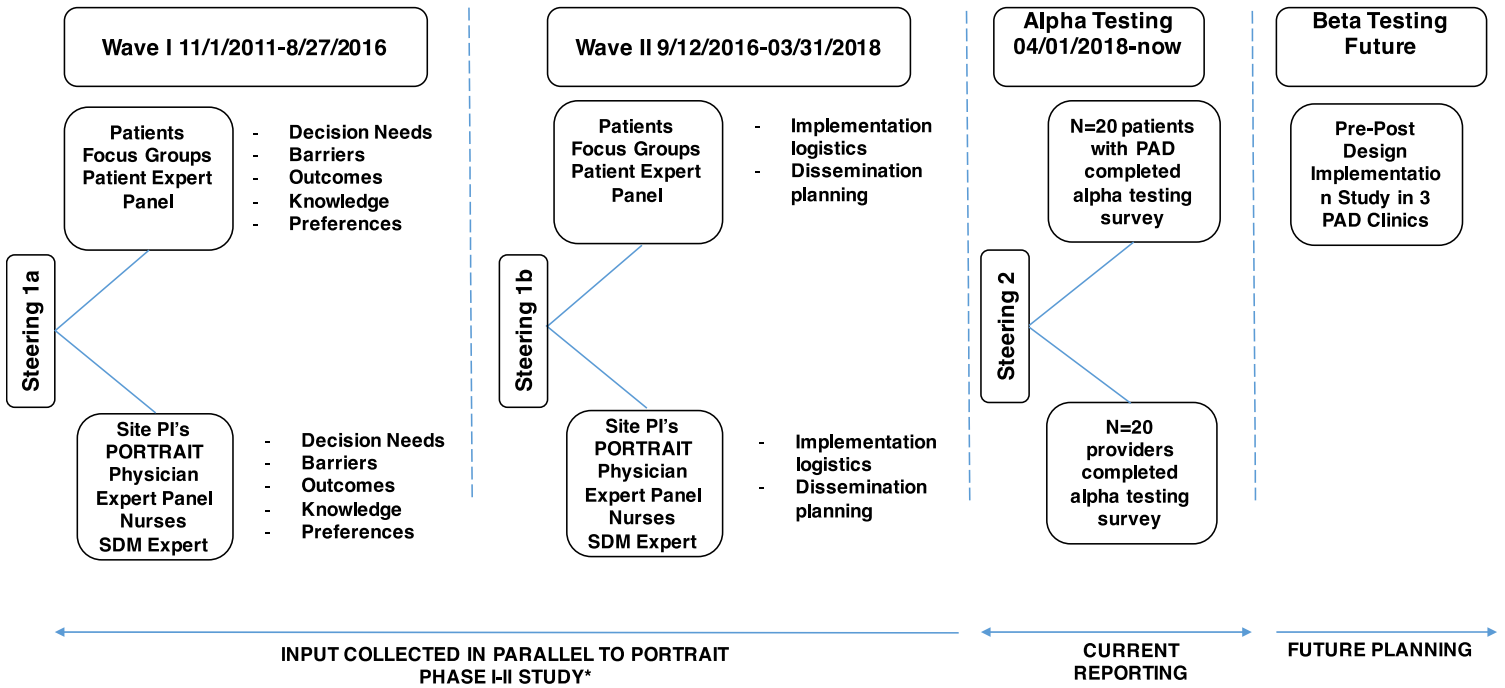
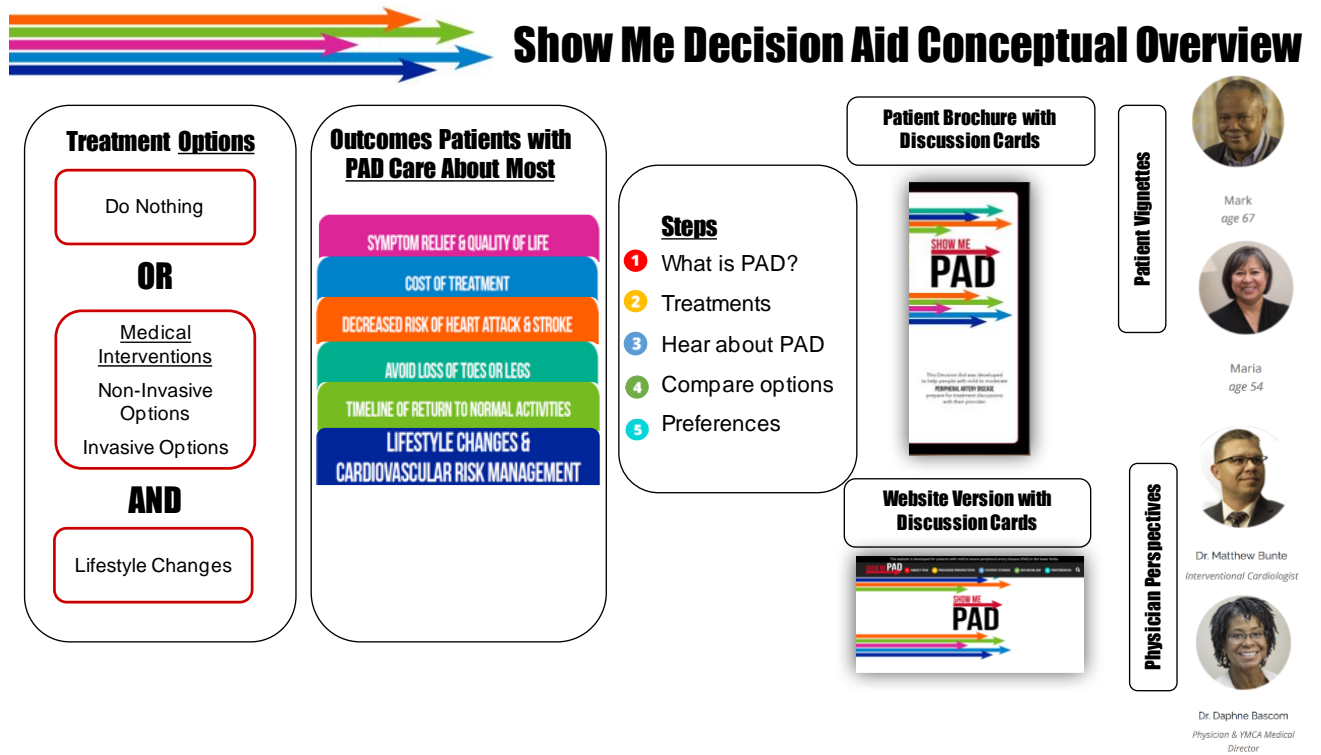


Figure 2 – Conceptual Overview of SHOW-ME PAD© Decision Aid



**Figure 3 – Describing Potential Use of SHOW-ME PAD© Decision Aid in Clinical Setting**

