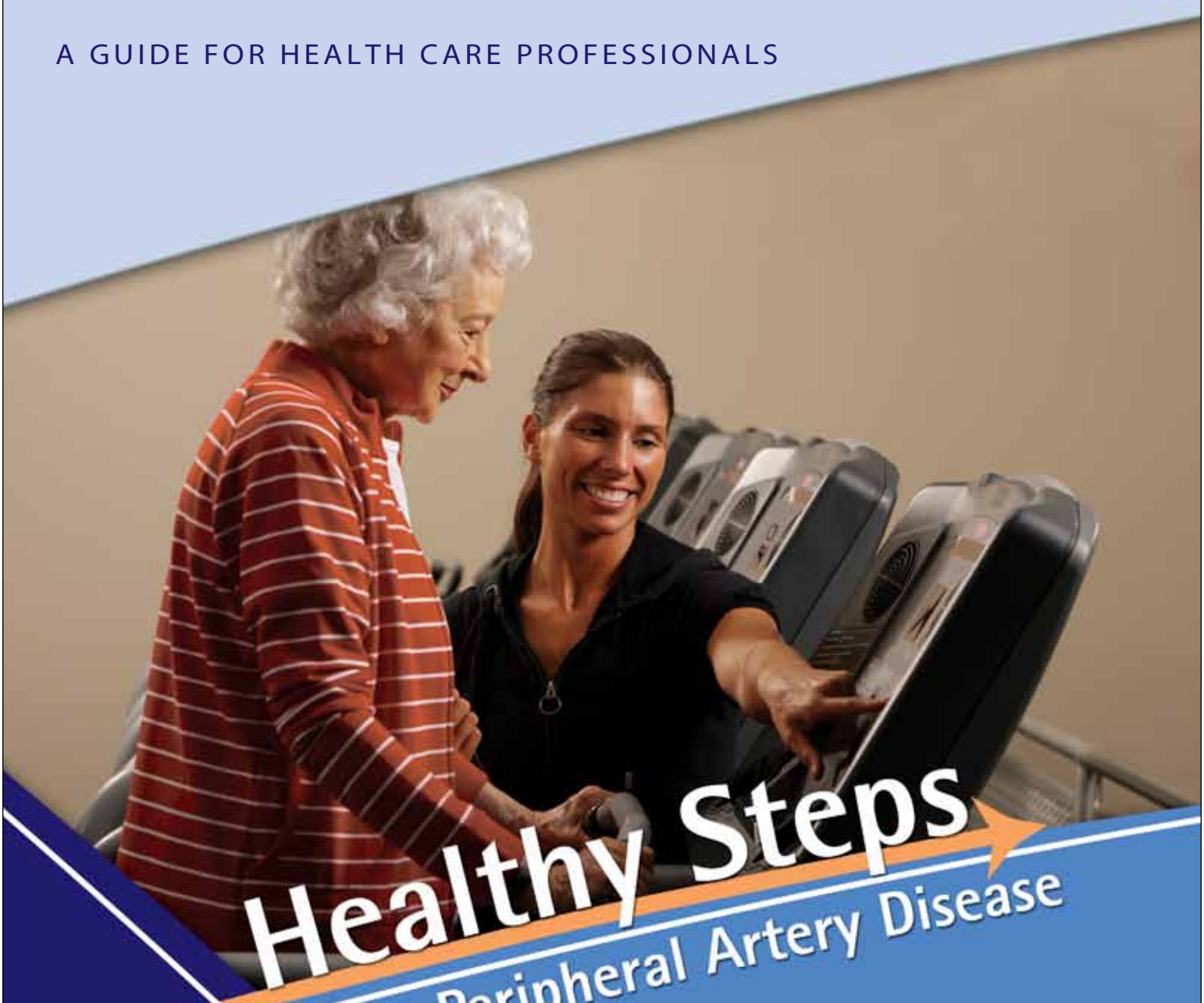
PAD EXERCISE TRAINING TOOLKIT

A GUIDE FOR HEALTH CARE PROFESSIONALS



Healthy Steps for Peripheral Artery Disease

AACVPR
American Association of Cardiovascular and Pulmonary Rehabilitation
Promoting Health & Preventing Disease

VASCULAR CURES

PAD EXERCISE TRAINING TOOLKIT

A GUIDE FOR HEALTH CARE PROFESSIONALS

This toolkit was developed jointly by the Vascular Disease Foundation (VDF) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR).

Please note that this toolkit is intended to be an online resource.

PAD EXERCISE TRAINING TOOLKIT

A GUIDE FOR HEALTH CARE PROFESSIONALS

This toolkit was developed to allow cardiac rehabilitation and other exercise and rehabilitation health care professionals to work within their communities to improve access to supervised exercise programs for people with intermittent claudication resulting from peripheral artery disease (PAD). Clinical practice guidelines and performance measures for adults with PAD stress the importance of supervised exercise to improve functional capacity, decrease symptoms and achieve systemic risk-reduction benefits. The toolkit includes information for exercise and rehabilitation professionals to implement appropriate and safe supervised exercise programs. It also includes practical tools such as sample brochures plus participant and staff education materials. This toolkit was developed jointly by the Vascular Disease Foundation (VDF) and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR).

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RATIONALE FOR EXERCISE TRAINING IN PEOPLE WITH PAD

PAD is the result of systemic atherosclerosis. The underlying disease process that affects the blood vessels is common to patients with coronary artery disease (CAD), stroke and diabetes mellitus. For example, many people undergoing coronary angiography have previously unrecognized PAD. Health care professionals working in rehabilitation or medical fitness programs need to understand the common coexistence of CAD, cerebrovascular disease and PAD, how exercise therapy can benefit program participants with PAD, and how they can develop exercise programs specifically designed for those with PAD, incorporating strategies for modifying the exercise prescription in the presence of existing co-morbidities such as CAD.

The most comprehensive clinical practice guidelines about PAD were published in 2006 by a writing group representing multiple organizations, the ACC/AHA Practice Guidelines for Management of Patients with PAD: Click to download the ACC/AHA guidelines document.

The accompanying set of slides for these guidelines is very helpful to understand incidence, pathophysiology, differential diagnosis and treatment of PAD. Click to download the slide set.

This toolkit directs readers to specific pages of the practice guidelines for more detailed information, when appropriate. Both the guidelines and slides are available to the public on the ACC websites in the links listed above.

ABOUT THE PAD PATIENT

Some of those utilizing this toolkit may not be familiar with the clinical characteristics of the common PAD patient. Here is some basic information to help you better understand the patient population effected by PAD.

The chance of having PAD increases as you get older. People over age 50 have a higher risk for PAD and the majority of patients will fall in this demographic. One in 20 adults over age 50 and one in five over age 70 will have PAD. A person's risk increases with these factors:

- Current or previous tobacco use
- Diabetes
- High blood pressure
- Abnormal blood cholesterol levels
- African American ethnicity
- Heart disease, heart attack or stroke

DIFFERENTIAL DIAGNOSIS

People with PAD may be asymptomatic or complain of exertional leg discomfort. Some present with the classic symptom of intermittent claudication (IC). This is activity-induced pain, aching or cramps in the calves, thighs or buttocks, which typically occurs during walking and resolves after a few minutes of rest or 5-10 minutes. Others present with atypical claudication-like symptoms which are exertional but do not consistently resolve with rest. More severe forms of PAD, such as critical limb ischemia, produce symptoms which include ischemic rest pain, non-healing wounds or gangrene and commonly require surgical or percutaneous intervention.

The symptoms of claudication from PAD can be confused with symptoms from other diseases of the lower extremities, including osteoarthritis, neuropathy, sciatica, myopathy and spinal stenosis. Useful signs and symptoms to differentiate these diseases are included in the ACC/AHA Practice Guidelines for the Management of Patients with PAD.
View the guidelines by clicking here.

Before recommending an exercise program for PAD, it is important to confirm that the exertional leg pain experienced by the participant is caused by arterial insufficiency (i.e., IC) and is not a symptom caused by another co-morbid condition such as those listed in Table 4 in the link above. IC generally improves with the exercise program described in this toolkit, whereas symptoms resulting from other conditions will not. Lower extremity PAD can be readily diagnosed using the ankle brachial index (ABI), which is a ratio of systolic blood pressure measured in the ankle and brachial arteries.

Interpreting the ABI:

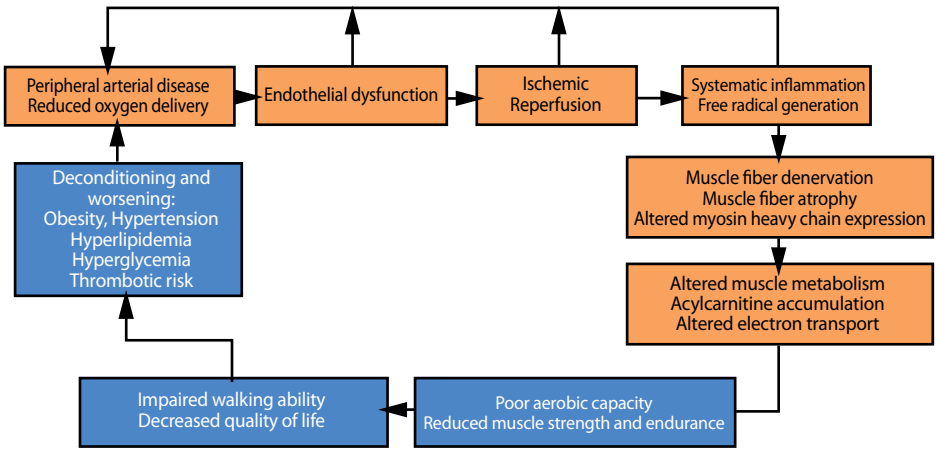
Noncompressible	>1.4
Normal ABI	1.00 – 1.30
Borderline (equivocal)	0.91 – 0.99
Mild to Moderate Impairment	0.41 – 0.90
Severe Impairment (Symptoms may occur at rest)	< 0.40

Physicians often evaluate specific peripheral artery anatomy with other tests such as ultrasonography, computed tomographic angiography (CTA), magnetic resonance angiography (MRA), or conventional angiography. Post-exercise ABIs, measured immediately after walking on the treadmill, can also be used to confirm the diagnosis. These methods are summarized in the ACC/AHA Practice Guidelines for the Management Management of Patients with PAD.
View the guidelines by clicking here.

PATHOPHYSIOLOGY AND EVIDENCED-BASED GUIDELINES

Whether they have leg symptoms or not, people with PAD and IC have significant functional impairment with regard to ambulatory activity. In contrast to angina resulting from CAD where cessation of exercise is recommended when pain occurs, with PAD it is recommended that participants exercise to the point of mild to moderate though not severe leg discomfort. This may be counter-intuitive because exercising to the point of myocardial ischemic pain before stopping is not safe for patients with heart disease, given the risk of ischemic-induced arrhythmias. However, there are benefits to exercising into mild to moderate claudication pain with little risk to the leg or cardiovascular system. In fact, exercising to the point of discomfort from IC may be an important aspect of an exercise training protocol for participants with IC, as it may contribute to the physiological adaptive changes needed for training effect. Unfortunately, the average person with PAD who feels pain when walking may cut back on activities that cause discomfort, resulting in further deconditioning, worsening cardiovascular (CV) risk factors, loss of leg strength and eventually disability.

THE CYCLE OF DISABILITY IN INTERMITTENT CLAUDICATION



Prospective studies and meta-analyses have consistently shown that supervised exercise training for participants with IC increases their walking distances, quality of life and overall functional capacity. The functional benefits of exercise training become obvious at four to eight weeks and continue to improve over 12 to 24 (or more) weeks.

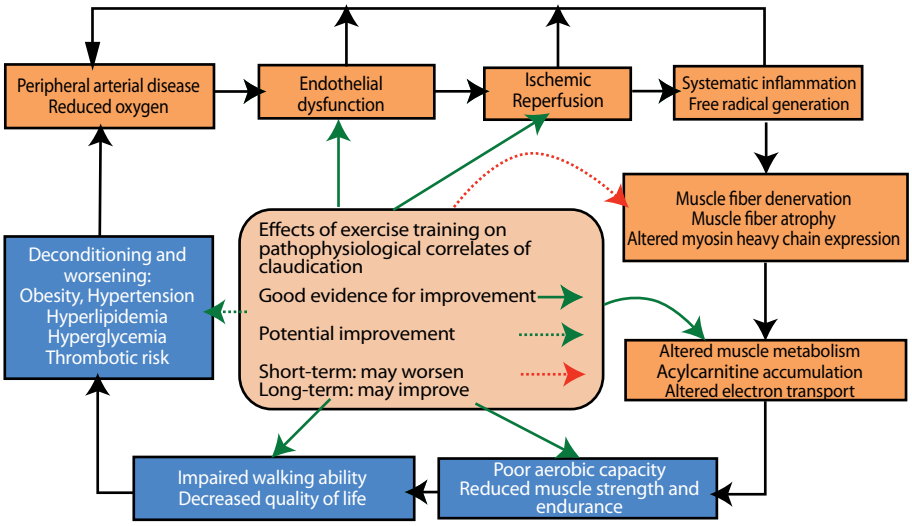
Functional benefits are greatest when

- the exercise sessions last 30 minutes or longer
- the sessions take place at least three times per week
- the exercise modality used is walking to near-maximal pain
- the program lasts six months or longer

MECHANISMS FOR EXERCISE-INDUCED IMPROVEMENTS

The mechanisms leading to exercise-induced improvements are not completely known, but may include changes in the way that oxygen is used by exercising the muscle, improved endothelial function, reduced cardiovascular disease risk factors and improved gait as well as increased blood supply. Current proposed mechanisms related to the effects of regular exercise in people with PAD and IC that disrupt the cycle of disability are included in the table below:

MECHANISMS BY WHICH EXERCISE MAY IMPROVE FUNCTION AND SYMPTOMS IN CLAUDICATION



GUIDELINES AND RECOMMENDATIONS

A program of supervised exercise rehabilitation is considered a primary treatment for people with PAD and IC. The most recent ACC/AHA clinical practice guideline for treatment of PAD rated exercise therapy for IC as a Class I, level of evidence A, recommendation, which compares very favorably to similar or lower levels of recommendation for medications or some revascularization procedures. This is the highest recommendation that is given to a treatment. Evidence about the benefits of exercise training for patients with IC is found in that document.
View the document by clicking here.

Based on the strength of evidence, supervised exercise training is included in the 2010 ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS Clinical Performance Measures for Adults with Peripheral Artery Disease.

Performance measures are designed to encourage health care professionals and facilities to develop systems and adopt practices that improve patient outcomes. Because supervised exercise improves outcomes for participants with IC and because supervised exercise is underutilized, this measure requires that physicians caring for patients with PAD discuss the option of exercise training and encourage referral to a supervised program. This measure was designed to assure that the role of supervised exercise in symptom management is not overlooked during discussions about management of IC, so that patients receive adequate information for informed decision-making about treatment of their symptoms and disease.

To view the ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 Performance Measures for Adults With Peripheral Artery Disease, click here.

MEDICAL CLEARANCE FOR EXERCISE

People with PAD often have co-existing CAD, in addition to other co-morbidities. However, CAD is often difficult to diagnose because the patient may have limited his or her activity because of IC, and CAD may not be revealed. For example, the patient may not report CAD symptoms during his or her routine activities, or an exercise stress test may not reveal exercise-induced angina or an abnormal ECG response because exercise capacity is limited by claudication rather than myocardial ischemia. Though it is important for participants to be evaluated by their health care provider prior to beginning an exercise program for PAD, it is not uncommon for CAD symptoms to appear as patients improve their walking capacity during their PAD exercise program. Health care providers should treat these patients aggressively for vascular risk factors, including hypertension, diabetes, hyperlipidemia and tobacco use since PAD is a marker for systemic atherosclerosis. After the initial diagnosis of PAD in those without known CAD, the risk of having CAD morbidity or mortality in the next five years is about 50 percent, which highlights the need for surveillance for new onset of cardiac symptoms during exercise and the need to include education and counseling about vascular risk factors, when appropriate, during exercise programs for participants with PAD.

Initial strategies for exercise professionals to use to evaluate participants during exercise training include careful review of vital signs and questioning for symptoms prior to, during, and after exercise, particularly for those with significant limiting IC.

Although exercise training is safe and effective for most patients with PAD and IC, there are some conditions in which exercise is medically contraindicated:

- Unstable angina
- Decompensated heart failure
- Uncontrolled cardiac arrhythmias
- Severe or symptomatic valvular heart disease
- Critical limb ischemia

Other conditions that could be aggravated by exercise include, but are not limited to, severe joint disease, uncontrolled diabetes and uncontrolled hypertension.

PRE-EXERCISE EVALUATION OF FUNCTIONAL CARDIOVASCULAR RESPONSE

It is important for the exercise professional to perform a functional evaluation including an exercise treadmill when possible prior to the patient's beginning an exercise program. This provides information regarding the claudication threshold, as well as heart rate and blood pressure response, for the exercise prescription. It can also be a useful screening tool for previously unrecognized exercise-induced symptoms and signs such as arrhythmias or ischemic ST-T wave changes. However, the usefulness of exercise testing to detect abnormal cardiac responses may be limited by leg pain before reaching a heart rate or blood pressure at which abnormal cardiac responses may occur. Paradoxically, after a PAD patient goes through exercise training, cardiac symptoms may be uncovered since patients often have improved walking capacity. Many centers use a treadmill exercise testing protocol at an initial fixed speed of 2.0 mph, gradually increasing the grade by either 2 or 3.5 percent every 2 to 3 minutes, depending on the patient's estimated exercise capacity. Other programs observe the patient during initial treadmill exercise at 2 mph and 0 percent incline for claudication threshold and severity, adjusting the incline until moderate (3-4 out of 5 on the claudication scale) claudication occurs, and then this observation is used to set initial exercise prescription.

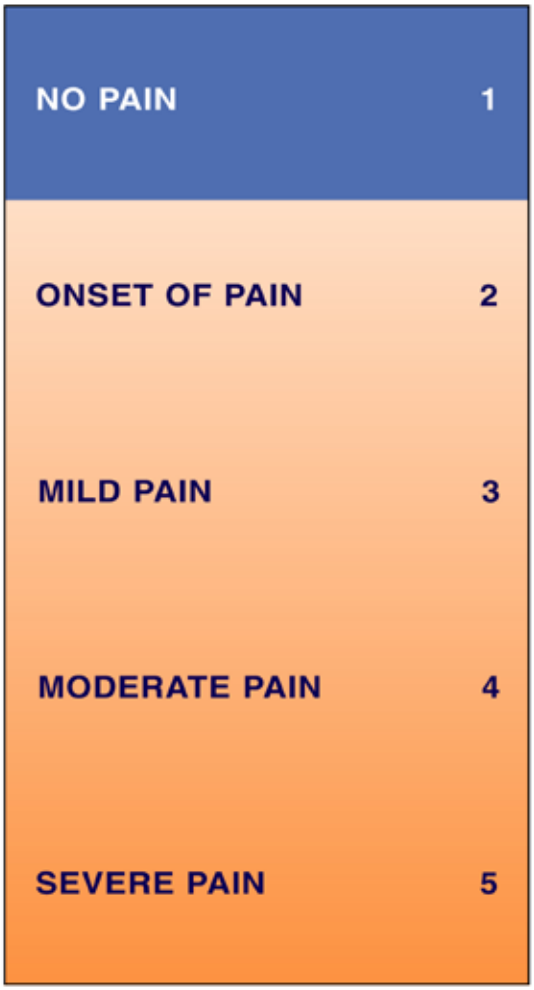
The time at which the patient first begins to feel claudication symptoms is defined as the initial claudication time (also called pain-free walking time) and the time at which he/she must stop exercise is designated as maximal walking duration. The work load which brings on claudication is considered the initial training work load. The claudication pain scale often used in clinical trials is as follows: 1= no pain, 2=onset of claudication pain, 3=mild pain, 4=moderate pain, and 5= severe pain.

Patients should also be monitored for cardiovascular symptoms, blood pressure and heart rhythm during this exercise evaluation; unexpected findings should be reported to their physician. The 6-minute walk test can also be used for baseline functional assessment, but it is less useful than treadmill testing for exercise prescription.

Finally, the pre-exercise assessment includes a careful evaluation of the lower extremity skin and feet, along with instruction regarding proper shoes to avoid skin irritation and breakdown. Patients with PAD are at significantly increased risk for non-healing skin ulcers, and careful foot and skin reassessment is extremely important, especially for those with diabetes and/or neuropathy.
Click here to download shoe/foot care information.

Those who use an assistive device for ambulation, have had a stroke or have evidence for peripheral neuropathy may benefit from referral to a physical therapist for additional evaluation and treatment.

THE CLAUDICATION PAIN SCALE



DESIGN OF THE PAD EXERCISE TRAINING PROGRAM

The supervised exercise program for patients with PAD and IC described here is based on current clinical practice guidelines.

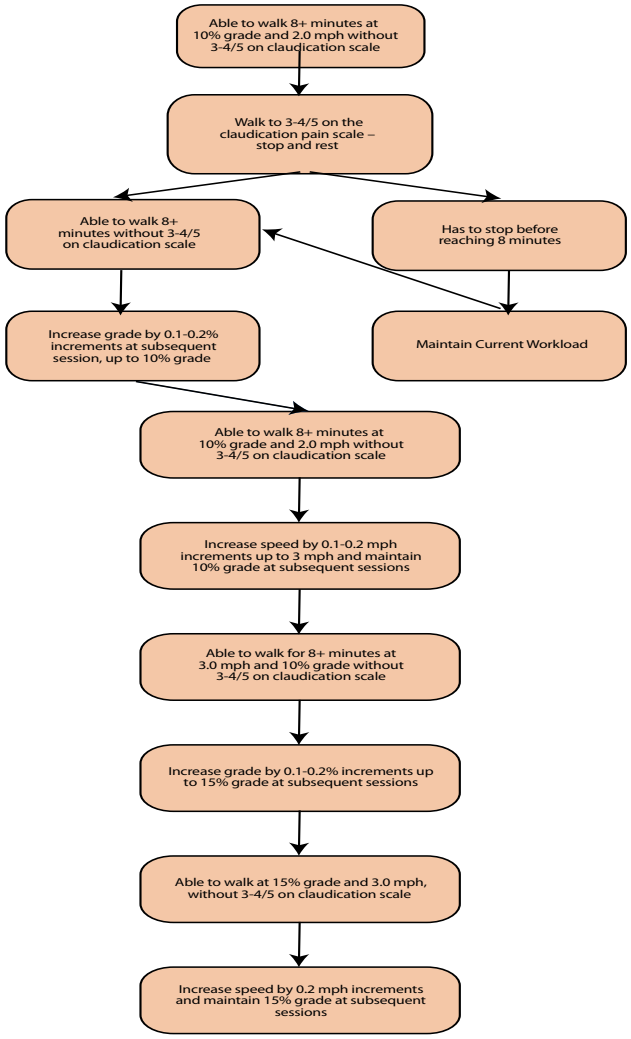
Supervised exercise is performed three times per week, generally in a cardiovascular rehabilitation or wellness program setting, usually for 12 to 24 weeks, for 1-hour per session. The 60-minute exercise session includes a 5-minute warm-up and 5-minute cool-down period.

EXERCISE PRESCRIPTION FOR TREADMILL WALKING

The initial exercise training intensity is established using a graded treadmill test or a functional evaluation during the initial exercise session, and is defined as the grade (% inclination) that brings on the onset of claudication pain (i.e., level 2 of 5 on the claudication scale), with the initial speed set at 2.0 mph. Some patients may not be able to tolerate a treadmill speed of 2 mph and may need to start the exercise program at a slower speed and progress as tolerated. Participants are asked to walk to a mild to moderate pain level (3-4 of 5 on the claudication scale), stop and sit down and rest until the claudication pain has completely abated, and then resume walking. The initial goal of the early training sessions is to have the participants accumulate 15 minutes or more of total treadmill time, excluding warm-up and cool-down, with the eventual goal to progress the participant to a cumulative exercise session of 50 minutes (including rest periods) as well as warm-up and cool-down periods of 5 minutes each for a total of 60 minutes per session.

Progression of the exercise training intensity should not occur during the current session, but should be initiated at the beginning of the next session. Thus, participants walk at a constant work-rate throughout each session without change. It should be noted that use of the claudication pain scale is an important tool for monitoring symptomatic improvements in exercise performance and resulting increases in exercise intensity.

If the patient is able to walk at a workload for 8 minutes or more before experiencing moderate claudication pain (3-4/5), then the grade is increased by a one-to two-percent increment for the following training session. Once a patient is able to walk at a 10.0 percent grade for 8 minutes or more, the speed is increased by 0.1 to 0.2 mph increments at the following session and may increase to 3.0 mph. If a patient is able to walk for 8 minutes or more at 3.0 mph / 10 percent grade, the grade is once more increased by 1 to 2 percent increments the following training session up to 15 grade percent (i.e., last increase is 1 percent increment). This is followed by increases in speed by 0.1 to 0.2 mph increments for the following training session as tolerated. See graphic below:



DESIGN OF THE PAD EXERCISE TRAINING PROGRAM (CONTINUED)

OTHER FORMS OF EXERCISE TRAINING

Treadmill walking is the cornerstone of an exercise program for people with IC, because the majority of the available evidence indicates that this form of exercise induces the physiological changes needed to decrease exercise-induced symptoms. The weight of this evidence has led to the current recommendations for PAD exercise therapy. There is a small emerging body of evidence to suggest that other modalities of aerobic training may also be beneficial in improving symptoms. These include pole striding (Langbein et al, 2002), pain-free treadmill walking (Mika et. al, 2005), and aerobic arm exercise (Walker et al 2002; Zwierska et al, 2005; Treat-Jacobson, Bronas, and Leon, 2009). However, these studies are relatively small pilot studies and need replication with larger samples to warrant changes in PAD exercise therapy guidelines. Additionally, resistance training has not been shown to reduce IC symptoms, but it has been shown to enhance metabolism, reduce cardiac risk factors, improve bone health and favorably alter body composition, among other benefits. Thus, resistance training can be done in addition to but not as a substitute for walking.

EDUCATION AND COUNSELING ABOUT VASCULAR RISK FACTORS

Risk factors for PAD are the same as those for CAD, so it is appropriate to invite these participants to attend support and education classes about tobacco cessation, medications, nutrition and stress reduction, when available.

PRECAUTIONS FOR PARTICIPANTS WITH DIABETES OR NEUROPATHY

When diabetes is present, there is often neuropathy, which results in painful burning, tingling, numbness and foot ulcers. Self-examination of the feet is important before and after exercise. Shock-absorbing shoes with ample room for the distal foot should be used. Pre-exercise finger-stick glucose should be checked and the individual should be monitored during exercise for signs of hypoglycemia. The exercise area should have glucose tablets/gels available to administer to participants during exercise when needed.

MAINTENANCE EXERCISE PROGRAMS

People with PAD and IC must continue regular walking exercise in order to maintain the benefits gained during supervised exercise. Some may prefer to exercise at home, but many may continue with exercise in a medical facility-based wellness program. There are no specific guidelines for transitioning to a home-based program. This will largely depend on the participant's progress, motivation and convenience. If the participant is sufficiently motivated to continue on his or her own and is no longer able or willing to attend the supervised program, then specific instructions should be provided to assure further progress or maintenance for the home-based program. Whether the participant opts to continue in a supervised program or continue at home, it is important that he or she make regular exercise a lifelong practice.

INTERVENTIONAL TREATMENT FOR PAD

Health care professionals working with people with PAD need to be aware of the indications for percutaneous and surgical intervention, rehabilitation and exercise implications of these procedures, and post-operative medical and nursing considerations. In addition, they must be able to recognize the signs and symptoms of critical and acute limb ischemia, which are contraindications to continued exercise therapy and require prompt medical attention and intervention. Further information about these conditions is found in the ACC/AHA Practice Guidelines for the Management of Patients with PAD.
View the document by clicking here.

An interventional procedure is recommended to treat signs and symptoms of ischemic rest pain (pain in the ball of the foot, toes or heel when the foot is elevated, requiring dependency for relief) or tissue loss and for those with vocational limiting claudication who have failed exercise and/or pharmacological therapy, such as cilastozol. There should be a reasonable likelihood of improvement when considering a procedure and all co-morbidities should be carefully evaluated before performing a procedure. The choice of a procedure is based upon the location and length of the atherosclerotic lesion.

Compression garments may be used with caution to control post-procedural edema. An ABI should be checked and compression should be used only if the ABI is at least 0.80. Ace wraps may be needed initially to avoid irritating the staples/sutures. The patient can be fitted for knee- or thigh- high compression as needed, and should receive instruction on the application and care of the garment. The garment should be applied first thing in the morning and removed at bedtime. The client should be cautioned to remove the garment at any time that it becomes uncomfortable or appears to be binding the extremity.

INTERVENTION	POST-PROCEDURE	EXERCISE CONSIDERATIONS
FOR FLOW LIMITING LESIONS IN THE COMMON AND EXTERNAL ILIAC ARTERIES		
• Angioplasty alone or with stent placement for suboptimal results after balloon angioplasty • Mechanical atherectomy	• Claudication is generally improved immediately • Excellent wound care for pre-existing foot wounds • Bruising can occur and may take several weeks to resolve • Return of symptoms generally indicates there is decreased flow though the repaired blood vessel • Follow-up surveillance with duplex scan and ABIs • Cessation of all nicotine products • Antiplatelet therapy with aspirin and/or clopidigrel is indicated • Avoid soaking feet and use moisturizers	• Exercise can be resumed in 72 hours and should be encouraged most days of the week • If a stent is in place, avoid extended periods of squatting that flexes the stent • For patients with a plantar foot wound, utilize non-weight bearing exercise • If symptoms return (possible restenosis), the patient should be referred to the vascular provider in an expedient manner • Excellent foot care

INTERVENTION	POST-PROCEDURE	EXERCISE CONSIDERATIONS
FOR LESIONS IN THE SUPERFICIAL FEMORAL POPLITEAL AREA		
• Percutaneous transluminal angioplasty • Stent placement when angioplasty did not produce the desired results Stent grafts are available; however, the long-term patency has not been established	• Symptoms of claudication generally improved immediately • Excellent wound care for pre-existing foot wounds • Bruising can occur and may take several weeks to resolve • Return of symptoms generally indicates that there is restenosis • Periodic surveillance with duplex and ABIs • Cessation of all nicotine products • Antiplatelet therapy with aspirin and/or clopidigrel is indicated • Avoid soaking feet • Liberal use of moisturizers	• Exercise can be resumed in 72 hours and should be encouraged most days of the week • If a stent is in place, avoid extended periods of squatting that flexes the stent • For patients with a plantar foot wound, utilize non-weight bearing exercise • If symptoms return (possible restenosis), the patient should be referred to the vascular provider in an expedient manner • Excellent foot care
AORTOBIFEMORAL BYPASS • Excellent long-term patency • Major surgery with risks: myocardial infarction, stroke, renal insufficiency, colon ischemia, distal embolism and impotence **ILEOFEMORAL BYPASS** • Disease confined to the external iliac artery • Provides inflow when the aorta is not involved • Lower risk than abdominal surgery **FEMORAL BYPASS** • For disease confined to one iliac artery	• Symptoms should completely resolve • Monitor nutritional status as appetite may be poor • Monitor for constipation, esp. if abdominal procedure • Excellent foot care • Periodic surveillance with ABIs • Duplex imaging if suspicion of graft stenosis • Leakage of clear fluid from groin incision likely lymph leak. Bed rest required • Cessation of all nicotine products • Antiplatelet therapy	• Out of bed the first day after surgery • Encourage walking • Resume regular exercise when wounds are healed • Limit lifting to not more than 10-20 pounds for 6 weeks after an abdominal procedure

INTERVENTION	POST-PROCEDURE	EXERCISE CONSIDERATIONS
AXILLOFEMORAL BYPASS GRAFT		
• Aortoiliac disease • Patients considered too high-risk for a major abdominal procedure	• Generally reserved for critical limb ischemia and not recommended for claudication • Patient may think there is a problem when able to feel the graft • Cessation of all nicotine products • Long- term anticoagulation often required • Periodic surveillance with ABIs • Monitor for wound drainage	• Should be out of bed the first day after surgery • Exercise can be resumed when the wounds are healed • Avoid tight belts or clothing that might constrict the graft
FEMORAL POPLITEAL OCCLUSIVE DISEASE		
• Femoral popliteal bypass with vein • Femoral popliteal bypass with PTFE (artificial material) • Heparin-coated PTFE graft provides better patency (Propaten®) • Superficial femoral endarterectomy	• May be used for patient with critical limb ischemia or for patients who have failed exercise • Staples generally remain in place 2-4 weeks • Leg will swell due to increased venous return • May need long-term anticoagulation • May shower after 48 hours • Cessation of all nicotine products • Better long- term results with vein bypasses • Risk factor management • Antiplatelet therapy • Requires graft surveillance for at least two years with duplex and ABIs	• Exercise can be resumed when wounds have healed • May be out of bed walking on the first day after surgery • Encourage leg elevation when sitting to reduce swelling • Assess for foot wounds • If there is a foot wound present, it is important to provide footwear that avoids pressure on the wound • Assure that wound management is continued • Compression garments can be used if the ABI is > 0.8 or greater

OUTCOMES EVALUATION

Continuous quality improvement requires collection and analysis of outcomes measures. *Are we helping our participants with PAD and IC achieve improved ambulation and better quality of life and are we doing it in a cost effective manner?* Tools to measure physical and functional outcomes are detailed below and have been validated and used in research settings. These tools can also be used by clinicians to track either individual patient or composite program outcomes.

TREADMILL EXERCISE TESTING

Treadmill exercise testing is an accepted method of evaluating walking capability in patients with claudication. Performing treadmill tests before and after an intervention can provide an objective assessment of change in this important measure. There are several protocols commonly used to document outcomes in research and clinical care, but each has some common elements.

- The test is performed on a motorized treadmill
- The patient is asked about claudication symptoms at regular intervals (i.e., every 30 seconds)
- The claudication onset time (the time when the first claudication symptoms begin) and maximum walking time (the time when the patient can go no farther and needs to stop) are documented
- Cardiopulmonary exercise testing to measure oxygen consumption may also be used to determine if there is a pulmonary or deconditioning limitation to exercise, or for a more accurate measure of cardiopulmonary function, but is not required for exercise prescription
- With each protocol, the participant continues walking until he or she cannot walk any longer

1. STANDARDIZED GRADED PROTOCOLS INCLUDE

a. Gardner-Skinner Protocol (Gardner et al, 1991)
   i. Treadmill speed is held constant at 2 mph
   ii. Treadmill grade begins at 0 percent and increases 2 percent every 2 minutes

b. Hiatt Protocol (Hiatt et al, 1990)
   i. Treadmill speed held constant at 2 mph
   ii. Treadmill grade begins at 0 percent and increases by 3.5 percent every 3 minutes

c. Bronas/Treat-Jacobson Protocol (Treat-Jacobson et al, 2009)
   i. Treadmill speed begins at 2 mph
   ii. Treadmill grade begins at 0 percent and increases by 3.5 percent every 3 minutes through 10.5 percent grade (12 minutes, stage 4)
   iii. Beginning with stage 5, the treadmill grade is kept constant at 10.5 percent and the speed increases by .5 mph every 3 minutes

2. STANDARDIZED FIXED SPEED/INCLINATION PROTOCOLS

a. Treadmill is set at a fixed grade (10-12 percent)
b. Treadmill speed is set at 2 mph or 3 km/hr

Choice of treadmill protocol is based on practitioner preference, as well as on an estimate of the participant's exercise tolerance.

OTHER STANDARDIZED WALKING TESTS

1. **Six-minute walk test** (Guyatt et al, 1985; Montgomery and Gardner, 1998)
    a. Participants are asked to walk up and down a 100-foot hallway for six minutes. They are instructed to cover as much distance as possible using normal walking speed.
    b. Distance walked is recorded.
    c. Distance can be adjusted to accommodate facility but must be standardized for all tests between and within patients.

2. **Shuttle Walk Test (Singh et al, 1992; Zwierska et al, 2004)**
    a. Participants walk back and forth between two cones placed ten meters apart on a flat floor.
    b. Walking speed is controlled by beeps recorded onto an audiotape.
    c. Participants begin walking upon hearing the first beep and aim to reach the opposite cone by the next beep.
    d. If a participant arrives before the beep, he/she is required to wait for the beep before walking back.
    e. Participants arriving after the beep are given verbal instructions to increase their walking speed in order to reach the opposite cone before the next beep.
    f. Participants usually achieve the correct pacing after two-three repetitions.
    g. The initial walking speed is three km/hour.
    h. At the end of each minute, the time interval between audible bleeps is decreased, resulting in a step-increase in walking speed of 0.5 km/hour.
    i. When the participant is unable to maintain the speed needed, the test ends and the time/distance is recorded.

OTHER STANDARDIZED PHYSICAL FUNCTION MEASURES

Short Physical Performance Battery (Guralnik et al, 1994). Includes:

1. **Four-meter walking velocity**
    a. Participants are asked to walk at their usual pace over a four-meter distance.
    b. Participants are instructed to stand with both feet touching the starting line and to start walking after a verbal command.
    c. Timing begins when the command is given, and the time in seconds needed to complete the entire distance is recorded.
    d. The test can be repeated twice and the best time is used to calculate walking speed in cm/sec.

2. **Repeated Chair Rise**
    a. This is performed using a straight-backed chair placed with its back against a wall.
    b. Participants are first asked to stand from a sitting position without using their arms.
    c. If they are able to perform the task, they are then asked to stand up and sit down five times, as quickly as possible.
    d. The time to complete the task will be recorded in seconds.
    e. This test can be repeated twice and the best time used.

3. **Standing Balance**
    a. Participants are asked to maintain balance in three positions:
        i. feet together (side- by- side position)
        ii. the heel of one foot beside the big toe of the other foot (semi- tandem position)
        iii. the heel of one foot in front of and touching the toes of the other foot (tandem position)
    b. For each of the three positions, participants are timed to a maximum of ten seconds.

QUESTIONNAIRES

Standardized, validated questionnaires can be used to measure functional capacity and quality of life. Many of these are copyright-protected, requiring permission before use.

Global Outcomes Questionnaires

1. SF-36 (especially the physical function and vitality sub-scales)
   copyrighted, permission required prior to use
2. Sickness Impact Profile (SIP)
3. Functional Status Questionnaire

Disease-Specific Questionnaires

1. Walking Impairment Questionnaire (WIQ):
   Developed by Regensteiner JG, Hiatt WR.
   Copyrighted, permission required prior to use
   Title: Regensteiner JG, Steiner JF, Hiatt WR. Exercise training improves functional status in patients with peripheral arterial disease.
   Citation: J Vasc Surg1996:23;104-115

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2. Peripheral Artery Questionnaire (PAQ):
   Developed by Spertus J, Jones P, Poler S, and Rocha-Singh K
   Title: The peripheral artery questionnaire: a new disease-specific health status measure for patients with peripheral arterial disease
   Citation: Am Heart J 2004 Feb;147(2):301-8)

3. Vascular Quality of Life Questionnaire (VascuQol)
   Developed by Morgan MB, Crayford T, Murrin B, and Fraser SC
   Title: Developing the Vascular Quality of Life Questionnaire: a new disease-specific quality of life measure for use in lower limb ischemia.
   Citation: J Vasc Surg 2001 Apr; 33(4):679-87.

4. Low Level Physical Activity Recall Questionnaire, copyrighted, permission required prior to use
   Developed by Regensteiner JG.
   Title: Regensteiner JG, Steiner JF, Hiatt WR. Exercise training improves functional status in patients with peripheral arterial disease.
   Citation: J Vasc Surg 1996:23;104-115

Finally, tracking program delivery outcomes such as attendance, demographics and referral sources can help managers and clinicians adopt marketing strategies to reach under served patients.

ADMINISTRATIVE CONSIDERATIONS FOR DEVELOPING A PAD EXERCISE TRAINING PROGRAM

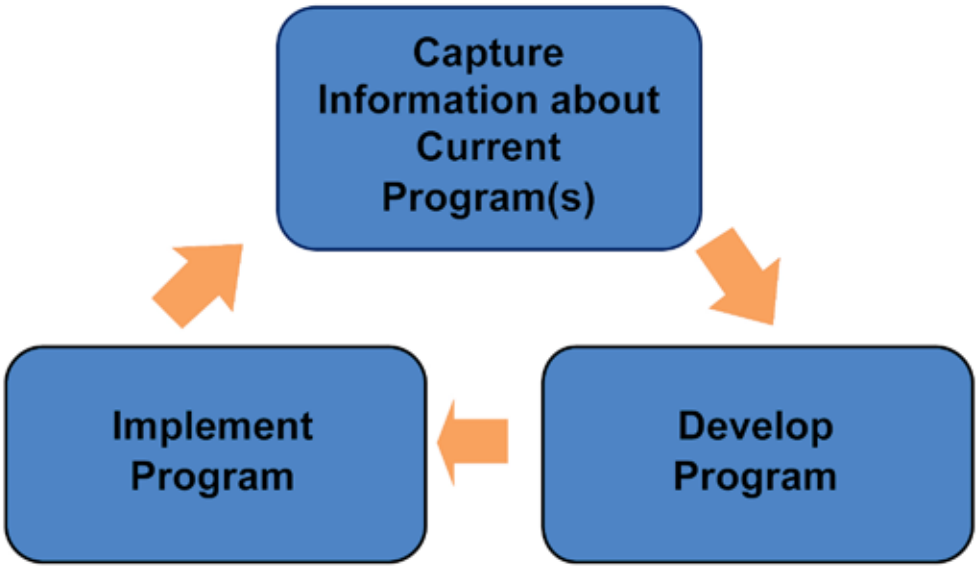
Development and implementation of a PAD rehabilitation program can be complex. However, by undergoing a diligent assessment of existing resources and staff, a PAD rehabilitation program can be fully implemented into existing cardiac rehabilitation programs. Launching a PAD rehabilitation program may take up to six months of planning in order to ensure appropriate allocation of resources and infrastructure.

One simple way to start a program would be to start including participants with PAD in the phase three (maintenance or wellness) classes of an existing cardiac rehabilitation program. As referrals and participation grow, a separate program for PAD participants could then be opened at a different time slot.

Implementing a PAD rehabilitation program involves three main areas of consideration. They include:

- Assessment of current programs
- Program development
- Program implementation

Understanding these three areas will provide a thorough examination of existing and incremental resources and can be the business plan for administrative/institutional support. The graphic below outlines a continuous process that should be utilized even after implementation.



ASSESSMENT OF CURRENT PROGRAMS

The first step in deciding to implement a new program is to identify and understand the operations of existing programs and services, including traditional and nontraditional rehabilitation as well as lifestyle modification programs. This provides an opportunity to maximize the use of existing resources before requesting potentially limited new or additional resources. Answering the questions listed below can facilitate this assessment process.

What is the existing strategy/plan?	• Ensure that implementing a PAD rehabilitation program will be in keeping with the existing strategies of the unit and institution.
Who are the current stakeholders?	• Identify internal stakeholders (referring physicians, rehabilitation staff, clinical staff, administration, etc.) and external stakeholders (referring physicians, patients, community, etc.) to understand the needs and level of support for a PAD rehabilitation program.
What are the larger long-term trends?	• Recognize evolving trends in the industry, institution and economy related to this specialized program and understand how to adapt to those trends.
What current processes are in place?	• Identify synergies and/or gaps which would need to be addressed when implementing the program.
What current resources are available to the program?	• Identify other multidisciplinary resources and educational materials within existing programs which could be utilized in the development of a PAD exercise training program. Click here to download educational materials.
What physical and human resource limits currently exist in developing the program?	• Recognize limits and develop strategies for facilitating program development relative to these areas.

PROGRAM DEVELOPMENT

Once an opportunity has been identified and the impact on the existing programs has been assessed, the next phase is to develop the program. Developing a PAD program entails an in-depth review of relevant clinical guidelines, a financial assessment and the first steps in allocating additional or existing resources.

Clinical Program Development

A clinical management team should be developed to outline the clinical protocols and policies and reach a consensus on the treatment guidelines that will be implemented in the program. The team should consist of:

- Physician (Medical Director)
- Program manager
- Two or three of the front-line clinical staff (designate one of them as the program leader)
- Multidisciplinary staff (social worker, dietician, physical therapist, etc.)

As with any new program developed in a health care setting, it is vital to review and understand the evidence-based guidelines that are relevant to this patient population. The clinical management team should review the evidence-based guidelines before developing the treatment protocols. These protocols should include treatment strategies that are within the scope and skill set of the staff.

KEY PUBLICATIONS

- TASC II – Inter-Society Consensus for the Management of Peripheral Arterial Disease
- ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease

Other important considerations when developing the clinical aspect of a PAD exercise training program are:

- Logistical policies and procedures (participant flow through the system)
- Frequency and duration of program
- Equipment needed
- Emergency/safety procedures
- Infection control
- Referral to other health care professionals

Financial Program Development

The information needed to assess and analyze the financial implications of developing a new PAD rehabilitation program will require the input and assistance from an administrative manager and perhaps a financial analyst. The analyses are not complex; however, there may be some institutional costs that are tied to program revenue of which clinical staff are not aware. On the other hand, there may be additional "downstream" revenue that may be generated as part of the new PAD exercise training program. These could include additional lab tests, stress testing, office visits, referrals, etc. By incorporating all potential costs and revenue, the financial analyst will create a return on investment (ROI) which will make it easier to gain institutional support.

Before meeting with the financial analyst, the team should have developed an idea of the necessary resources to run the program. It is essential to be prepared when meeting with the financial group because this process, if not well vetted, could delay implementation.

Some examples of information to prepare prior to meeting with them include:

- Potential number of new participants
- Potential number of total visits
- Incremental clinical staff needed
- Incremental support staff needed
- Incremental equipment or materials needed
- Potential impact on "downstream" services
- General idea of fee structure (flat fees, tiered fees, insurance opportunities, etc.)
- Billing process

TIP

If the program can be implemented with minimal incremental resources to start, the ROI will look much better and may allow a quicker implementation.

RESOURCE ALLOCATION

Now is the time to start documenting and identifying how resources will be moved or re-allocated in order to implement the new PAD rehabilitation program. Take into consideration the slow growth of the program and do not necessarily implement all potential resources at the beginning. Resource re-allocation may include:

- Adjusting staff shifts to cover the new PAD participants
- Designating specific times of the day when PAD participants will exercise
- Adding specific education class times for PAD participants
- Identifying a specific time and staff member to do intakes on PAD participants
- Providing administrative time to program leader for continual evaluation and development of the program
- Identifying a specific time when treadmills may be available for PAD participants
- Confirming that sufficient handicap parking spaces are available

Sample Program Ramp-Up Schedule

Months 0-3	25% of Resource Allocation
Months 4-6	50% of Resource Allocation
Months 7-10	75% of Resource Allocation
Months 11+	100% of Resource Allocation

Note: An evaluation of program success benchmarks should be done every three months to determine if additional resources should be allocated.

Gaining Institutional Support

The final step in the development of a new PAD rehabilitation program may be the most difficult. Gaining institutional support to implement a new program can depend on a variety of factors including the ROI analysis, success of current programs, economic conditions, etc. It is crucial that due diligence be spent on this aspect of the program development as it will become the working framework as the program is implemented.

Creating an executive summary of the new program may be the best way to concisely and effectively make the case to administration for the implementation of the program. An executive summary will summarize all the aspects that have been previously listed and should also include information on the long-term assessment of the success of the program.

Components of an Executive Summary

- Summarize the proposal in a two to three page statement
- Highlight the clinical and financial opportunities
- Tie into the organization's mission and vision statements
- Identify staff and facility resources

PROGRAM IMPLEMENTATION

After the program has received institutional support, the months of planning and analysis are utilized to implement the program. Program implementation involves taking many of the opportunities identified in the first steps and turning them into strategy. It involves capitalizing on the synergies with the other programs, leveraging changes with the competitors and taking the protocols and processes developed and putting them into action.

A new PAD exercise training program can be implemented simply by initiating the new protocols and processes identified in the clinical program development step. However, to truly provide a robust and successful program, several strategies should be considered. These strategies will be used to attract new participants and communicate implementation of the new PAD rehabilitation program.

Marketing

Marketing strategies can vary in scope and cost; the key in all marketing strategies is communicating the need, opportunity and differentiation of the program. The target audience and the method to reach that audience will vary. The first step of the marketing campaign is to identify the target audience.

1. Who would be the potential referral base (cardiologists, PCP, vascular specialists, etc.)?
2. Are there existing marketing campaigns that are targeting PAD participants (institutional, regional, national) that could be capitalized on?
3. What are the potential communication avenues available within the institution (grand rounds, hospital newsletter, group e-mail, etc.)?

The aggressiveness of the marketing campaign will be determined by current and future capacity of the program, desired growth, and financial support. The table on the following page outlines various levels of marketing campaigns and examples of marketing strategies.

Marketing (continued)

SMALL FINANCIAL INVESTMENT	MODERATE FINANCIAL INVESTMENT	HIGH FINANCIAL INVESTMENT
• Think of how to use existing communication methods • E-mails to physician groups • Card or note on CR/PR patient's entry or exit letter introducing program • Market in your existing programs • Flyers sent to referring physician offices • Grand rounds	• Direct to patients usually costs a little more • Marketing within your own organization • Health fairs • Brochures in physician offices • Web page marketing • Google AdWords • Open houses • Physician office visits	• Newspaper/Magazine advertisements • Radio advertisements • Conference/CME Course sponsorship • Direct to companies Utilization of these strategies usually will require a very positive ROI – will need institutional support

Linking to Hospital/Clinic-Based Resources

An effective strategy to improve the flow of participants into a new program is to work directly with hospital units or clinics where health care professionals see patients with PAD daily. Offer to attend a staff meeting or shadow in their unit or clinic – sharing face-to-face time so that the new program becomes top of mind when they are seeing people with PAD is the ultimate goal. Consider developing a simple referral pad that could be used by the hospital units or clinics to easily refer participants into the PAD rehabilitation program. Utilize electronic order sets, if possible. An example of a written referral is shown on the right:

Peripheral Arterial Disease (PAD) Rehabilitation

Supervised PAD rehab is a Class IA recommendation for the treatment of peripheral arterial disease.

Our program consists of exercise physiologists and nurses who are trained to develop exercise programs and provide in-depth education for individuals with PAD.

Our program is offered [INSERT FREQUENCY AND DURATION]

To refer a patient call XXX-XXX-XXXX

Patient's Name: _____

Medical Records #: _____

PAD Rehab: _____ days per week for _____ weeks

Pertinent medical information:

_____

_____

BARRIERS AND OBSTACLES

Implementation of new programs may encounter barriers and obstacles depending on the level of institutional support, existing resources and experience of the staff. Although often considered formidable roadblocks, these barriers can be overcome and can ultimately strengthen the program and its long-term sustainability. Each barrier will be encountered at different aspects of the implementation process, and each will have different strategies to overcome it. Examples of barriers and obstacles and potential strategies are listed below.

BARRIERS AND OBSTACLES	POTENTIAL STRATEGIES
Marketing Resources	• Understand target market • Link financial allocation of marketing campaign to potential profits • Utilize low-cost information technology methods (e.g., e-mail) • Link to existing marketing campaigns
Financial Resources	• Team up with financial analyst • Know existing program's book of business • Build upon other ROIs that have been done for other programs • ROIs may not necessarily be needed for all programs – depends on incremental needs • Probably will have to do more with less until program grows • Set charge for the program competitively – do not accept finance department's first recommendation • Look at the program as a potential financial gift opportunity
Patient Pay vs. Insurance Coverage	• Identify aspects of the program that can be covered by insurance • Price to the market – do not overprice • Link to existing maintenance programs • Consider tiered pricing structure that decreases as the level of supervision decreases • Consider pitching the program to private insurances o Identify if the insurance company covers other special programs o Contact prevention management director o Present executive summary o Suggest pilot program • Bill insurances – the only way insurance companies will recognize a need is if they see the charges come through, with appropriate clinical documentation

(continued on next page)

BARRIERS AND OBSTACLES (CONTINUED)

BARRIERS AND OBSTACLES	POTENTIAL STRATEGIES
Stretching existing staff and facilities thin	• Ensure staff has buy-in for the proposed program • Use as an opportunity for professional growth – consider getting younger staff involved • Take inventory of current staff responsibilities – reallocate and consolidate • Examine non-traditional shifts • Pilot with existing staff before committing/asking for incremental staff • Examine current facility utilization rate – is all the equipment used all the time? • Examine use at non-traditional times • Run the program concurrently with existing programs

MISCELLANEOUS ADMINISTRATIVE CONSIDERATIONS

Staff Education

This toolkit includes a Power Point presentation designed to reinforce the educational material in Chapters 1-10. Click here to link to slides. It also includes a sample Staff Competency Tool to document training and competency. Click here to view this document.

Equipment

If the appropriate equipment is already available in the cardiac rehabilitation or wellness center, then there is no additional special exercise equipment that is needed for an exercise program for individuals with PAD.

Treadmills are the most effective and widely utilized exercise equipment. Therefore, careful consideration to the utilization of treadmills will be important when developing the program.

Obviously, the emergency response equipment (e.g., defibrillator, oxygen) used for cardiac rehabilitation programs is also needed during exercise training for participants with PAD.

Although it is not necessary to implementing an exercise training program, staff should be familiar with and understand the use of a handheld Doppler. This is the equipment used to assess the severity of PAD and it will be important for staff to understand its purpose and the results when providing education to the patients. Click here for information about Dopplers.

MISCELLANEOUS ADMINISTRATIVE CONSIDERATIONS (CONTINUED)

Reimbursement

At the present time, most insurance companies, including Medicare, do not cover supervised PAD exercise programs. Several strategies are underway nationally to increase coverage. In 2001, a CPT code was established for supervised PAD rehabilitation programs, and it should be utilized when rendering services. It would be important, however, to notify participants that if their insurance company is billed, it may not cover the cost of the program.

CPT 93668: Peripheral artery disease (PAD) rehabilitation, per session.

Peripheral artery disease (PAD) rehabilitative physical exercise consists of a series of sessions, lasting 45-60 minutes per session, involving the use of either a motorized treadmill or track to permit each patient to achieve symptom-limited claudication. Each session is supervised by an exercise physiologist or nurse. The supervising provider monitors the individual patient's claudication threshold and other cardiovascular limitations for adjustment of workload. During this supervised rehabilitation program, the development of new arrhythmias, symptoms that might suggest angina or the continued inability of the patient to progress to an adequate level of exercise may require physician review and examination of the patient. These physician services would be separately reported with an appropriate level E/M service code.

RESOURCES FOR HEALTH CARE PROFESSIONALS

GUIDELINES AND PERFORMANCE MEASURES

1) American College of Sports Medicine. ACSM's guidelines for exercise testing and prescription. 7th edition, 2006.

ACSM's exercise prescription for persons with PAD is consistent in mode, frequency, duration and workload to those established for other cardiorespiratory populations. These guidelines identify that exercise should be a large-muscle activity, three to five times per week, at an intensity of 50-85 percent of heart rate reserve (HRR) or a rating of perceived exertion (RPE) of 12-16, for a duration of 20-60 minutes. Treadmill and track walking are the most effective approaches to reduce claudication. The treadmill workload should initially elicit claudication symptoms within three to five minutes. The patient walks at this workload until reaching a point of moderate severity (level 3 of 5). This should be followed by a brief period of sitting or standing to allow relief of symptoms. For the duration of exercise-rest-exercise, the pattern should be repeated. The ideal exercise duration for optimal symptomatic relief is between 35 and 50 minutes.

2) Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, Hiratzka LF. Murphy WR, Olin JW. 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). *Circulation 113(11):e463-654, 2006 Mar 21*

Guidelines related to exercise rehabilitation in PAD:
(a) Exercise and Lower-extremity PAD Rehabilitation
Class I

1. A program of supervised exercise training is recommended as an initial treatment modality for patients with intermittent claudication. (Level of evidence: A)
2. Supervised exercise training should be performed for a minimum of 30–45 minutes, in sessions performed at least three times per week for a minimum of 12 weeks. (Level of evidence: A)

Class IIb
The usefulness of unsupervised exercise programs is not well established as an effective initial treatment modality for patients with intermittent claudication. (Level of evidence: B)

3) Olin JW, Allie DE, Belkin M et al. ACCF/AHA/ACR/SCAI/SIR/SVM/SVN/SVS 2010 performance measures for adults with peripheral artery disease:
a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Performance Measures, the American College of Radiology, the Society for Cardiac Angiography and Interventions, the Society for Interventional Radiology, the Society for Vascular Medicine, the Society for Vascular Nursing, and the Society for Vascular Surgery (Writing Committee to Develop Performance Measures for Peripheral Artery Disease). J Am Coll Cardiol 2010;56. Published online November 29, 2010.

Performance measures related to treatment of patients with peripheral artery disease include:

- Ankle-brachial index (ABI) in at-risk patients
- Statin therapy to lower the LDL cholesterol to less than 100 mg/dL
- Smoking cessation interventions to help active smokers stop
- Antiplatelet therapy with aspirin or clopidogrel to reduce risk of heart attack, stroke or death in people with history of symptomatic PAD
- Supervised exercise programs
- Lower extremity vein bypass graft surveillance
- Monitoring of abdominal aortic aneurysms The Supervised Exercise performance measure states:
- Patients with intermittent claudication should be offered supervised exercise training
- If no supervised exercise program is available, then the healthcare provider must give explicit written or verbal instructions for unsupervised exercise and document the reason why a supervised exercise program cannot be offered

REVIEW ARTICLES

1) Wind, J, Koelemay, M.J.W. Exercise therapy and the additional effect of supervision on exercise therapy in patients with intermittent claudication. Systematic review of randomized controlled trials. *European Journal of Vascular & Endovascular Surgery* 34(1):1-9, 2007.

A systematic review was performed of all randomized controlled trials (RCTs) comparing supervised exercise therapy to unsupervised exercise regimens or observation in patients with intermittent claudication. The studies were evaluated specifically for the outcomes of PWD and AWD. Fifteen manuscripts, published between 1990 and May 2006, were eligible for analysis, evaluating 761 patients. In the studies comparing supervised exercise to standard care, the weighted mean difference in pain-free walking distance (PWD) and absolute walking distance (AWD) was 81.3 meters (95 percent CI; 35.5-127.1) and 155.8 meters (95 percent CI; 80.8-230.7), respectively. In the studies comparing supervised to unsupervised exercise therapy, the weighted mean difference in PWD and AWD was 143.8 meters (95 percent CI; 5.8-281.8) and 250.4 meters (95 percent CI; 192.4-308.5). The meta-analysis concluded that exercise therapy increases the PWD and AWD in patients with intermittent claudication. Supervised exercise therapy increases the PWD and AWD more than standard care. However, the additional value of supervision over unsupervised exercise regimens needs further clarification.

- Supervised exercise therapy increases pain-free and maximal walking distances in patients with claudication more than standard care (81 meters and 156 meters).
- Supervised exercise therapy also increases pain-free and maximal walking distances more than unsupervised exercise programs in the studies evaluated in this review (144 meters and 250 meters).

2) Bendermacher BLW, Willigendael EM, Teijink JAW, Prins MH. Supervised exercise therapy versus non-supervised exercise therapy for intermittent claudication. *Cochrane Database of Systematic Reviews* 2006, Issue 2. Art. No.: CD005263. DOI:10.1002/14651858. CD005263. pub2.

A review of eight randomized and controlled clinical trials (N=319) was done to evaluate the effects of supervised versus non-supervised exercise therapy on the maximal walking time or distance for people with intermittent claudication. All trials used a treadmill walking test as one of the outcome measures and the follow-up ranged from 12 weeks to 12 months. In general, the supervised exercise regimens consisted of three exercise sessions per week. The overall quality of the included trials was good, though the trials were all small with respect to the number of participants, ranging from 20 to 59. Supervised exercise therapy showed statistically significant and clinically relevant differences in improvement of maximal treadmill walking distance compared with non-supervised exercise therapy regimens, with an overall effect size of 0.58 (95 percent confidence interval 0.31 to 0.85) at three months. This translates to a difference of approximately 150 meters increase in walking distance in favor of the supervised group. The authors concluded through this review that supervised exercise therapy is suggested to have clinically relevant benefits compared with non-supervised regimens, which is the main prescribed exercise therapy for people with intermittent claudication. However, the clinical relevance has not been demonstrated definitely and will require additional studies with a focus on the improvements in quality of life.

- Supervised exercise therapy showed statistically and clinically relevant differences in improvement of maximal treadmill walking distance compared with non-supervised exercise therapy regimens at three months.
- Supervised exercise therapy is suggested to have clinically relevant benefits compared with non-supervised regimens.

REVIEW ARTICLES (CONTINUED)

3) Regensteiner J, Stewart K. Established and evolving medical therapies for claudication in patients with peripheral arterial disease. *Nature Clinical Practice: Cardiovascular Medicine* 2006; 3: 604-610.

Claudication resulting from peripheral artery disease causes substantial impairment in the ability to carry out normal daily activities. The medical treatments for claudication that are currently available are exercise rehabilitation and one drug, cilostazol. Pentoxifylline, which improves red cell deformability, lowers fibrinogen levels and decreases platelet aggregation, has been used historically, but frequency of use has declined because of limited effectiveness. Exercise rehabilitation, while efficacious, has been underused in the past. This therapy is, however, currently the subject of several large research projects. These studies are investigating mechanisms by which exercise therapy could benefit people with claudication and are also directly comparing it with other therapies. Concurrently, several new drug therapies for claudication are in the process of being evaluated. These research efforts might increase the available armamentarium and thereby help to alleviate the impairments associated with this symptom. The aim of this article is to discuss the current medical treatments being developed for use in patients with claudication resulting from peripheral arterial disease.

- Peripheral artery disease is a common form of atherosclerotic disease.
- Claudication is a disabling symptom of peripheral artery disease, but few medical treatments are available to treat the condition.
- Numerous agents are currently under evaluation as claudication therapies.
- Exercise training is an efficacious therapy for claudication but is underused in the clinical setting.

4) Bulmer AC, Coombes JS. Optimizing exercise training in peripheral arterial disease. *Sports Medicine* 2004; 34: 983-1003.

Peripheral artery disease (PAD) is an obstructive condition where the flow of blood through peripheral arteries is impeded. During periods of increased oxygen demand (e.g., during exercise), peripheral limb ischemia occurs, resulting in the sensation of muscle pain termed "claudication." As a result of claudication, subjects' ability to exercise is greatly reduced, affecting their quality of life. Although many treatment options for patients with PAD exist, exercise training is an effective and low-cost means of improving functional ability and quality of life. Currently, there are limited specific recommendations to assist the exercise prescription and programming of these individuals. This review summarizes data from 28 exercise training studies conducted in patients with PAD and formulates recommendations based on their results. The review recommended that exercise training for patients with PAD should involve three training sessions per week comprising 45 minutes of intermittent treadmill walking in a supervised environment for a time period of 20 weeks or more. Encouragement and direction are given to further research aimed at investigating the effectiveness of training programs in these patients.

- Exercise training is an effective and low-cost means of improving functional ability and quality of life in patients with PAD.
- Exercise training for patients with PAD should involve three training sessions per week comprising 45 minutes of intermittent treadmill walking in a supervised environment for a time period of 20 weeks or more.

REVIEW ARTICLES (CONTINUED)

5) Stewart KJ, Hiatt WR, Regensteiner JG, Hirsch AT. Exercise training for claudication. *New England Journal of Medicine* 347(24):1941-51, 2002 Dec 12

Exercise training appears to be an effective treatment for claudication, the primary symptom of peripheral artery disease. Exercise-induced increases in functional capacity and lessening of claudication symptoms may be explained by several mechanisms, including measurable improvements in endothelial vasodilator function, skeletal-muscle metabolism, blood viscosity and inflammatory responses. The evidence of exercise-training-induced increases in leg blood flow and oxygen delivery is less robust, and these mechanisms are unlikely to account for the large improvements in pain-free walking that can be achieved. Improvements in the biomechanics of walking also contribute to increased walking ability. Although exercise training has multiple beneficial effects, current knowledge does not permit accurate estimation of the relative contribution of each mechanism.

- Exercise training is an effective therapy for patients with claudication.
- There are multiple factors, both systemic and local, that are related to improvement.
- Further research is needed to determine the relative contribution of each mechanism.

6) Leng GC, Fowler B, Ernst E. Exercise for intermittent claudication. *The Cochrane Database of Systematic Reviews* 2000, Issue 2. Art.No.: CD000990. DOI:10.1002/14651858. CD000990.

A review of randomized trials of exercise regimens in patients with leg pain on walking (intermittent claudication) was done to determine the effects of exercise for leg pain. A total of ten trials (N=250) qualified for review based on methods and quality. All trials used a treadmill walking test as one of the outcome measures and follow-ups ranged from 12 weeks to 15 months. There was some variation in the exercise regimens used, although all recommended at least two weekly sessions of, mostly, supervised exercise. All trials used a treadmill walking test as one of the outcome measures. The overall quality of the included trials was generally good, though the trials were all small (20-49 patients). Exercise therapy significantly improved maximal walking time (minutes) (weighted mean difference 6.51, 95 percent confidence interval 4.36 to 8.66, fixed effect model [FE]), with an overall improvement in walking ability of approximately 150% (range 74 to 230 percent). Exercise produced significant improvements in walking time compared with both angioplasty at six months (weighted mean difference 3.30, 95 percent confidence interval 2.21 to 4.39, FE) and antiplatelet therapy (weighted mean difference 1.06, 95 percent confidence interval 0.15 to 1.97, FE), and did not differ significantly from surgical treatment. In one small trial, exercise was less effective than pentoxifylline (weighted mean difference -0.45, 95 percent confidence interval -0.66 to -0.24, FE). The reviewers concluded that exercise is of significant benefit to patients with leg pain and is an inexpensive, low-risk therapy.

- In PAD patients, exercise therapy significantly improved maximal walking time (minutes) an average of approximately 150 percent.
- Exercise produced significant improvements in walking time compared with angioplasty at six months and did not differ significantly from surgical treatment.
- Exercise is an inexpensive, low-risk, and very effective therapy for patients with PAD.

ADDITIONAL SELECTED STUDIES

1) Treesak C, Kasemsup V, Treat-Jacobson D, Nyman JA, Hirsch AT. Cost-effectiveness of exercise training to improve claudication symptoms in patients with peripheral arterial disease. [Comparative Study. Journal Article] *Vascular Medicine* 9(4):279-85, 2004 Nov

Exercise rehabilitation is a proven, yet poorly available, treatment for intermittent claudication, the primary symptom of peripheral artery disease (PAD). Exercise rehabilitation is effective, non-invasive and associated with minimal cardiovascular risk in appropriate patients. Percutaneous transluminal angioplasty (PTA), especially of the iliac segment, is an alternative effective treatment for claudication. There are, however, minimal data currently available to compare the cost-effectiveness of these two interventions. We compared the cost-effectiveness of three- and six-month exercise programs with that of iliac PTA without stenting, using the incremental cost-effectiveness ratio [ICER = (Cost2 - Cost1)/ (Effectiveness2 - Effectiveness1)]. The ICER represented the price of an additional meter walked derived from each treatment based on conservative models of success of each procedure and specific care assumptions. PTA and exercise efficacy data were derived from a literature review and exercise costs were modeled per the current CPT code 93668. Effectiveness was defined as absolute claudication distance (ACD) at three and six months. Three treatment alternatives were assessed: (1) no treatment, (2) PTA, and (3) exercise rehabilitation. At three months, PTA was more effective than exercise therapy and resulted in an additional 38 meters at an additional cost of $6,719, for an ICER of $177/meter. At six months, however, exercise was more effective than PTA, resulting in an additional 137 meters walked, and costs less ($61 less per meter gained). In conclusion, exercise rehabilitation at six months is more effective and costs less than PTA, and is therefore cost-saving. The cost-effectiveness and availability of claudication treatments has national implications for future PAD care; however, data to inform these care choices can best be obtained in prospective clinical trials.

- Exercise rehabilitation is cost-effective compared to PTA, especially after six months.
- The cost-effectiveness of exercise might be increased if compared to lower extremity arterial stenting, which is increasingly common, because of the increased costs of PTA and stenting compared to PTA alone.

2) Perkins JMT, Collin J, Creasy TS, Fletcher EW, Morris PJ. Exercise training versus angioplasty for stable claudication. Long- and medium-term results of a prospective, randomized trial. *European Journal of Vascular and Endovascular Surgery* 1996; 11: 409-413.

A prospective, randomized trial was done to compare percutaneous transluminal angioplasty (PTA) against exercise training in the treatment of stable claudication. Fifty-six patients with unilateral, stable, lower limb claudication assessed prior to randomization, at three monthly intervals for 15 months, and at approximately six years follow-up. Thirty-seven patients were available for long-term review. The outcomes measured were ankle/ brachial pressure index (ABPI), treadmill claudication and maximum walking distances, and percentage fall in ankle systolic pressure after exercise. The results showed significant increases in ABPI in the patients treated with PTA at all assessment to 15 months. However, in terms of improved walking performance, the most significant changes in claudication and maximum walking distance were seen in the exercise training group. At long-term follow-up, there was no significant difference between the groups. Subgroup analysis by angiographic site of disease showed greater functional improvement in those patients with disease confined to the superficial femoral artery treated by exercise training. Conclusions identified that exercise training confers a greater improvement in claudication and maximum walking distance than PTA, especially in patients with disease confined to the superficial femoral artery.

- When comparing PTA and supervised exercise training, the most significant changes in claudication and maximal walking distance were seen in the exercise training group, especially in patients with disease confined to the superficial femoral artery.
- Over time, the exercise training group continued to improve, while the PTA group improved initially and then declined.

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STAFF EDUCATION MATERIALS

A series of staff education materials are available.

1) PAD Rehabilitation Toolkit: A Guide for Health Care Professionals slide set
Click here to download the slide set

2) ACC's PAD Guidelines and Slide sets
Click here to download this document

3) Staff Competency Tool
Click here to download this document

4) The PAD Atlas

Developed in partnership with the National Minority Quality Forum (NMQF), the PAD Atlas is a database that maps by zip code PAD prevalence down to the street level.
To access the PAD Atlas, click here.

5) Slides on Lower Extremity PAD

The PAD Coalition offers a comprehensive slide library, comprised of seven sections, of the lower extremity PAD guidelines:

- Section 1: Introduction, Epidemiology and Prognosis
- Section 2: Clinical Presentation
- Section 3: Treatment to Improve Outcomes
- Section 4: Medical Treatment for Intermittent Claudication
- Section 5: Revascularization
- Section 6: Post-Surgical Care
- Section 7: Conclusions and PAD Resources

Click here to access the slide set.

SAMPLE MARKETING MATERIALS

A series of sample marketing materials have been created to help market and promote your program to patients.

Sample Flyer

A sample customizable flyer that you can post in your facility or anywhere else to attached patients can be downloaded here in PDF format.

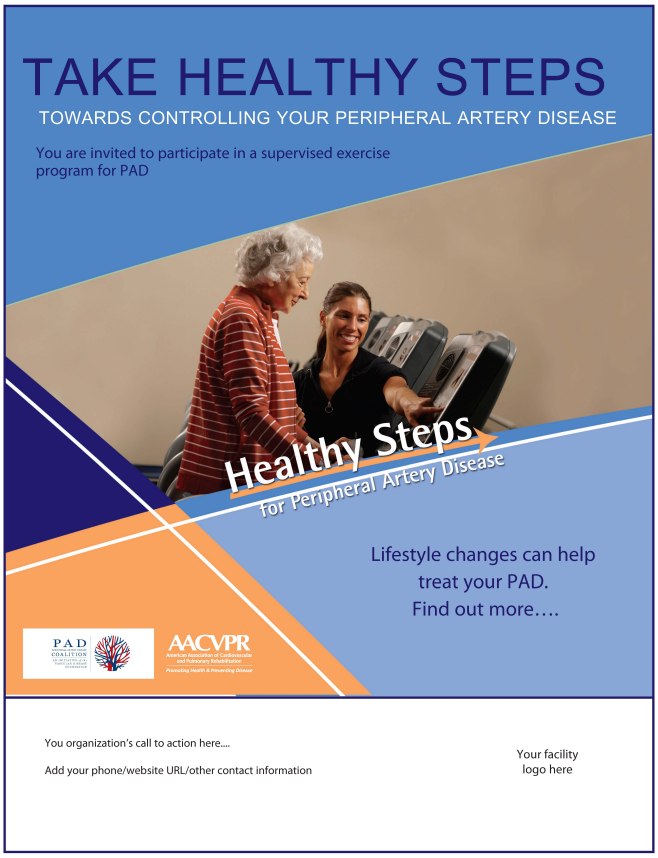
Download the flyer by clicking here

Advertisements

And several customizable advertisements have been created for placement in your facilities local newsletter or magazine. This can even be placed in local newspapers or online.

To access the full-page ad, click here

To access the quarter-page ad, click here



RESOURCES FOR PATIENTS

There are numerous resources that you can direct you patients to where they will find trustworthy, non-biased educational information about PAD.

Vascular Cures is the only 501(c)3 nonprofit organization representing the millions of patients with Vascular Disease in the U.S. We focus on creating long-term, shared resources to accelerate development of new treatments and improve patient health. Vascular Cures offers free educational flyers and more on its website here. The Vascular Disease Foundation (VDF) ceased operations in January 2014. In October 2014, Vascular Cures acquired most of VDF's digital assets and educational resources.

VASCULAR CURES

All life saving tips are in PDF format available for free download and are reproducible.
www.vasculardisease.org/education-prevention/knowledge-is-power/educational-flyers/

American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)

AACVPR is dedicated to reducing morbidity, mortality and disability from cardiovascular and pulmonary disease through education, prevention, rehabilitation, research and disease management. Central to the core mission is the improvement of the quality of life for patients and their families.

For more information visit:
www.aacvpr.org/

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Editor's Note: *For the purpose of this document PAD is referred to as either peripheral artery disease or peripheral arterial disease depending on the source of the information. Please note that the acronym is pronounced P-A-D rather than "PAD."*

NOTES