

PREVENTION OF AMPUTATION IN VETERANS EVERYWHERE (PAVE) PROGRAM

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive communicates the policy and responsibilities for the Prevention of Amputation in Veterans Everywhere (PAVE) Program, which outlines the scope of care and treatment provided to Veterans at risk of primary or secondary limb loss.

2. SUMMARY OF MAJOR CHANGES: Major changes include:

- a. Added any cause sensory neuropathy to the list of at risk conditions.
- b. Clarifies that a foot risk score of 2 or 3 is not definitively determined until the foot care specialists complete the examination and makes the final declaration.
- c. Updated the link to the Amputee and PAVE Pyramid cubes.
- d. Updated the minimum data set for patient tracking to include the number of patients in each risk group, major/minor and Above Knee Amputations/Below Knee Amputations (AKA/BKA) amputation ratios, new ulcers per year and the percent of those new ulcers with diabetes.
- e. Updated the PAVE Oversight Committee adding a Mental Health representative.
- f. Updated the PAVE Oversight Committee to specify the direct reports as the Assistant Deputy Under Secretary for Health for Patient Care Services, Chief Consultant for Rehabilitation Services, and the Chief Consultant for Specialty Care Services.
- g. Updated the PAVE Coordinators role to include; Ensure the committee meets at least yearly, maintain meeting minutes, collects, reviews and analyses program data to drive program improvement, develops in collaboration with the PAVE committee, Chief of Staff, program goals and objectives, collaborates with the amputation care providers and/or other related committees and services, ensures the annual report is completed and reviewed with the Chief of Staff.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Office of Rehabilitation Services (10P4R) and the Office of Specialty Care Services (10P4E) are responsible for the contents of this directive. Questions may be addressed to the National Program Director, Podiatry Service at 216-231-3286.

5. RESCISSION: VHA Directive 2012-020, dated August 20, 2012, is rescinded.

March 31, 2017

VHA DIRECTIVE 1410

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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PREVENTION OF AMPUTATION IN VETERANS EVERYWHERE (PAVE) PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) directive communicates the policy and responsibilities for the Prevention of Amputation in Veterans Everywhere (PAVE) Program, which outlines the scope of care and treatment provided to Veterans at risk of primary or secondary limb loss. **AUTHORITY:** Public Law 102-405, Veterans Medical Programs Amendments of 1992.

2. BACKGROUND

a. Throughout the history of the Department of Veterans Affairs (VA), providing care to Veterans with amputations has always been among VA's highest priorities. To many Americans, a Veteran with an amputation epitomizes the sacrifices made on our Nation's behalf. VA strives to provide care in order to prevent and treat lower extremity complications that can lead to amputation, and to restore function, thereby improving quality of life for Veterans who have already undergone an amputation.

b. The enactment of Public Law 102-405, Veterans Medical Programs Amendments of 1992, emphasized the importance of providing the best possible care to patients with amputations. That law identified Veterans with limb loss as a special disability group and chartered the Advisory Committee on Prosthetics and Special-Disabilities Programs, which reports annually to the Secretary of Veterans Affairs on the effectiveness of such programs.

c. The VA Preservation-Amputation Care and Treatment Program at VA medical facilities was established in 1993 to meet the changing needs of the Veteran population (i.e., more amputations due to neuropathic and vascular conditions and fewer traumatic amputations). It represented a model of care developed to prevent or delay amputation through proactive early identification of patients who are at risk of limb loss. The problems encountered by patients with diabetes, end stage renal disease, peripheral vascular disease and sensory neuropathy best demonstrate the need for this program. There is an estimated 1 to 4 percent annual incident rate and a 15 to 25 percent lifetime risk for ulceration in patients with diabetes. Currently, the prevalence of diabetes in VHA is about 24 percent making this a priority clinical issue for Veteran care. Faced with Service members with traumatic amputations who are leaving the military and coming to VA for care, VHA is addressing the unique needs of these patients to ensure that the Veteran receives optimal and compassionate patient centered care through the VHA Amputation System of Care (ASoC).

(1) Since its inception in 1993, the PAVE program has made significant strides in implementing evidence-based prevention practices. VA data (which does not include Medicare and private sector data) has shown a steady decrease in proximal (higher level) amputations in favor of more limb sparing distal amputations, which improve the Veterans functional capacity. .

(2) With the estimated cost of care associated with foot ulcer in persons with osteomyelitis at \$46,000 per year and first lower extremity amputations ranging from \$30,000 to \$50,000, effective prevention leads to substantial economic benefit to VHA. The 2010 VHA-Department of Defense (DoD) Clinical Practice Guideline: Management of Diabetes Mellitus (DM) promotes:

(a) Yearly foot inspections and risk assessments at site of entry to the VA health care system;

(b) Appropriate referral to a foot care specialist for more in-depth evaluation, final risk assessment, and treatment/management; and

(c) Selection of proper footwear (for high risk patients) and self-foot care behavior education as a prevention strategy for lower extremity complications including infection, ulceration, and amputation.

d. The PAVE program provides a model of care for:

(1) Those patients “at-risk” for primary amputation (patients with diabetes, end stage renal disease, peripheral vascular disease and any cause sensory neuropathy); and

(2) Those patients who have already suffered an amputation (whether traumatic or as a complication of another disease process).

e. Utilizing a PAVE Team Coordinator incorporates interdisciplinary management of care utilizing available resources on the prevention side and rehabilitation side including, but not limited to: primary care, infectious disease, diabetes teams, nurse, podiatrist, vascular surgeon, rehabilitation physician, therapists (physical, occupational, recreational, etc.), social worker, mental health care and prosthetic and/or orthotic personnel.

f. The PAVE Program and the ASoC programs are closely linked and coordinate efforts in order to address the prevention of first amputation, the rehabilitation needs of patients who suffered an amputation, and the prevention of a second amputation in those patients with an amputation. At a minimum, the program provides for:

(1) A brief foot check for at-risk populations, such as Veterans with diabetes, peripheral vascular disease, end stage renal disease (ESRD), or other neuropathic conditions that increase susceptibility to amputation risk (see appendix A). **NOTE:** *Referral for final determination of high-risk Veterans should be done by podiatry/foot care specialist.*

(a) Identification of potential high-risk patients, based upon foot risk factors that would determine the appropriate care and/or referral to the extent the Veteran is eligible (see appendix A).

(b) Timely and appropriate referral and ongoing follow-up of patients based on an algorithm produced by the local PAVE Clinic Team (see appendix A).

(c) A referral to a mental health consultation team, as needed, to assess coping and to provide support either in an individual or group format. **NOTE:** *This approach avoids stigmatizing anyone as being singled out as having mental or emotional issues and also minimizes the potential for missing someone who is "suffering in silence." Medical facilities are encouraged to establish or refer Veterans with amputations to a peer support program or Amputee Support Groups or Clinics for ongoing support.*

(d) A system to identify and track patients with amputation or those at risk for amputation through all appropriate levels of care. **NOTE:** *The VHA Support Service Center (VSSC) Clinical Programs, Amputations Treatment and Prevention Pyramid Cubes can be found at: <http://vssc.med.va.gov>. This is an internal VA Web site that is not available to the public.*

(e) Collaboration with any existing amputee clinic team or other relevant primary care clinics, to provide a model of at-risk limb care through interdisciplinary coordination in tracking patients with amputations, or those at risk of limb loss, from day of entry through all appropriate care levels, back into the community. This would include at a minimum the numbers of patients in each risk score, major/minor amputation ratios, AKA/BKA amputation ratios, new ulcers per year and the percent of those with diabetes. **NOTE:** *This case management oversight complements the activities of the medical facility treatment staff and Amputee Clinic Team and is not meant to replace or be counterproductive to any phase of clinical patient care.*

g. The findings of the OIG report titled, "Healthcare Inspection: Foot Care for Patients With Diabetes and Additional Risk Factors for Amputation (11-00711-74, published January 17, 2013 indicated that "approximately one-third of patients with diabetes who were at increased risk for amputation had no documentation of required foot care." Further the report recommended that "... the Under Secretary for Health implement a plan to ensure compliance with VHA's requirement that patients who are at moderate or high risk for amputation be examined by a foot care specialist at least once each year." This was accomplished in the Deputy Undersecretary for Health for Operations and Management (10N) Memorandum to all Network Directors (10N1-23) dated February 22, 2013 which directed each VISN to provide risk assessment for all patients deemed at high risk for amputation and to implement a plan to ensure compliance. That plan included adding a new reporting element to the annual PAVE report requiring PACT to document specialty foot care visits for moderate to high risk patients within VHA, the private sector or those who have refused referral using a minimum of a 30 random chart review process. Results of this chart review are reported years in the annual PAVE report.

3. POLICY

It is VHA policy that the PAVE Program be established and maintained at all VA medical facilities. **NOTE:** *Any newly established medical center is expected to implement the PAVE Program within 6 months of opening.*

4. RESPONSIBILITIES

a. **VA Central Office PAVE Oversight Committee Chief.** The VA Central Office PAVE Oversight Committee is comprised of field-based clinical leaders from endocrinology or diabetes, podiatry, physical medicine and rehabilitation, prosthetics, nursing, the Veterans Integrated Service Network's (VISN) Office of Quality and Safety, Mental Health and other subsequently identified representatives. The VA Central Office PAVE Oversight Committee Chief is responsible for:

(1) Communicating to the Offices of Deputy Under Secretary for Health for Policy and Services, Chief Consultation for Rehabilitation Services and the Chief Officer for Specialty Care Services on its activities.

(2) Selecting PAVE Oversight Committee members from the field, based on their related clinical/administrative expertise, with approval from their medical centers and program office.

(3) Making recommendations for data collection and analyses to permit program evaluation of the foot check, surveillance salvage and rehabilitative components of the PAVE program including:

(a) Identification of Veterans at risk for or who have sustained an amputation.

NOTE: *The data captured for reporting are found in the VSSC Clinical Programs, Amputations Treatment and Prevention Pyramid Cubes: <http://vssc.med.va.gov>. This is an internal VA Web site that is not available to the public.*

(b) Age adjusted and stratified rates of major Above Knee Amputations (AKA), Below Knee Amputations (BKA), minor amputations, and lower extremity non-venous ulcers at the VISN and facility levels. **NOTE:** *The data captured for reporting are found in the VSSC Clinical Programs, Amputations Treatment and Prevention Pyramid Cubes: <http://vssc.med.va.gov>. This is an internal VA Web site that is not available to the public.*

(c) Patient knowledge and performance of recommended self-foot-care practices.

(d) Adherence to this directive with respect to formal policies and coordination strategies.

(4) Using all analyses to identify best practices from the field.

(5) Making recommendations to the Deputy Under Secretary for Health for Policy and Services, Chief Consultant for Rehabilitation Services and Chief Consultant, Specialty Care Services for program improvements to affect excellence in patient-centered care.

b. **National PAVE Director - National Program Director, Podiatry Service.** The National PAVE Director is the National Program Director, Podiatry Service who serves as Chair of the VA Central Office PAVE Oversight Committee and is responsible for:

(1) Oversight of the PAVE program, including administrative management of the PAVE program and development of critical pathways, clinical recommendations, quality indicators of care and performance measures.

(2) Conducting facility and VISN survey.

(3) Providing a national PAVE Annual Report for the VA Central Office PAVE Oversight Committee and VISN's to use in determining adherence to this Directive.

(4) Updates to the Advisory Committee for Prosthetics and Special Disabilities, when such updates are requested.

c. **Veterans Integrated Service Network (VISN) Director.** The VISN Director is responsible for:

(1) Ensuring that each VA medical facility has a formal PAVE Program or is meeting the intent of this directive.

(2) Reviewing the PAVE Program annually, to assess program status.

(3) Objectively defining any further evaluation and restructuring of local PAVE program initiatives.

d. **VA Medical Facility Director.** The VA medical facility director is responsible for ensuring that there is a PAVE program and a PAVE Committee to coordinate efforts to address the primary amputation prevention needs of "at risk" patients, and the secondary amputation prevention needs for those patients who have already suffered an amputation. This includes patients who underwent their amputations outside the VA system of care (e.g., Operation Enduring Freedom, Operation Iraqi Freedom, Operation New Dawn, private hospital, etc.). **NOTE:** *This may be accomplished by the PAVE coordinators incorporating their efforts with the ASoC programs or other amputation prevention committees within the medical centers.*

e. **Facility Chief of Staff.** The facility Chief of Staff (COS) is responsible for:

(1) Designating a PAVE Coordinator, providing appropriate training, and ensuring availability of foot specialty care, compliant with designated performance measures (e.g., External Peer Review Program (EPRP)).

(2) Coordinating the efforts of all medical disciplines required for treatment of patients at risk of limb loss or amputation.

(3) Developing local policy memoranda specifically identifying the responsibilities and actions to be taken by each of the involved services (i.e., Medical, Surgical, Physical Medicine and Rehabilitation, Podiatry, Nursing, Primary Care, Social Work, Mental Health and Prosthetic and Sensory Aids), to identify and treat patients at risk of limb loss or those who are amputees.

(4) Defining local policy and care algorithms to identify and track all patients at risk of limb loss or amputees from the day of entry into the VA health care system through all levels of care. **NOTE:** *This would include at a minimum the numbers of patients in each risk score, major/minor amputation ratios, AKA/BKA amputation ratios, new ulcers per year and the percent of those with diabetes.*

(5) Ensuring an annual outcome evaluation of the PAVE Program, including a review of local facility and VISN amputation ratios and new ulcers.

(6) Developing a formal performance plan to evaluate the program locally and provide evidence of the use of this data in subsequent program modulation.

(7) Completing an annual facility PAVE report and forwarding it to the VISN Director through the facility director, by December 30th of each year.

(8) Ensuring that facility guidelines regarding universal brief foot checks are developed and utilized by all clinicians providing principal care to patients at risk for amputation (see appendix A).

f. **Facility PAVE Coordinator.** The facility PAVE Coordinator is responsible for:

(1) Tracking the numbers of patients in each risk score, major/minor amputation ratios, AKA/BKA amputation ratios, new ulcers per year and the percent of those with diabetes.

(2) Functioning as:

(a) Organizational support for the PAVE Program by:

1. Ensuring the committee meets at least yearly.

2. Maintaining meeting minutes.

3. Collecting, reviewing and analyzing program data to drive program improvement.

(b) Communication conduit between administration and PAVE team providers.

(c) Developing, in collaboration with the PAVE committee and Chief of Staff, program goals and objectives.

(d) Collaborating with amputation care providers and/or other related committees and services.

(e) Ensuring the annual report is completed and reviewed with the Chief of Staff.

5. REFERENCES

a. Public Law 102-405, Veterans Medical Programs Amendments of 1992.

- b. VHA Handbook, 1173.9, Footwear and Shoe Modifications._
- c. VA/DoD Clinical Practice Guideline for the Management of Diabetes Mellitus, The Office of Quality and Performance, VA, Washington, DC & Quality Management Division, United States Army MEDCOM, 2010.

SUGGESTED BRIEF FOOT CHECK RECOMMENDATIONS

1. BRIEF FOOT CHECK

The brief foot check does not establish the final foot risk score; it serves as a guide for appropriate and timely referral for examination and determination of foot risk score. This brief foot check should be done at the initial entry point to the VA health care system and then yearly, or more often, depending on the final foot risk score. This would involve:

- a. Visual inspection of the skin surface for any lesions, deformities, color or temperature changes or ulcers;
- b. Foot Check for circulation, i.e., the palpation of pedal pulses in the foot; and
- c. Sensory testing using a Semmes-Weinstein 5.07 monofilament to check for loss of protective sensation. **NOTE:** *The brief foot check may be performed by any health care provider including but not limited to physicians, optometrists, registered nurses, licensed practical nurses, and health technicians.*

2. HIGH RISK FOOT EXAMINATION (for Foot Risk Score 2 and 3 patients)

This involves a more in-depth evaluation of the foot's circulation and sensation as well as foot deformities. During this examination, patients are evaluated by a "foot care specialist," e.g., Prevention of Amputation in Veterans Everywhere (PAVE) program member, vascular surgeon, podiatrist, or other health care professional demonstrating appropriate education, training, competencies and licensure necessary to provide such care. This is where the definitive foot risk score is established.

3. RISK ASSESSMENT LEVEL

"At-risk" is defined as patients with diabetes, peripheral end stage renal disease, vascular disease and any cause sensory neuropathy, who are considered highly susceptible to develop foot ulcers. "High Risk" is defined as any patient who has had an amputation for any reason, and patients with a foot risk score of 2 or 3.

- a. **Level 0, Normal Risk.** These patients have no evidence of sensory loss, diminished circulation, ulceration, or history of ulceration or amputation. Patients with diabetes should receive foot care education and annual brief foot check. These patients do not require therapeutic footwear.
- b. **Level 1, Low Risk.** These individuals demonstrate one or both of the following:
 - (1) Foot deformity or minor foot infection (and a diagnosis of diabetes).

(2) Patient education, preventative care and an annual brief foot check are required. The patients in this category and the following two categories (Level 2 and Level 3) should not walk barefoot. Special attention is to be directed to shoe style and fit. These individuals do not need therapeutic footwear.

c. **Level 2. Moderate Risk.** These individuals demonstrate sensory loss (inability to perceive the Semmes-Weinstein 5.07 monofilament) and may have one of the following additional findings:

(1) Diminished circulation as evidenced by absent or weakly palpable pulses (this would require follow-up examination to determine level of vascular disease before a final risk score can be determined).

(2) Foot deformity or minor foot infection and a diagnosis of diabetes.

(3) These individuals require therapeutic footwear and orthoses to accommodate foot deformities, to compensate for soft tissue atrophy, and to evenly distribute plantar foot pressures. Patient education, regular preventive foot examination and care in podiatry or other foot care specialty clinic. Patient health education (PHE) must include the implications of sensory loss and the importance of daily foot inspections. **NOTE:** May require Diabetic Socks and Depth Inlay Shoes based on clinical judgment.

(a) Diabetic Socks are defined as hosiery specifically designed to reduce pressure or friction to the foot (see appendix A, paragraph 3.d.(4)(b)1).

(b) Depth Inlay Shoes which are prefabricated shoes with a higher toe box to accommodate for hammer toes and other foot deformities. This shoe may also accommodate the insertion of special inserts (see appendix A, paragraph 3.d.(4)(b)2).

d. **Level 3. High Risk.** These individuals demonstrate peripheral neuropathy with sensory loss (i.e., inability to perceive the Semmes-Weinstein 5.07 monofilament) and diminished circulation and foot deformity, or minor foot infection and a diagnosis of diabetes, or any of the following by itself:

(1) Ulcer or Prior ulcer, osteomyelitis or history of prior amputation;

(2) Severe Peripheral Vascular Disease (PVD) (intermittent claudication, dependent rubor with pallor on elevation, or critical limb ischemia manifested by rest pain, ulceration or gangrene);

(3) Charcot's joint disease with foot deformity; and

(4) End Stage Renal Disease. These individuals are at highest risk of lower extremity events, because:

(a) Individuals in this category require extra depth footwear with soft molded inserts. They may require custom molded shoes and braces (e.g., double upright brace, patella tendon bearing orthoses, etc.).

(b) Careful observation, regular preventive foot care, and footwear modifications that may include, based on clinical judgment: Diabetic Socks, Depth Inlay Shoes, or Custom-Molded Orthopedic Shoes.

1. Diabetic Socks are defined as hosiery specifically designed to reduce pressure or friction to the foot (refer to the VHA Prosthetic Clinical Management Program: Clinical Practice Recommendations: Diabetic Socks).

2. Depth Inlay Shoes which are prefabricated shoes with a higher toe box to accommodate for hammer toes and other foot deformities. This shoe may also accommodate the insertion of special inserts (refer to VHA Handbook 1173.9).

3. Custom-Molded Orthopedic Shoes are shoes fabricated over a special modified last in accordance with prescriptions and specifications to accommodate gross or greater foot deformities or shortening of a leg at least 1 and one-half inches or greater (refer to VHA Handbook, 1173.9 Footwear and Shoe Modifications).

4. SMOKING

A history of smoking, although not shown to be an independent risk factor for lower extremity amputation, clearly raises the risk level for other morbid vascular complications such as peripheral arterial disease, stroke and myocardial infarction and as such aggressive smoking cessation counseling is recommended.

5. SUGGESTED REFERRAL STRATEGY

a. **Level 0 Normal Risk.**

(1) These patients should be screened annually;

(2) Patient education and self-care instruction can be delivered during the encounter or the patient can be referred to a diabetes educator; and

(3) Refer, if appropriate, to a primary care provider for their systemic conditions.

b. **Level 1 Low Risk.**

(1) These patients should be screened annually;

(2) Patient education and self-care instruction which can be delivered during the encounter or the patient can be referred to a diabetes educator;

(3) Refer, if appropriate, to primary care provider for their systemic conditions;

(4) Refer to podiatry or foot care specialist for examination if deformity exists; and

(5) If foot check results in findings suggestive of loss of protective sensation, poor circulation or foot deformity, referral to podiatry or foot care specialist for examination may be appropriate.

c. **Level 2 Moderate Risk.**

(1) Patient education and self-care instruction which can be delivered during the encounter or can be referred to a diabetes educator;

(2) Referral, if appropriate, to a primary care provider for their systemic conditions;

(3) Refer to podiatry or foot care specialist for examination and on-going care;

(4) The addition of a foot hygienist (LPN, RN, NP, etc.) as part of the podiatric clinical team helps address the increased need for basic foot care under the direction of the chief of podiatry allowing the podiatric physician to treat more complex foot and ankle conditions. **NOTE:** *The required training program for mid-level providers of basic foot care is found on TMS ID# 28493*

(5) Refer for non-invasive vascular laboratory testing to determine the degree of circulatory impairment, if there is evidence of impaired circulation on the brief foot check; and

(6) Refer to vascular surgery if diminished circulation.

d. **Level 3 High Risk.**

(1) Patient education and self-care instruction which can be delivered during the encounter or can be referred to a diabetes educator;

(2) Referral if appropriate to primary care provider for their systemic conditions;

(3) Refer to podiatry or foot care specialist for examination and on-going care;

(4) Refer for non-invasive vascular laboratory testing to determine the degree of circulatory impairment if there is evidence of impaired circulation on the brief foot check;

(5) Refer to vascular surgery if diminished circulation;

(6) Provide therapeutic footwear and orthoses to accommodate foot deformities, to compensate for soft tissue atrophy, and to evenly distribute plantar foot pressures;

(7) If acute condition is present immediate, referral is indicated; and

(8) Evaluate for secondary complications and refer to the appropriate discipline.