

August 20, 2012

**PREVENTION OF AMPUTATION IN VETERANS EVERYWHERE (PAVE)
PROGRAM**

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines policy for the Prevention of Amputation in Veterans Everywhere (PAVE) Program, which implements the scope of the care and treatment provided to Veteran patients at risk of primary or secondary limb loss.

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 passage 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, and peripheral vascular disease 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 increasing numbers of traumatic amputations from the battlefield and many of these Servicemembers leaving the military and coming to VA for care, VHA is addressing the unique needs of these patients by adapting the system to ensure that the Veteran receives optimal and compassionate patient centered care through the Amputation System of Care.

(1) Prior 1993, approximately 9,000 amputations were performed each year at VA medical facilities. Since the program's implantation, total amputations have decreased to less than 5,000 a year. More impressive is the decline in amputation rates from 10.2 percent in 2000 to 4 percent

THIS VHA DIRECTIVE EXPIRES AUGUST 31, 2017

VHA DIRECTIVE 2012-020

August 20, 2012

in 2010 (maximum amputation at discharge) within the at-risk diabetic population, demonstrating a substantial improvement in coordinated care for patients with “at-risk” foot conditions (see the Amputation ProClarity cube at: <http://klfmenu.med.va.gov>).

(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;

(b) Appropriate referral to a foot care specialist for more in-depth evaluation and treatment; and

(c) Selection of proper footwear 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 and peripheral vascular disease), and

(2) Those who have already suffered an amputation (whether traumatic or as a complication of another disease process) and are at risk for a second amputation.

e. Utilizing a 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 Amputation System of Care (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 Att. A).

(a) Identification of 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 Att. A).

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

(c) A visit by their mental health consultation team, to assess coping and to provide support, as needed, 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) ProClarity Cubes can be found at: <http://klfmenu.med.va.gov>.*

(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. **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.*

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. ACTION

a. **VA Central Office PAVE Oversight Committee.** The VA Central Office PAVE Oversight Committee, 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, and other subsequently identified representatives, is responsible for:

(1) Communicating to the Office of Rehabilitation Services on its activities.

(2) Selecting 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 National High Risk Amputation Registry, VSSC Clinical Programs ProClarity Cube at: <http://klfmenu.med.va.gov>.*

(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 National*

VHA DIRECTIVE 2012-020

August 20, 2012

*Amputation and Ulcer Data Base, VSSC Clinical Programs ProClarity Cubes at:
<http://klfmenu.med.va.gov>.*

(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 PAVE Oversight Committee for program improvements to effect excellence in patient-centered care.

b. **National PAVE Director, Director, Podiatry Service.** The National PAVE Director is the Director, Podiatry 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 surveys, and

(3) Providing a national PAVE Annual Report for the VA Central Office PAVE Oversight Committee 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. **VISN Directors.** The VISN Director is responsible for:

(1) Ensuring that each 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. **Facility Director.** The Facility Director is responsible for ensuring 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 had 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 in existing primary amputation prevention committees within the medical centers.*

e. **Facility Chief of Staff (COS)**. The Facility 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 data set must include, at a minimum, baseline tracking data as well as demographics, foot risk score, prosthetic provision and hospital utilization.*

(5) Ensuring an annual outcome evaluation of the PAVE Program, including a review of local facility and VISN amputation rates for both diabetic and non-diabetic populations.

(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 Att. A).

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

(1) Tracking patients with amputation, or those at risk of limb loss, from the day of entry into the VA health care system through all appropriate care levels.

(2) Functioning as:

(a) Organizational support for the PAVE team,

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

(c) Facilitator for a smooth transition of the DOD patient into the VA health care system.

VHA DIRECTIVE 2012-020

August 20, 2012

5. REFERENCES

a. 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

b. VHA Handbook, 1173.9.

6. FOLLOW-UP RESPONSIBILITY: The Office of Rehabilitation Services and Office of Patient Care Services is responsible for the contents of this Directive. Questions may be addressed to the Director, Podiatry at (202) 231-3286.

7. RESCISSIONS: VHA Directive 2006-050 is rescinded. This Directive expires August 31, 2017.

Robert A. Petzel, M.D.
Under Secretary for Health

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ATTACHMENT A

SUGGESTED BRIEF FOOT CHECK RECOMMENDATIONS

1. BRIEF FOOT CHECK. 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. FOOT EXAMINATION. 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.

3. RISK ASSESSMENT LEVEL. "At-risk" is defined as patients with diabetes, peripheral vascular disease and end stage renal disease, 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 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:

VHA DIRECTIVE 2012-020

August 20, 2012

(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 subpar. 3d(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 subpar. 3d(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) 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) More frequent clinic visits are required with careful observation, regular preventive foot care, and footwear modifications to 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 ½ inches or greater (refer to VHA Handbook, 1173.9).

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 MI and as such aggressive smoking cessation counseling is recommended.

5. SUGGESTED REFERRAL STRATEGY

a. At the 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 can be referred to a diabetes educator.

(3) Refer, if appropriate, to 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 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.

(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.

VHA DIRECTIVE 2012-020

August 20, 2012

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 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; and
- (5) 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.