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PRESERVATION-AMPUTATION CARE AND TREATMENT (PACT) PROGRAM

1. PURPOSE: This Veterans Health Administration (VHA) Directive expands the scope of the care and treatment provided to veteran patients at risk of limb loss or with a history of amputation(s) through the Preservation-Amputation Care and Treatment (PACT) Program.

2. BACKGROUND

a. Throughout the history of the Department of Veterans Affairs (VA), the care that is provided to veterans with amputations has always been among our highest priorities. To many Americans, the veteran with an amputation epitomizes the sacrifices made on our Nation's behalf. Consequently, 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 the 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. It also chartered, by law, the Advisory Committee on Prosthetics and Special-Disabilities Programs. *NOTE: The Committee reports annually to the Secretary of Veterans Affairs on the effectiveness of such programs.*

c. VA's PACT Program 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 represents a model of care developed to prevent or delay amputation through pro-active early identification of patients who are at risk of limb loss. The problems encountered by patients with diabetes best demonstrate the need for this program. The Centers for Disease Control and Prevention (CDC) estimate that approximately 15 percent of individuals with diabetes develop foot ulcers, and it is estimated that 15 to 20 percent of those ulcers will result in lower extremity amputations. Presently, VHA is faced with increasing numbers of traumatic amputations from the battlefield, with many of these soldiers leaving the military and coming to the VA for care. VHA is preparing for the unique needs of these patients and adapting the VHA system to ensure that these patients receive optimal medical and compassionate patient-centered care.

(1) Prior to implementation of the PACT Program, approximately 9,000 amputations were performed each year at VHA medical centers. Since implementation of the PACT Program, total amputations have decreased to less than 5,500 per year. More impressive is an overall decline in amputation rates from 8.05 in 1999 to 3.94 in 2005 (age standardized and 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 Data Web Site at: <http://vaww1.va.gov/vhaamputationdata>) .

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(2) With the estimated cost of care associated with amputation ranging from \$40,000 to \$75,000, effective prevention should also lead to substantial economic benefit to VHA. Although these numbers are impressive, the Healthy People 2010 Workgroup estimates that 50 percent of all amputations performed on individuals with diabetes can be prevented with proper professional foot care and patient education, including the use of prescription drugs and the use of appropriate footwear to permit healing and/or prevent diabetic foot ulcers. As a result, the PACT initiative provides local, Veterans Integrated Services Network (VISN), and VHA Central Office leadership with an excellent opportunity for collaborative performance improvement.

d. The PACT Program provides a model of care for those patients “at-risk” for amputation and for those who have already suffered an amputation. Utilizing a Team Coordinator, it incorporates interdisciplinary management of care utilizing available resources including 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. It tracks every patient with amputation, or those at risk of limb loss, from day of entry into the VA health care system, through all appropriate care levels.

3. POLICY: It is VHA policy that a PACT Program be established at each VA medical centers.

4. ACTION

a. **VHA Central Office PACT Oversight Committee.** The Offices of Acute Care and Rehabilitation in Patient Care Services, including the Director of Podiatry Service, (who serves as the Committee Chairperson), the Director of Surgical Service, and the Director Physical Medicine and Rehabilitation, are responsible for oversight of the PACT Program. Responsibilities include administrative management of the PACT Program and development of critical pathways, clinical recommendations for quality indicators of care, and performance measures. The Committee Chairperson is responsible for updates to the Advisory Committee for Prosthetics and Special Disabilities when such updates are requested. The Committee communicates about its activities with the Chief Consultant for Rehabilitation Services. *NOTE: This case management oversight will complement the activities of the medical center treatment staff and Amputee Clinic Team and is not meant to replace or be counterproductive to any phase of clinical patient care.*

b. **VHA Central Office Multidisciplinary PACT Committee**

(1) The VHA Multidisciplinary PACT Committee, made up of clinical leaders from endocrinology and/or diabetes, podiatry, Physical Medicine and Rehabilitation (PM&R), Prosthetics, nursing, the VISNs, Office of Quality and Performance (OQP), and other subsequently identified representatives, is responsible for advising the VHA PACT Oversight Committee on recommendations for data collection and analyses to permit program evaluation of the screening, surveillance, salvage, and rehabilitative components of the PACT Program, including:

(a) Identification of veterans at risk for or who have sustained an amputation (see the National High-risk Amputation Registry).

(b) Age adjusted and stratified rates of major (above the knee amputations (AKA) and below the knee amputations (BKA)) and minor amputations, and lower extremity non-venous ulcers at VISN and facilities (see the National Amputation and Ulcer Data Base).

(c) Patient knowledge and performance of recommended self foot care practices, and their satisfaction with foot care.

(d) VISN and facility adherence to the PACT Directive with respect to formal policies and coordination strategies (see National PACT Survey of the Field)

(2) The PACT Committee uses these analyses to identify best practices from the field, and to make recommendations to achieve excellence in patient-centered care to the PACT Oversight Committee for program improvements

c. **VISN Director.** The VISN Director is responsible for:

(1) Ensuring that each medical center within the VISN has a formal PACT Program.

(2) Reviewing the annual PACT report to assess program status and for objectively defining any further evaluation and restructuring of local PACT program initiatives.

(3) Improving performance of the External Peer Review Program (EPRP) measures relating to screening of veterans for foot risk, and for ensuring that such individuals are receiving foot care appropriate for their risk level.

d. **Facility Director.** The Facility Director, or designee, is responsible for:

(1) Ensuring that a PACT Program is established. This must be done in collaboration with any existing amputee clinic team or other relevant primary care clinics, and will be used 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.

(2) Ensuring that the PACT Program contains, at a minimum:

(a) Screening of at-risk populations, i.e., veterans with diabetes, peripheral vascular disease, end-stage renal disease (ESRD), or other conditions that increase susceptibility to amputation risk (see Att. A.).

(b) Identification of high-risk patients, based upon foot risk factors that would determine the appropriate care and/or referral. (see Att B.).

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(c) Timely and appropriate referral and ongoing follow-up of patients based on an algorithm produced by the local PACT or Amputee Clinic Team (see Att. C).

(d) Offering each patient who has suffered an amputation a visit by the 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."*

(e) A system to identify and track patients with amputation or those at risk for amputation. *NOTE: The VA Central Office Patient Care Services High-risk Amputation Registry is an acceptable resource from which to develop such a system.*

(3) Designating a PACT Program Coordinator to provide for: *NOTE: The assignment of a coordinator would most appropriately be made from the Chief of Staff to an individual who is considered a "champion" for amputation care and prevention.*

(a) Organizational support for the PACT team,

(b) Communication conduit between administration and PACT and Amputee clinic team providers, and

(c) A smooth transition for the Department of Defense (DOD) patient into the VA system.

(4) Ensuring that the annual facility PACT report is completed by November 15 of each fiscal year and that it is forwarded to the VISN Director.

e. **Chief of Staff.** The facility Chief of Staff is responsible for:

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

(a) The formal identification of a PACT Coordinator,

(b) Ensuring availability of foot specialty care,

(c) Compliance with designated performance measurement (e.g., the EPRP), and

(d) Annual outcome evaluation of the PACT Program.

(2) 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.

(3) Defining local policy and care algorithms to:

(a) 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 should include, at a minimum, baseline tracking data as well as demographics, foot risk score, prosthetic provision and hospital utilization.*

(b) Evaluate annually the outcomes of the facility PACT Program, including a review of local facility and VISN amputation rates for both diabetic and non-diabetic populations. For those facilities noted to have higher than average amputation rates, the Chief of Staff's office needs to develop a formal performance plan to evaluate the program locally and provide evidence of the use of this data in subsequent program modulation.

(c) Ensure that facility screening guidelines regarding universal foot checks and foot screenings are developed and utilized by all clinicians providing principal care to patients at risk for amputation (see Att. A).

(4) Ensuring the National High Risk Amputation Registry is reviewed within 30 days of receipt and review of recommended actions.

(5) Meeting with PACT Coordinator to review the draft annual report and develop written actions for the annual report to be submitted to the VISN Director through the Medical Center Director.

5. REFERENCES

a. Singh, N, Armstrong, D, Lipsky, B: "Preventing Foot Ulcers in Patients With Diabetes," Journal of the American Medical Association (JAMA). January 12, vol 293, no2 p 217-228: 2005.

b. Boulton AJM, Vilekyte,L, Ragnarson-Tennvall, G, G, Apelqvist,J. "The Global Burden of Diabetic Foot Disease," Lancet. November 12, Vol 366, 2005.

c. Tennvall, GR, Apelqvist, J, Eneroth, M. "Costs of Deep Foot Infections in Patients with Diabetes Mellitus," Pharmacoeconomic. Sept;18(3):225-38: 2000.

d. Gordior A. Scuffham P. Shearer A. Oglesby A. Tobian JA.: "The Health Care Costs of Diabetic Peripheal Neuropathy in the US," Diabetes Care. Jun 26(6):1790-5: 2003.

e. Peters, EJG, Lavery, LA: Effectiveness of the Diabetes Foot Risk Classification System of the International Working on the Diabetic Foot, Diabetes Care. Volume 24, Number 8, August, 2001.

f. VHA Prosthetic Clinical Management Program: Clinical Practice Recommendations on the Prescription and Issuance of Diabetic Socks, dated February 25, 2002.

g. VHA Handbook 1173.1.

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h. VHA Handbook, 1173.9, Footwear and Foot Orthoses.

i. American Diabetes Association. "Peripheral Arterial Disease in People with Diabetes. (Consensus Statement)," Diabetes Care. 26 (12): December 2003.

j. AHA Practice Guidelines For the Management of Patients With Peripheral Arterial Disease. Hirsch et al 2005.

k. Mayfield JA, Reiber GE, Sanders LJ, Jannisse D, Pogach L. "Preventive Foot Care in People with Diabetes," American Diabetes Association Technical Review. Diabetes Care 21(12): 2161-2177, December 1998.

6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant for the Rehabilitation Services (117) is responsible for the contents of this Directive. Questions may be addressed to 202-273-8486.

7. RESCISSIONS: VHA Directive 96-007 is rescinded. This Directive expires on September 30, 2011.

S/Michael J. Kussman, MD, MS, MACP
Acting Under Secretary for Health

DISTRIBUTION: CO: E-mailed 9/15/06
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ATTACHMENT A

SUGGESTED SCREENING RECOMMENDATIONS

1. FOOT SCREENING

Foot screening involves:

- a. Visual inspection of the skin surface for any lesions, deformities, color, temperature changes, or ulcers;
- b. Screening 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.

2. FOOT EXAMINATION

The foot examination 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., Preservation-Amputation Care and Treatment (PACT) program member, vascular surgeon, podiatrist, or other health care professional demonstrating appropriate education, training, competencies, and licensure necessary to provide such care.

ATTACHMENT B

RISK ASSESSMENT LEVEL

NOTE: 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.

1. DEFINITIONS

- a. **At-risk.** "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.
- b. **High-Risk.** "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.
- c. **Diabetic Socks.** Diabetic socks are defined as hosiery specifically designed to reduce pressure or friction to the foot (see VHA Prosthetic Clinical Management Program: Clinical Practice Recommendations: Diabetic Socks see: <http://vaww1.va.gov/prosthetics/docs/FinalCPRDiabeticSocks.pdf>).
- d. **Depth Inlay Shoes.** Depth Inlay Shoes 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 VHA Handbook, 1173.9).
- e. **Custom-molded Orthopedic Shoes.** 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 a shortening of a leg at least 1 and ½ inches or greater (see VHA Handbook, 1173.9).

2. LEVEL 0, NORMAL-RISK

These patients at Level 0 normal risk have no evidence of sensory loss, diminished circulation, foot deformity, ulceration, or history of ulceration or amputation. Although these patients do not require therapeutic footwear, patients with diabetes need to receive foot care education and annual foot care.

3. LEVEL 1, LOW-RISK

Individuals at Level 1, normal risk, demonstrate one or both of the following:

- a. 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), or

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b. Foot deformity or minor foot infection (and a diagnosis of diabetes). Patient education and preventative care 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; however, these individuals do not need therapeutic footwear.

4. LEVEL 2, MODERATE-RISK

a. Individuals at Level 2, moderate risk, demonstrate sensory loss (i.e., the 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); or

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

b. Individuals at Level 2, moderate risk, 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 care, and annual foot screening are required. Patient health education (PHE) must include the implications of sensory loss and the importance of daily foot inspections. *NOTE: The patient may require Diabetic Socks and Depth Inlay Shoes based on clinical judgment.*

5. LEVEL 3, HIGH-RISK

a. Individuals at Level 3, high risk, demonstrate peripheral neuropathy with sensory loss (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 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.

(4) End-stage Renal Disease.

b. Individuals at Level 3, high risk, are at highest risk of lower-extremity events. 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.). More frequent clinic visits are required with careful observation, regular preventive foot care, and footwear modifications. *NOTE: Based on clinical judgment, the patient may require Diabetic Socks, Depth Inlay Shoes, or Custom-Molded Orthopedic Shoes.*

6. INDIVIDUAL WITH TRAUMATIC AMPUTATION

In the case of the individual with traumatic amputation, at least one follow-up visit annually to evaluate prosthetic fit and componentry, maintain optimal functional status, and prevent or treat secondary complications is required. The follow-up visit is best made through a direct consultation in the clinic involving the amputation clinic team, but may occur or through a telephone consultation.

ATTACHMENT C

SUGGESTED REFERRAL STRATEGY

1. **Level 0, Normal-Risk.** These patients need to be screened annually and need:
 - a. Patient education and self care instruction.
 - b. Appropriate care for their systemic conditions.

2. **Level 1, Low-Risk.** These patients need to be screened annually and need:
 - a. Patient education and self care instruction
 - b. Appropriate care for their systemic conditions.
 - c. Non-invasive vascular laboratory testing to determine the degree of circulatory impairment if there is evidence of impaired circulation on the screening exam
 - d. Referral to vascular surgery if diminished circulation
 - e. Referral to podiatry or foot care specialist for examination if deformity exists.
 - f. Referral to podiatry or foot care specialist for examination may be appropriate if the screening results in findings suggestive of loss of protective sensation, poor circulation or foot deformity.

3. **Level 2, Moderate-Risk.** These patients need to be screened annually, and need:
 - a. Patient education and self care instruction
 - b. Appropriate care for their systemic conditions.
 - c. Refer to podiatry or foot care specialist for examination and care.
 - d. Non-invasive vascular laboratory testing to determine the degree of circulatory impairment if there is evidence of impaired circulation on the screening exam
 - e. Referral to vascular surgery if diminished circulation
 - f. Therapeutic footwear and orthoses to accommodate foot deformities, to compensate for soft tissue atrophy, and to evenly distribute plantar foot pressures.

4. **Level 3, High-Risk.** The Level 3, high-risk patient needs:
 - a. Patient education and self care instruction

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- b. Appropriate care for the patient's systemic conditions.
- c. Referral to podiatry or foot care specialist for examination and care.
- d. Non-invasive vascular laboratory testing to determine the degree of circulatory impairment if there is evidence of impaired circulation on the screening exam
- e. Referral to vascular surgery if diminished circulation
- f. Therapeutic footwear and orthoses provided to accommodate foot deformities, to compensate for soft tissue atrophy, and to evenly distribute plantar foot pressures.
- g. Immediate referral, as indicated, if acute condition is present.
- h. Evaluation for secondary complications and referral to the appropriate discipline.



VHA Amputation Data

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Charts on Inpatient Amputation Care

Medical Data Limitations:

The Office of Patient Care Services website has been designed to provide information to VHA healthcare professionals, support networks, and other interested audiences. These data include only those amputations occurring within VA facilities and do not include any procedures occurring outside VA facilities within the private sector. Users are encouraged to read the Methodology Section on this Website before attempting to interpret findings. Some factors influencing these results are not known. These factors include: case-mix, PACT/foot-care programming, and surgical limb salvage capabilities.

- Choose if you want Amputation Rate Calculations or Amputation Ratio Calculations
- Make a selection from each dropdown list below that category.
- Multiple values for YEARS and VISN may be chosen by pressing the *cntr + left mouse button*.
- To view the graphs in a Printer-Friendly version, make sure the Printer-Friendly Graphs checkbox is checked.
- To provide any feedback or suggestions regarding the VHA Amputation Data application, please contact [Patient Care Services](#).

Amputation Rate Calculations		Amputation Ratio Calculations	
YEARS:	Note: Facility amputation rate information provided for site specific information purposes only. Small cohort sizes and inter-facility transfer practices do not support inter-facility comparisons.	AGE:	<input type="text"/>
	<input type="text"/>	All Age Groups	
	VISN:	Select Age Group	
	<input type="text"/>	RATE:	
	FACILITY:	AMPUTATION TYPE:	
	<input type="text"/>	COHORT:	

Printer-Friendly Graphs

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