Supplemental Materials

Michael E. DeBakey Veterans Affairs Medical Center

Houston, Texas

Countless health care providers and other individuals have contributed to the clinical care of patients with foot ulcers in the Michael E. DeBakey Veterans Affairs Medical Center and associated outpatient clinics during the past decade. We appreciate the efforts of all these individuals. Here we recognize the individuals who have been members of teams that are a regular part of multidisciplinary care for foot ulcer patients or who have made other contributions to the system of care for foot ulcer patients or to our improving our understanding of the disease process. Listed by specialty, then alphabetically by last name:

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The Evolution of Our Evidence-Based Practices

This summarizes many examples of how our clinical practice and our research efforts have informed one another and how these findings are applied to our clinical management. We focus on the published research of our clinicians not for self-promotion but rather to provide specific examples of how the interrelationship between research and clinical practice improves each.

Management of Foot Infection

Because of our vascular team's ownership of limb salvage, we have had a primarily surgical approach to the management of foot infections, including osteomyelitis. Specifically, 92% of our patients have had surgical biopsies and cultures taken as part of their operative treatment. These have been used to select an antimicrobial regimen directed to the organisms identified. Antimicrobial regimens have consisted predominately of oral antibiotics (95%) since 2011[1]. Ceftriaxone is the primary empiric antibiotic given to patients who have not yet had operative treatment or whose culture results are pending. We use empiric vancomycin only for patients who have a positive nares swab or who have clinical signs of an abscess based on prevalence rates we found in a prior analysis. Finally, contrary to guidelines emphasizing the importance of Gram positive organisms, our analyses have shown that Gram negative organisms are associated treatment failure[2] and that methicillin-resistant Staphylococcus aureus is not[3]; for this reason, we have focused more attention on improving outcomes in patients with these organisms. We re-biopsy if treatment failure occurs, as we have observed shifts in microbial species involved during treatment[4].

We have made novel contributions to understanding the systemic impact of foot infection. Specifically, we first described acute kidney injury associated with foot osteomyelitis in 2017[5]. We use the presence of acute kidney injury as a clinical sign of foot infection, we have modified our selection of inpatient and outpatient antibiotics accordingly (selective use of vancomycin based on the aforementioned factors, minimizing use of sulfamethoxazole and trimethoprim). We have also described acute cardiac complications (new myocardial infarctions, worsening heart failure, and new arrhythmias) occurring with severe foot infections[6]. Although the prevalence was only 6.6% among the 274 patients analyzed, patients with these new cardiac events have a significantly higher 1 year mortality. We therefore consult our medical teams for further cardiac workup when acute cardiac complications are seen. Lastly, we've described an unusual syndrome of severe anemia, weight loss, hyponatremia, hyopalbuminemia, and uremia and other metabolic derangements occurring in a series of patients with beta-hemolytic streptococci[7]. We are particularly aggressive in controlling infection in patients with this constellation of findings.

The Identification of Peripheral Artery Disease

Our approach to identifying peripheral artery disease (PAD) has also evolved based on research findings. With award funding from the Society for Vascular Surgery, we performed a formal decision analysis with a probabilistic Markov which we expected would support our approach at that time: selective angiography done based on the results of non-invasive arterial testing (specifically, toe pressure <60mmHg). Findings from the analysis, however, suggested that the sensitivity in identifying PAD might be increased by deciding on angiography simply based on weak or absent pedal pulses and using non-invasive testing to instead corroborate adequate arterial perfusion in patients with palpable pedal pulses[8]. These findings have now been corroborated in an observational study[9].

Decision Making: Revascularization and Limb Salvage vs. Leg Amputation vs. Palliative Wound Care

We generally pursue revascularization and limb salvage – even in patients with advanced comorbidities[10] or marginal functional status[11]. We favor endovascular interventions, however, for patients with end-stage renal disease[12].

Leg amputation is generally still the only alternative that many surgeons provide to patients who are not candidates for revascularization and limb salvage. It had been

ours prior to an aforementioned cost-utility study. In this study, wound care alone (i.e. without revascularization) was included as a strategy analyzed with the intent of demonstrating the clinical harms associated with missing the diagnosis of PAD. Unexpectedly, the model predicted the strategy of wound care alone would actually produce better health outcomes and lower total costs than leg amputation[13]. We subsequently reported outcomes of this "palliative wound care" alternative to leg amputation for a selected group of patients with advanced comorbid conditions; these research findings[14] and much more clinical experience since have confirmed that it is indeed a good and generally preferable alternative to leg amputation.

Leg amputation is typically now recommended to patients who are not a candidate for revascularization and limb salvage but have one or more of the following characteristics: infection that is not controlled by surgical therapy (e.g. minor amputation) and limited-course antibiotics and causing secondary infection or other systemic effects (ex. weight loss, anorexia, malaise); pain that is not controlled by medications or image-guided nerve injections; wounds that patients or care providers cannot or will not manage due to voluminous fluid output or foul odor; or mobility that is impaired by the foot wound and that may improve with leg amputation.

Revascularization for PAD

Our approach to treating PAD has been informed by cost-utility studies that suggest infrainguinal bypass may be more clinically effective and cost-effective that endovascular intervention[13]. Spliced vein conduits seem better in patients without adequate single-segment saphenous vein, but bypasses done with polytetrafluoroethylene (PTFE) and a distal vein patch provide good outcomes too[15,16]. In 2011, cryopreserved allograft vein was the conduit used for 9% infrainguinal bypasses, but this has been eliminated because of findings suggesting it was associated with poorer clinical outcomes and higher costs@ [15]. Similarly, we reduced the usage of stent-grafts used in infrainguinal endovascular interventions from 28% in 2011 to 9% in 2017 and <5% currently based on findings suggesting a significantly poorer patency and higher rate of acute limb occlusion with these devices[17]. We employ bundled interventions (pre-operative nasal and skin decontamination for methicillin-sensitive Staphylococcus aureus, routine perioperative antibiotics, chlorhexidine/alcohol [ChloraPrep™] skin preparation, wound closure using subcuticular sutures, and incisional negative pressure wound therapy dressings for groin wounds) that has lead to a 5-fold reduction in superficial or deep surgical site infections[18].

We have employed a strategy of surgical closure of many foot wounds early after revascularization[19]. This approach was initially based on the post-operative care of the incident foot ulcer being identified as a cost-driver for the overall strategy of revascularization and limb salvage[13].

Ensuring Adequate Access to Timely Specialty Care

Data available through the VHA Support Service Center helped us recognize that our hospital system had half the number of podiatrists and also lower rates of podiatry clinic visits for veterans at moderate and high risk (PAVE II and III, respectively) than VHA hospitals of comparable size. We proposed an action plan that has resulted in successfully hiring two additional podiatrists, and we have a plan to increase the frequency of podiatry clinic visits for these at-risk patients.

We have done work with state-level data has helped us identify groups of people within Texas who experience high rates of leg amputation: persons categorized as black or Hispanic and persons living in specific geographic locations[20–23]. Based on findings suggesting higher rates of leg amputations and poorer access to specialty care among people in east Texas, one of the authors (N.R.B.) began seeing vascular surgery patients at VHA community-based outpatient VHA clinic in Lufkin, a town of 35,000 people located 127 miles from Houston.

Primary Prevention of Foot Ulcers

Data analyses have helped us direct our primary prevention efforts. An economic model suggested that primary prevention efforts had a much higher potential for cost-savings that limb salvage treatment, including efforts that might be low effectiveness but have low cost[24]. Based on this, we developed a 500-word plain language

trifold brochure that discusses preventative care actions[25].

With the help of the information technology specialists, we generated lists of veterans of all races/ethnicity living in high amputation-rate zip codes in our region and mailed them our brochures with an explanatory cover letter, timed along with April as "Amputation Awareness/Prevention Month." We have now completed two rounds of mailings, with brochures and letters sent during the last round to 3,512 veterans. Several of our specialty clinics have in-person or video-based outpatient clinic within the identified area of high amputation rates.

Supplemental References:

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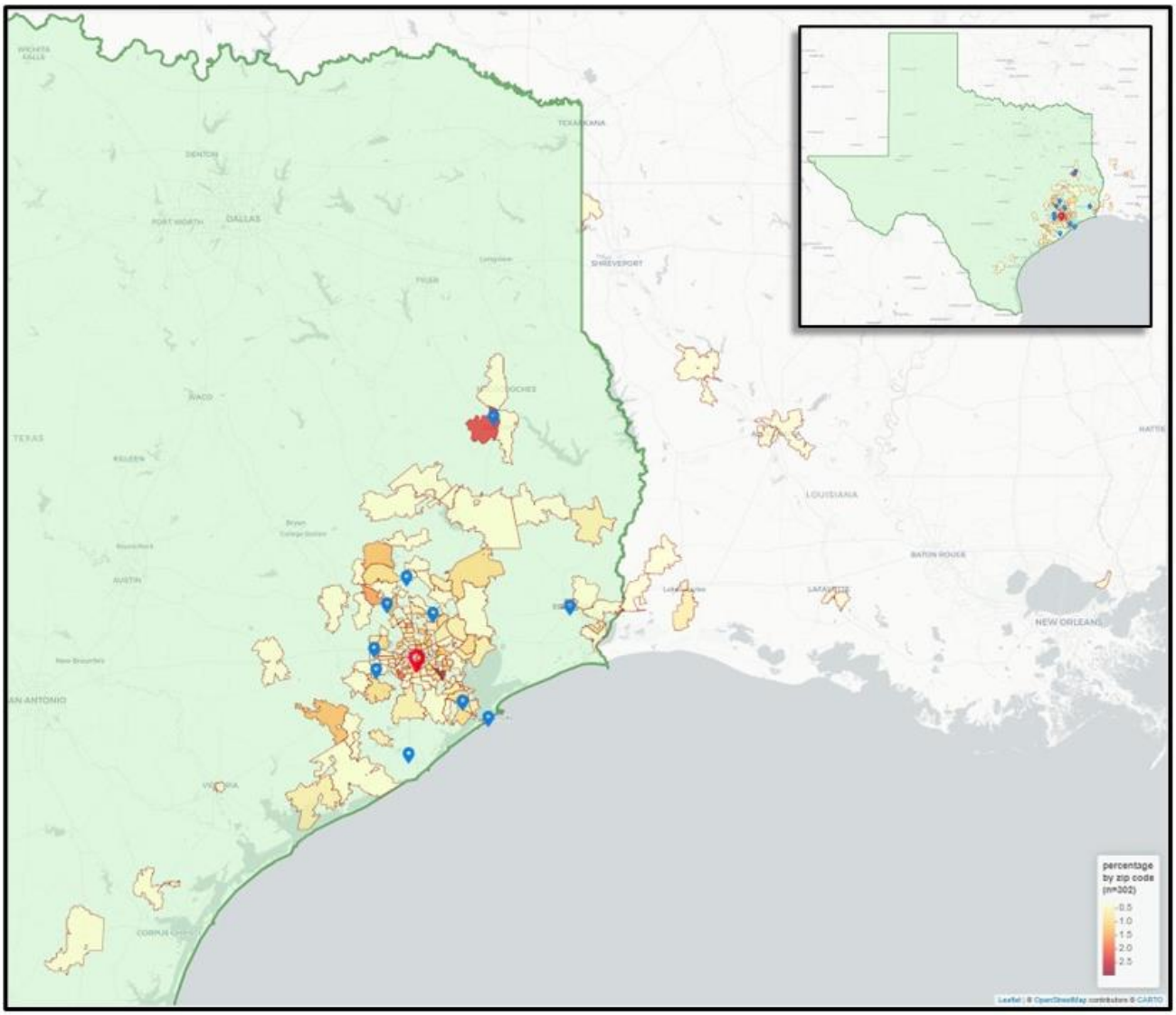
Supplemental Table 1: Comparison of sex- and zip code-matched cohorts of patients with foot ulcers treated at the Michael E. DeBakey Veterans Affairs Center (MEDVAMC; n=100) versus at other non-federal hospitals in Texas (n=200).

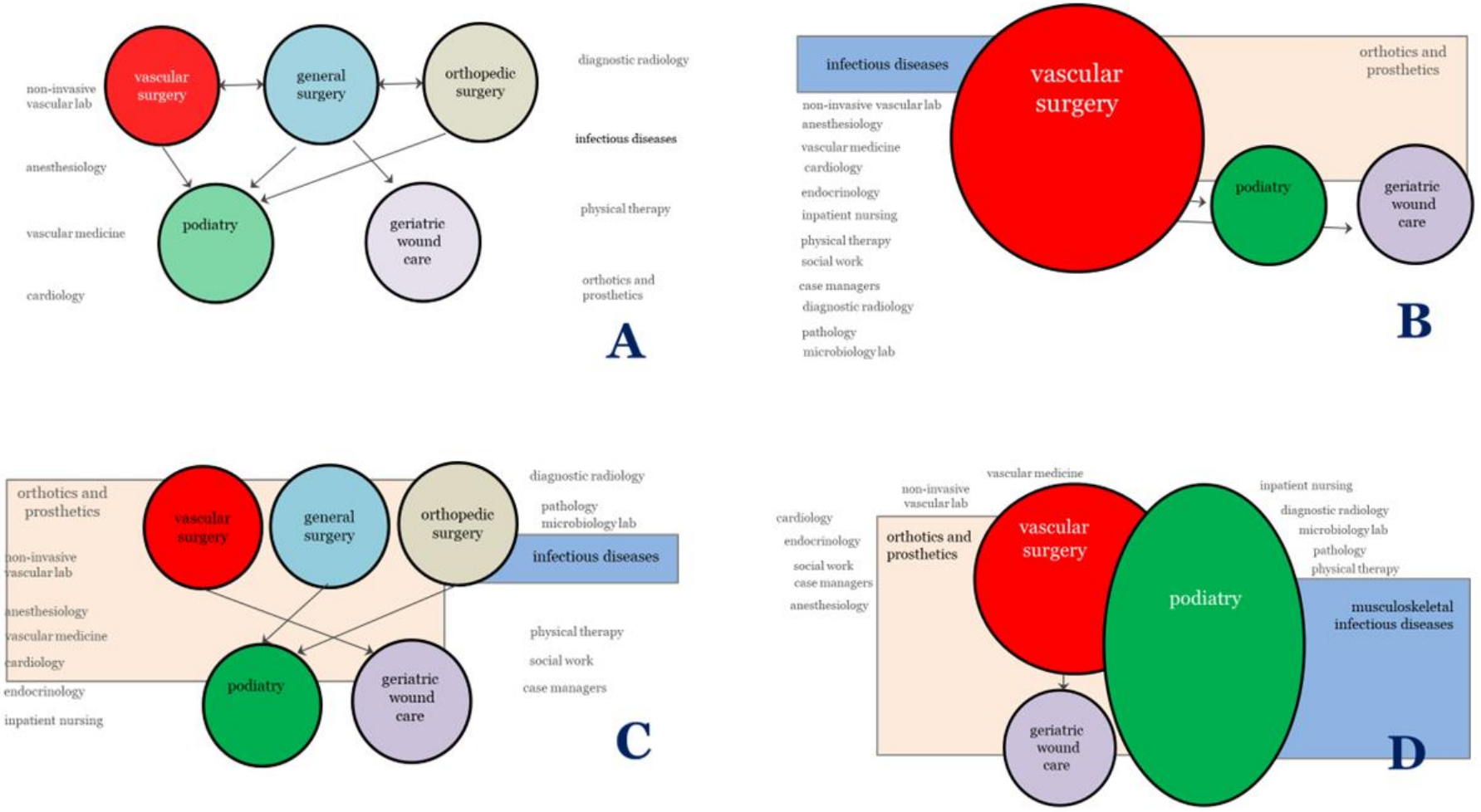
characteristic	MEDVAMC (N=100)	non-VA (N=200)	p value
male gender	99 (99.0%)	198 (99.0%)	1.000
patient age			< 0.001
- 45-49	0 (0.0%)	16 (8.0%)	
- 50-54	2 (2.0%)	16 (8.0%)	
- 55-59	3 (3.0%)	32 (16.0%)	
- 60-64	25 (25.0%)	24 (12.0%)	
- 65-69	18 (18.0%)	19 (9.5%)	
- 70-74	23 (23.0%)	26 (13.0%)	
- 75-79	19 (19.0%)	25 (12.5%)	
- 80-84	5 (5.0%)	17 (8.5%)	
- 85-89	3 (3.0%)	17 (8.5%)	
- 90+	2 (2.0%)	8 (4.0%)	
race			< 0.001
- White	50 (50.0%)	112 (56.0%)	
- Black	46 (46.0%)	43 (21.5%)	
- Native American	2 (2.0%)	0 (0.0%)	
- Asian or Pacific Islander	0 (0.0%)	2 (1.0%)	
- unknown	2 (2.0%)	43 (21.5%)	
ethnicity			0.010
- not Hispanic	95 (95.0%)	165 (82.5%)	
- Hispanic	5 (5.0%)	33 (16.5%)	
- unknown	0 (0.0%)	2 (1.0%)	
foot infection	39 (39.0%)	46 (23.0%)	0.004
ulcer located on heel	18 (18.0%)	67 (33.5%)	0.005
diabetes mellitus	84 (84.0%)	138 (69.0%)	0.005
chronic kidney disease	50 (50.0%)	66 (33.0%)	0.004
end-stage renal disease	17 (17.0%)	43 (21.5%)	0.358
systolic heart failure	28 (28.0%)	35 (17.5%)	0.035
>40 mile travel to treating hospital	22 (22.2%)	21 (10.7%)	0.008

MEDVAMC, Michael E. DeBakey Veterans Affairs Medical Center

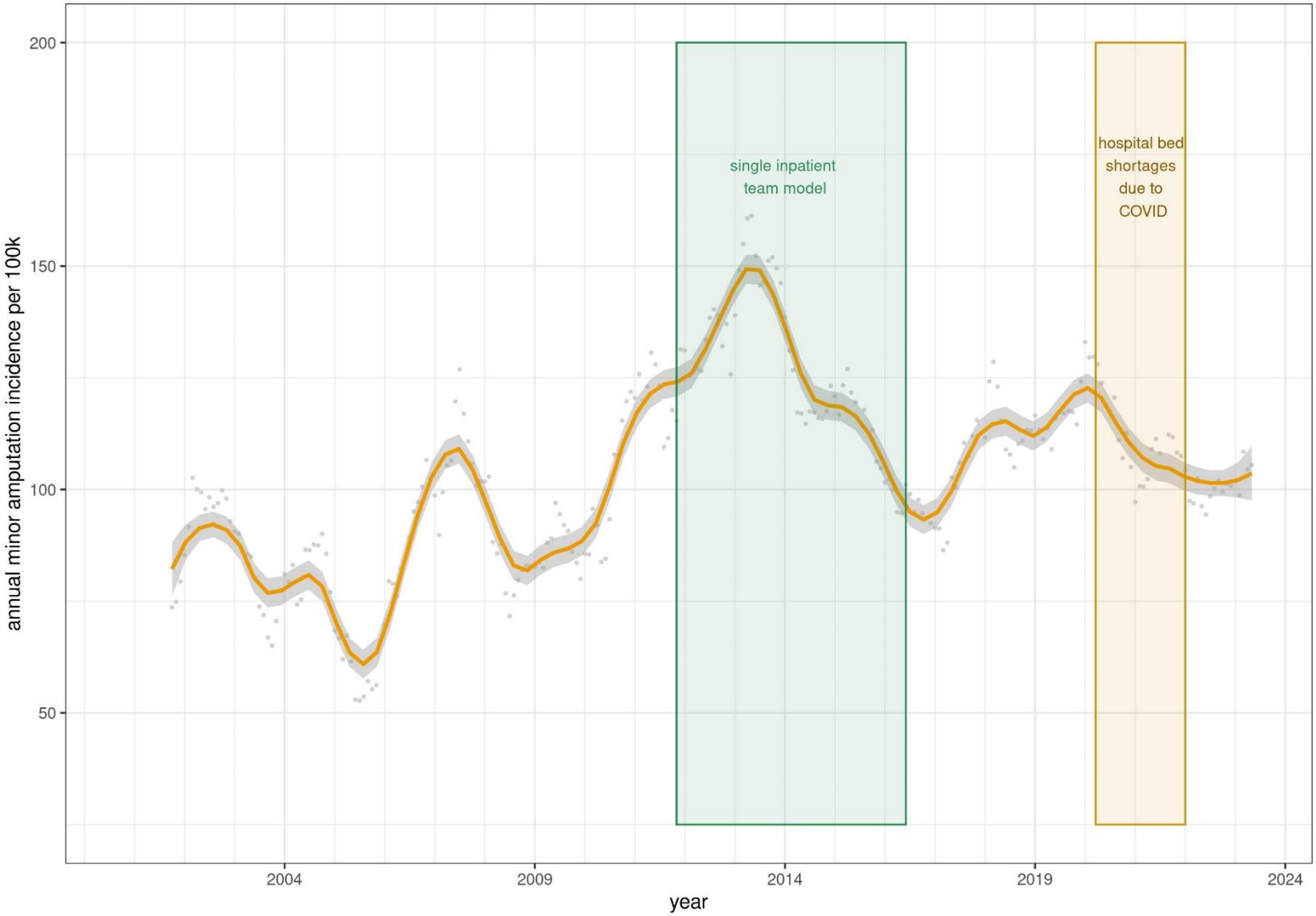
Supplemental Figure A: MEDVAMC limb salvage patients and treatment locations. Green shows the state of Texas and its border. Red marker shows location of MEDVAMC in central Houston; additional blue markers show the locations of the ten Community-Based Outpatient Clinics (CBOCs) associated with MEDVAMC. The heat map (yellow-orange-red coloring) shows the zip code of residence for Veterans treated for foot infection and limb salvage at MEDVAMC, demonstrating an encashment area spanning from the mid-coastal Texas in the southwest, southeastern Louisiana to the west, and Alexandria, Louisiana to the north. Inset demonstrates the southeast Texas region of interest.



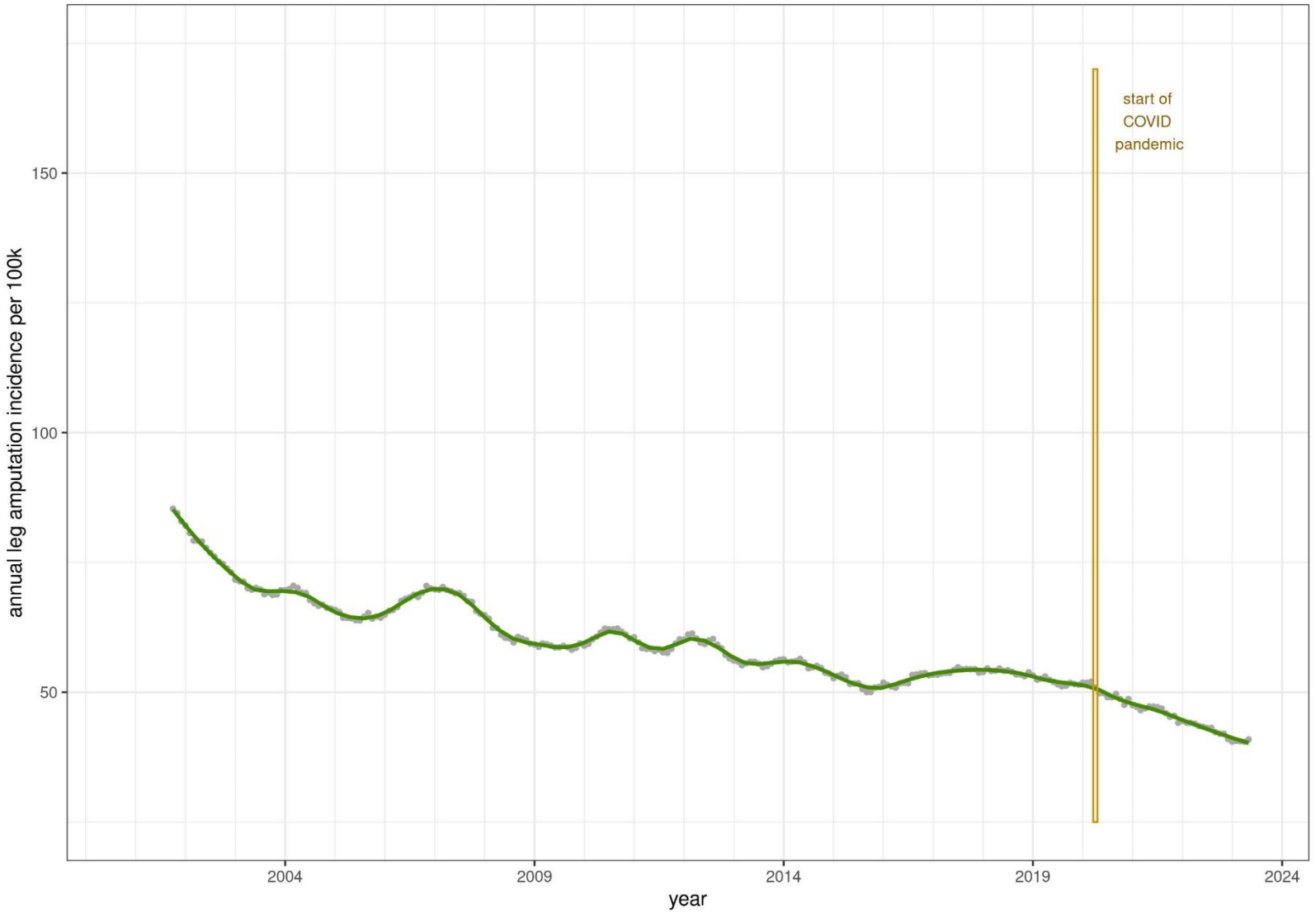
Supplemental Figure B: Inpatient specialty team involvement in limb salvage efforts at MEDVAMC, 2001 to 2023. Circle size demonstrates patient volume, arrows denote referrals, and overlap denotes multidisciplinary management.



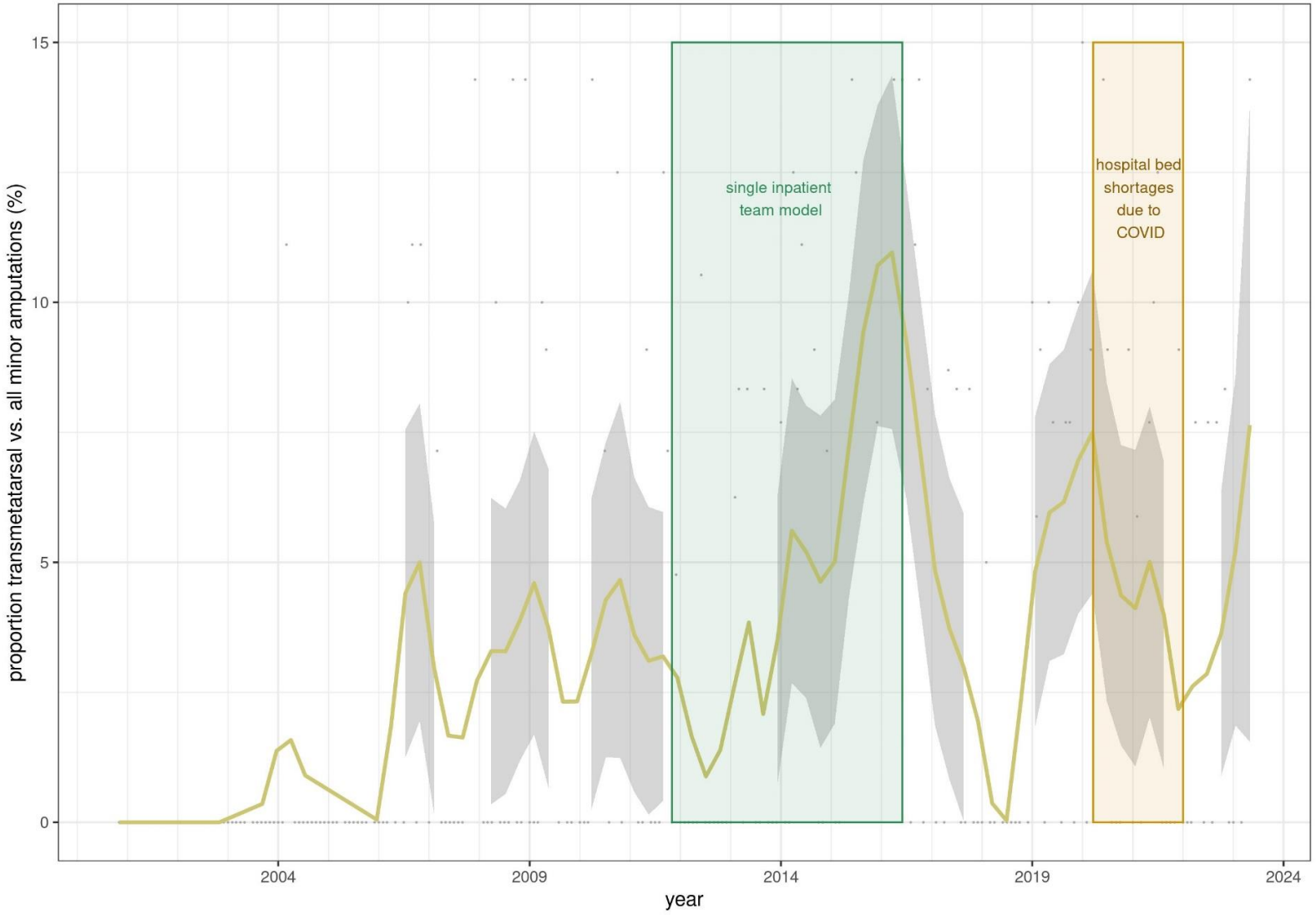
Supplemental Figure C: Rolling 12-month incidence rate of minor amputations (per 100K persons) at MEDVAMC, 2001 to 2023.



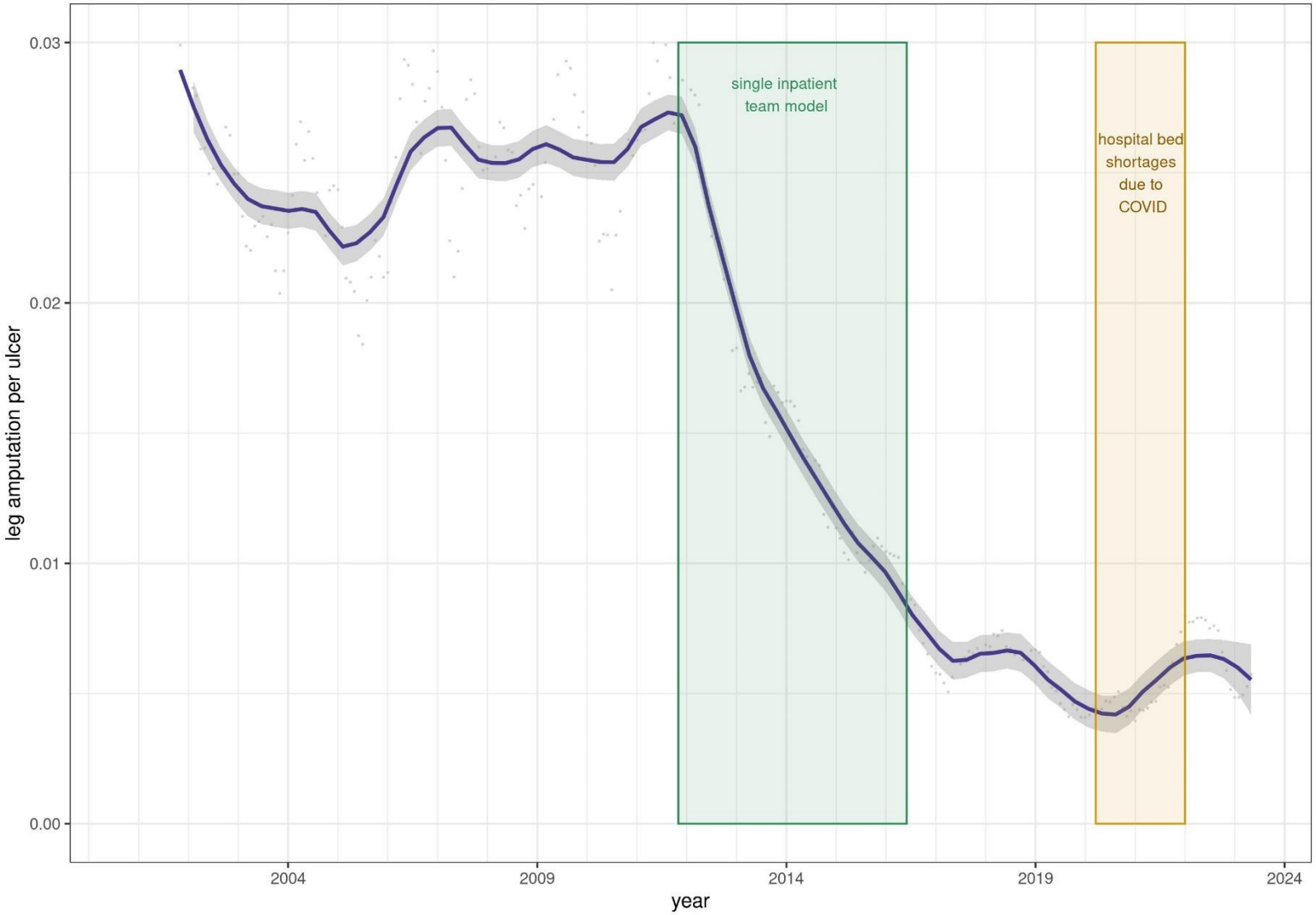
Supplemental Figure D: Rolling 12-month incidence rate of major amputations (per 100K persons) in the VHA system, 2001 to 2023.



Supplemental Figure E: Rolling 12-month proportion of minor amputations done as transmetatarsal (all-toe) amputations at MEDVAMC, 2001 to 2023.



Supplemental Figure F: Rolling 12-month ratio of leg (major) amputations per foot ulcer at MEDVAMC, 2001 to 2023.



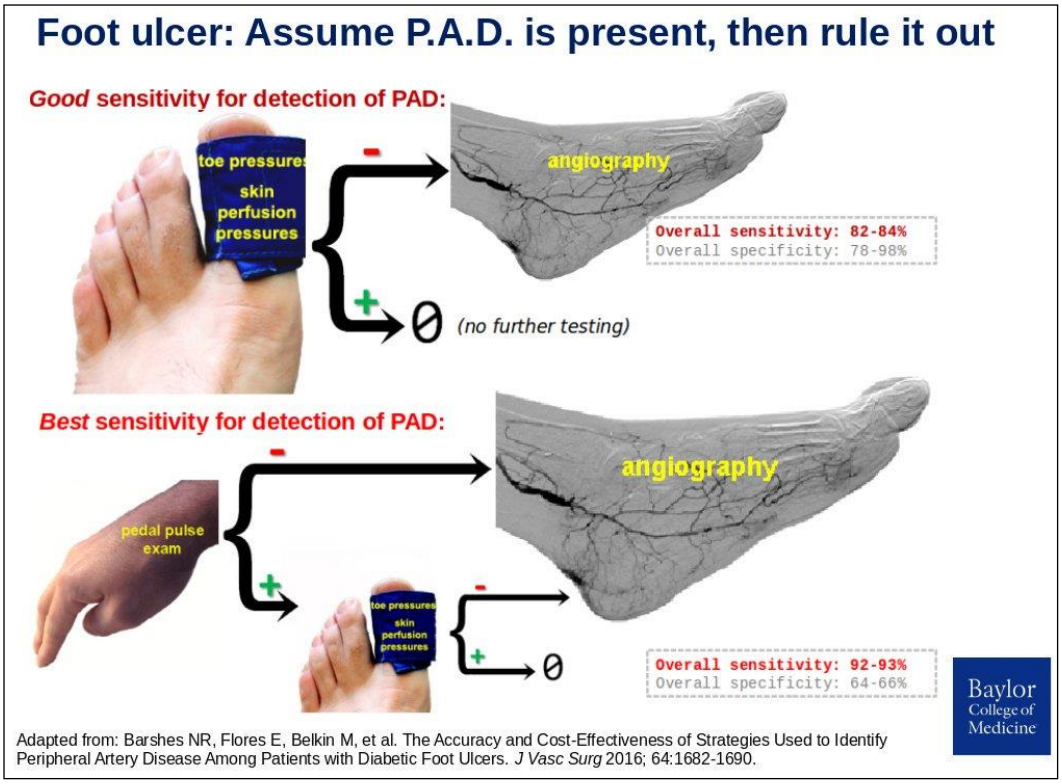
This document is intended to provide guidance for the evaluation of patients with non-healing foot ulcers. The goal of this guidance is to avoid delays in identifying underlying causes, to avoid delays in providing standard care, and to ensure the responsible utilization of health care resources. For the purposes of this guideline, a ***non-healing foot ulcer*** is defined as a full-thickness epithelial defect distal to the malleoli that demonstrates less a percent wound area reduction (PWAR) less than 50% over 4 weeks[1].

In brief**,** all patients with a non-healing foot ulcer should *at least* receive –within four weeks of meeting the definition of non-healing foot ulcer or within four weeks of initial visit – the following: (1) testing for peripheral artery disease; (2) a foot x-ray; and (3) an offloading calf-length boot.

1. Obtain either an ANGIOGRAM or TOE PRESSURES in <u>ALL</u> PATIENTS to evaluate for peripheral artery disease.

Digital subtraction angiography should be performed to ensure in-line flow to the affected angiosome(s) in the following circumstances[2]:

a) Pedal pulses are weak or absent
b) Toe pressures are <60mmHg or toe-brachial index of <0.7
c) Ulcer size >3cm
d) Infection requiring >3cm incision for drainage
e) Multiple foot ulcers
f) Ulcer located on foot rather than toe (i.e. midfoot, heel, dorsal foot)
g) Anticipated partial foot (transmetatarsal [all-toe] or Lisfranc) amputation.



If at least two other improvements in management can be made (ex. initiating optimal wound care + optimal offloading therapy) in patients with toe pressures >40mmHg AND a small (<3cm) toe ulcer, angiography should be scheduled in 4 weeks, allowing time to assess for >50% percent wound area reduction.

The use of toe pressures or a toe-brachial pressure index as a substitute for an angiogram should mainly be reserved for corroborating adequate arterial circulation in patients with at least one *normal* (2+ palpable) pedal pulse <u>AND</u> a small (<3cm) ulcer confined to a toe.

Patients with prior ipsilateral endovascular revascularization 6+ months ago should have toe pressures obtained. Patients with prior open surgical revascularization 6+ months ago should have a duplex ultrasound evaluation to ensure patency.

2. Obtain either an X-RAY, MAGNETIC RESONANCE IMAGING or BIOPSY for <u>ALL</u> PATIENTS to evaluate for osteomyelitis.

ALL patients with a non-healing foot ulcer should have radiographic imaging to evaluate for osteomyelitis. This evaluation should begin with plain x-rays (ordered as toes, foot, or heel, depending on the area) done within the past 30 days. Percutaneous bone biopsy or surgery should be considered for obvious bony deformities suspicious for osteomyelitis in an area contiguous with an ulcer.

Magnetic resonance imaging or percutaneus image-guided bone biopsy (with specimens for both pathology and microbiology) should be requested in the following situations: (1) wound probes to bone; (2) x-ray changes suggestive of osteomyelitis in an area contiguous with the ulcer; (3) erythrocyte sedimentation rate >55 mm/hr, C-reactive protein >44mg/mL, procalcitonin >0.33ng/mL[3] without clinical signs of soft tissue infection; (4) continued non-healing despite adequate arterial circulation, offloading, and wound care.

[1] P. Sheehan *et alia*, *Plast Reconstr Surg* 2006; 117(7 Suppl):239S.
[2] N.R. Barshes *et alia*, *J Vasc Surg* 2016; 64:1682.
[3] F. Hadavand et alia, Arch Acad Emerg Med 2019; 10:37.

3. Provide proper OFFLOADING FOOTWEAR to ALL PATIENTS; consider surgical offloading for some.

The Ossur® DH OffLoading Walker™ with customized offloading insert (or, if unavailable, another calf-length boot that does not allow flexion or extension at the ankle) should be provided for offloading. The Darco Wound Care Shoe System™ may be substituted only if the ulcer is on the dorsum of the foot or the dorsum of the toes. An uncushioned cast shoe should NEVER be used.

Ossur® DH Walker:
the ***BEST***

Darco Wound Care Shoe™System:
***sometimes* ok**

cast shoe:
Don't ever use, potential HARM

Some patients should be evaluated for surgical forms of offloading. Specifically, gastrocnemius recession or tendon Achilles lengthening should be considered for all patients who cannot dorsiflex past neutral position (90° angle between foot and calf) or who are undergoing forefoot amputation.

4. Provide ADVANCED WOUND CARE to ALL PATIENTS.

The following are considered contemporary options for advanced wound care (formulary options in **bold**):

	Component:	Options to use:
1	in contact with the ulcer bed, *infection present*	a) cadexomer iodine gel (Iodosorb, Smith & Nephew) ± Mepitel® (Molnlycke Health Care) b) Iodoflex or Iodoform (Smith & Nephew) c) SilvaSorb (Medline) gel d) Acticoat Flex 3 (Smith & Nephew) moistened with water, not saline e) Aquacell® Ag Extra (ConvaTec) f) Tritec™ Silver (Milliken / Medline) g) Hydroferra Blue® (Hollister) h) 0.125% sodium hypochlorite (Dakin's) solution used *twice daily* and for ≤5 days
1	in contact with the ulcer bed, *uninfected*	a) collagenase ointment (Santyl, Smith & Nephew; avoid CarraKlenz with use) b) MediHoney® gel (DermaSciences) + ____ c) PluroGel® (Medline) d) Promogram™(Acelity) e) negative pressure wound therapy dressings (Acelity)
2	second (absorbant) layer + holding it in place	a) 2x2" or 4x4" gauze ±ABD pad b) Alleyvn foam (Smith & Nephew)
3	to hold it in place	a) cast padding + ACE elastic wrap with 2" paper tape b) Mepilex® (Molnlycke Health Care) c) 2" paper tape or Medipore™ tape (3M)

DO NOT:

a. use **wet-to-dry dressings**, as these permit continued bacterial growth, macerate surrounding skin, and perform non-selective, low-efficacy debridement. A randomized trial has reported a -50% reduction in wound area with collagenase vs. 0.8% increase with saline-moistened gauze[4].
b. use undiluted **Betadine solution**, **alcohol solution**, bleach, or other cleaning materials not approved for wound care.
c. use **silk** or **rayon tape** directly on skin or on dressings
d. use **implants** or **grafts** as an ulcer healing adjunct unless peripheral artery disease and osteomyelitis have been ruled out (as described above), there is no active soft tissue infection, and the area reduction of the ulcer has been documented as being less than 50% over a 4 weeks despite adequate offloading and advanced local wound care (as described above).

5. Urge complete TOBACCO ABSTINENCE in ALL PATIENTS, utilizing freely-available local and national smoking cessation resources (MEDVAMC Veterans Kick Butts meetings, 800-QUIT-NOW).

6. Ensure optimal medical management in ALL PATIENTS, including diabetes management that is largely concordant with recommendations from major U.S. medical societies. This should be done in conjunction with the patient's primary care clinician or through a specialty medical clinic.

[4] A Tallis *et alia, Clin Ther* 2013; 35:1805.

Department of Veterans Affairs Veterans Health Administration

addressee

Dear _____,

We’re sending you this information because your health care team has identified risk factors for limb loss. This may be because you have diabetes with impaired sensation (*neuropathy*), kidney failure, or peripheral artery disease It may also be because you have previously had a foot ulcer, foot infection, partial foot amputation, or leg amputation. Either way, our providers here at the Michael E. DeBakey Veterans Affairs Medical Center want to help you minimize your risk.

In brief:

1. Partner with your healthcare providers to manage diabetes and high blood pressure.
2. If you smoke, work with your providers and www.smokefree.gov or 800-QUIT-NOW to get tobacco free.
3. Inspect at your feet every day.
4. Ask your primary care team to refer you to the appropriate specialist care if you do note any foot sores or wounds.

I hope you are doing well and that you find this information helpful!

Neal Barshes, M.D.

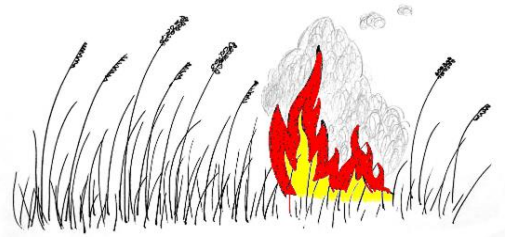
Signs of a Foot Infection

Infection can destroy your foot as fast as a wildfire moving through a dry grass prairie.

If you have an opening (*ulcer*) in the skin of your foot, look out for these symptoms:

1. New pain or swelling in your foot.
2. Fluid draining.
3. Foul odor.
4. Chills, sweats, or fever.
5. Sick to your stomach.
6. No appetite for food.

If you have any of these, see to a doctor or emergency room at an experienced medical center **by the end of the day**.



Your Foot Infection *Action Plan*

1. Go to a large hospital with specialist doctors. NOTE: This might *not* be the hospital closest to your home.

2. Ask to see a **surgeon** who treats **foot infections**.

3. Ask to see **specialist** who can check (and -- if needed -- *improve*) the **circulation to your foot**. This might include a surgeon that specializes in vascular, cardiac, or general surgery. Certain other specialty physicians, such as cardiologists (heart specialists) or radiologists may also be able to do this.

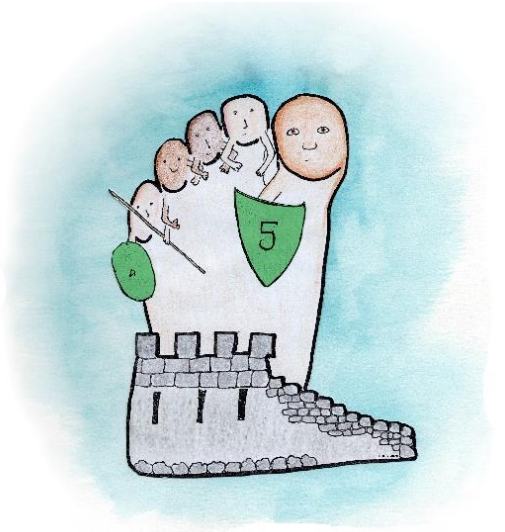
You will have a **higher risk** of having a **leg amputation** if you go to a hospital without a specialist who can treat poor circulation.

YOU are the most important advocate for your health. Be an active part of your health care team!

Brochure written and illustrated by Neal R. Barshes, M.D., M.P.H..

Have diabetes?

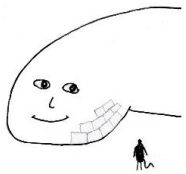
GUARD your FEET!



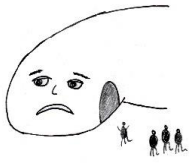
Diabetes affects FEET

You wouldn't be where you are today if not for your feet. Take care of them!

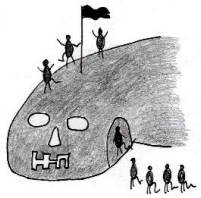
Skin that is healthy and whole is best defense against infection.



People with diabetes are at risk for getting sores (*ulcers*) on their feet.



If untreated, these ulcers can allow infections and dead tissue (*gangrene*) to develop. These problems may lead to loss of part or all of your foot (*amputation*).



The best way to avoid a leg amputation is to **maintain healthy skin** on your foot!

What is my RISK?

☐ HIGH RISK

- If you've had an amputation of a toe or any other part of your foot.
- If you have *peripheral artery disease* (poor circulation, or "hardening" of the arteries).
- If you get dialysis for kidney failure.

☐ MEDIUM RISK

- If you have *neuropathy* (numbness, cannot feel the bottom of your feet)

☐ LOW / NORMAL RISK

- None of the above risk factors

What should I DO?

1. **Look at your feet and your shoes <u>every</u> <u>day</u>**. Look out for sores, cuts, cracks, or blisters.Use a mirror if you can't see your foot. Look at the inside or outside of your shoe. See a doctor or other health care provider if you find a problem.
2. **Quit smoking – completely and forever.** Cigarettes cause devastating health problems. Seek support at 1-800-QUIT-NOW or *<u>www.smokefree.gov</u>*
3. Never walk barefoot – even in your home. Wear shoes and socks that are comfortable and fit well.
4. Work with your doctor on your blood pressure, cholesterol, and glucose control (incl. your *hemoglobin A1c* number).

Scan here for informational videos:

(Text excerpt and data tables from a request for funding for additional staff podiatrists at MEDCVAMC, 2018.)

The Operative Care Line (OCL) requests an additional 2.0 FTEE Podiatrists to improve the quality of care, increase access to preventative care, and reduce the leg amputation rate at MEDVAMC, thus increasing our organizational chart.

MEDVAMC serves a veteran population that is similar in size and risk level to the veteran populations served by the Temple VA (station 674) and the Dallas VA (station 549; see Table 1). Our facility, however, currently only has about one-third as many Podiatry FTEs (see Table 2). Specifically, per 10,000 moderate and high-risk patients, the Temple VA has 4.40 podiatry FTEs, the Dallas VA has 3.10 FTEs, and MEDVAMC has 1.26 FTEs.

At-risk MEDVAMC patients have fewer podiatry visits than the Temple VA (see Table 3). For example, 76% of moderate- and high-risk patients at MEDVAMC have had no podiatry visits within 18 months compared to 52% at the Temple VA. We suspect that the smaller number of podiatry FTEs contributes to this. The total number and the incidence rate of new non-healing ulcers are higher at MEDVAMC than at the Dallas or Temple VAs (Table 4).

Finally, MEDVAMC has a leg amputation incidence rate approximately double that of the national average and of the Temple VA (Table 5). Together, this data suggests that there are opportunities for improvement in both the prevention and treatment of foot ulcers at MEDVAMC.

Multidisciplinary efforts in the treatment of foot ulcers has led to significant reductions at MEDVAMC since 2011. Nonetheless, we would still like to reduce our facility's leg amputation incidence to below the national average over the next five years. We feel that hiring two additional podiatrists would help. In particular, we are proposing that one podiatrist be dedicated to the treatment of foot infections, primarily in an inpatient setting:

We feel that hiring two additional podiatrists would help. In particular, we are proposing that one Podiatrist will be dedicated to the **treatment of foot infections**, primarily in an **inpatient** setting**:**

1. Providing consultation on to emergency department patients and hospital inpatients with a foot ulcer, foot gangrene, or a foot infection. The role of consultation will be shared with the vascular, orthopedic and general surgery teams. If admission is indicated, will admit to the vascular surgery team, the orthopedic surgery team, the general surgery team, or an inpatient medicine team.
2. Performing operations to treat acute foot infections. This will be done in addition to operations done by orthopedic, general and vascular surgery teams.
3. Performing elective procedures that will provide or foster complete wound healing after the successful treatment of infection.
4. Performing elective operations to reduce risk for re-ulceration, incl. tenotomies, gastrocnemius recessions, arthroplasties, and osteotomies.
5. Referring patients to outpatient follow-up with additional podiatry outpatient appointments after wound healing has been achieved.
6. Providing nail care for high-risk veterans residing in the Community Living Center (CLC) units, the spinal cord injury rehabilitation units, and palliative care inpatient units. Will collaborate with existing teams and providers in these units to provide care of any existing foot wounds for these patients.

The second Podiatrist would be dedicated to the **prevention of foot ulcers and infections**, primarily in an **outpatient** setting:

7. Establish and running an at-risk clinic to provide preventive care to MEDVAMC outpatients at moderate and high risk for limb loss. The identification of moderate and high risk patients will use this facility's health factor data (initiated by the Prevention of Amputation in Veterans Everywhere program) to identify and contact moderate- and high-risk MEDVAMC patients (NOTE: Feasibility of this has been established in working with MEDVAMC Operative Care Line CACs). Nail care for high-risk veterans will be provided at these visits. The goal will be increasing

the proportion of high- and moderate-risk veterans seen within 6 months from 15% (Table 3) to 30% and the proportion seen within 7-12 months from 5% to 15%.

8. Will ensure the provision of podiatric care at the Charles Wilson Community-Based Outpatient Clinic (CWCBOC) in Lufkin, Texas. This will include:
    a. Being available to provide support via phone or video to non-podiatrist CWCBOC staff (nurse practitioners, nail care technicians, other non-physician mid-level providers) providing podiatric care.
    b. Directly evaluating and managing high- and moderate-risk veterans with podiatric needs at a podiatry clinic at CWCBOC at least once a month.
    c. Reducing non-VA community care expenditures for podiatric needs to an annual limit of $50,000 (from an annual average of $589,327 for fiscal years 2018-2020 per AMCMS Management Reports; see attached).

We would plan to hire podiatrists with residency training +/- fellowship training. To enable persons graduating residency or fellowship training in June 2018, we are asking for immediate consideration of this request for these additional FTEs.

(Text excerpt and data tables from a request for funding for additional staff podiatrists at MEDCVAMC, 2018.)

Table 1: The population (and relative proportion) classified as being at risk for lower extremity amputation [*data source: VHA Support Service Center (VSSC) Amputation Cube, Amputation Risk by Facility; data as of 10/31/2018, living patients only].*

	Texas VHA Hospital A	**Texas VHA Hospital B**	**MEDVAMC (Houston)**
Total at-risk population	21,949 (100%)	30,445 (100%)	28,681 (100%)
Normal risk	9,957 (45%)	11,996 (39%)	13,198 (46%)
Low risk	2,257 (10%)	3,246 (11%)	2,946 (10%)
Moderate risk	2,606 (12%)	4,114 (14%)	3,504 (12%)
High risk	7,129 (32%)	11,089 (36%)	9,033 (31%)
Moderate + high subtotal	9,735 (44%)	15,203 (50%)	12,537 (44%)

(Text excerpt and data tables from a request for funding for additional staff podiatrists at MEDCVAMC, 2018.)

Table 2: The population (and relative proportion) classified as being at risk for lower extremity amputation [*source: VHA Support Service Center (VSSC) Productivity Cube, provided by Prevention of Amputation in Veterans Everywhere (PAVE) national director Dr. Jeffrey Robbins].*

	Texas VHA Hospital A	**Texas VHA Hospital B**	**MEDVAMC (Houston)**
Podiatry RVU sum	20,441	25,430	10,065
MD FTE	4.44	4.72	1.58
Adjusted MD FTE	**4.28**	**4.72**	**1.58**
Productivity measure	**4,771**	**5,010**	**5,821**
Encounters	14,368	12,116	5,656
Unique patients	6,062	4,622	2,819

(Text excerpt and data tables from a request for funding for additional staff podiatrists at MEDCVAMC, 2018.)

Table 3: The number (and relative proportion) of veterans at moderate and high risk for lower extremity amputation with podiatry visits in various time ranges [*data source: VHA Support Service Center (VSSC) Amputation Risk Cube, Foot Visits and At Risk Patients; living patients only]*.

	Texas VHA Hospital A	**Texas VHA Hospital B**	**MEDVAMC (Houston)**
All risk levels, total	21,949 (100%)	30,445 (100%)	28,681 (100%)
Last foot visit within 6 months	4,337 (20%)	3,229 (11%)	2,509 (9%)
Last foot visit within 7-12 months	2,613 (12%)	1,137 (4%)	1,001 (3%)
Last foot visit within 13-18 months	1,012 (5%)	855 (3%)	682 (2%)
No visits within last 18 months	13,987 (64%)	25,224 (83%)	24,489 (85%)
Moderate and high risk levels, total	9,735 (100%)	15,203 (100%)	12,537 (100%)
Last foot visit within 6 months	2,790 (29%)	1,797 (12%)	1,841 (15%)
Last foot visit within 7-12 months	1,361 (14%)	749 (5%)	679 (5%)
Last foot visit within 13-18 months	558 (6%)	579 (4%)	455 (4%)
No visits within last 18 months	**5,026 (52%)**	**11,448 (75%)**	**9,562 (76%)**

(Text excerpt and data tables from a request for funding for additional staff podiatrists at MEDCVAMC, 2018.)

Table 4: The number of new non-healing ulcers [*data source: VHA Support Service Center (VSSC) Non-Healing Ulcer Cube, Ulcer Patients and Rate per 1,000 by VISN].*

	Texas VHA Hospital A	**Texas VHA Hospital B**	**MEDVAMC (Houston)**
New ulcers	1,804	2,586	2,752
Ulcer rate / 1000	8.1014	8.8971	12.1160

(Text excerpt and data tables from a request for funding for additional staff podiatrists at MEDCVAMC, 2018.)

Table 5: The number and incidence (per 1,000 unique patients) of lower extremity major (i.e. above-ankle) and minor (toe or partial foot) amputations in fiscal year 2018 [*data source: VHA Support Service Center (VSSC) Amputee Cube, Daily Procedures & Rates by Fiscal Year; lower extremity only].*

	Texas VHA Hospital A	**Texas VHA Hospital B**	**MEDVAMC (Houston)**	**VHA national**
Total major amputations	45	104	99	3,333
Major amputation incidence rate	**0.4249**	**0.9466**	**0.9386**	**0.5315**
Total minor amputations	88	126	122	6,050
Minor amputation incidence rate	0.8308	0.9836	1.1567	0.9647
Unique patients	105,919	128,107	105,477	6,271,208

The Development of an Evidence-Based Approach to **Leg Amputation Prevention**

Neal R. Barshes, M.D., M.P.H.

Our clinical experiences have focused our research efforts. Our research findings have evolved our clinical practice. This summary is presented not to promote our published works but rather to describe the basis of our novel clinical approaches and to provide examples demonstrating how collaborative clinical research focused on practical questions can improve clinical outcomes.

The Management of Foot Infection

Because of our vascular team's ownership of limb salvage, we have had a primarily surgical approach to the management of foot infections, including osteomyelitis. Specifically, 92% of our patients have had surgical biopsies and cultures taken as part of their operative treatment. These have been used to select an antimicrobial regimen directed to the organisms identified. Antimicrobial regimens have consisted predominately of oral antibiotics (95%) since 2011[1]. Ceftriaxone is the primary empiric antibiotic given to patients who have not yet had operative treatment or whose culture results are pending. We use empiric vancomycin only for patients who have a positive nares swab or who have clinical signs of an abscess based on prevalence rates we found in a prior analysis. Finally, contrary to guidelines emphasizing the importance of Gram positive organisms, our analyses have shown that Gram negative organisms are associated treatment failure[2] and that methicillin-resistant Staphylococcus aureus is not[3]; for this reason, we have focused more attention on improving outcomes in patients with these organisms. We re-biopsy if treatment failure occurs, as we have observed shifts in microbial species involved during treatment[4].

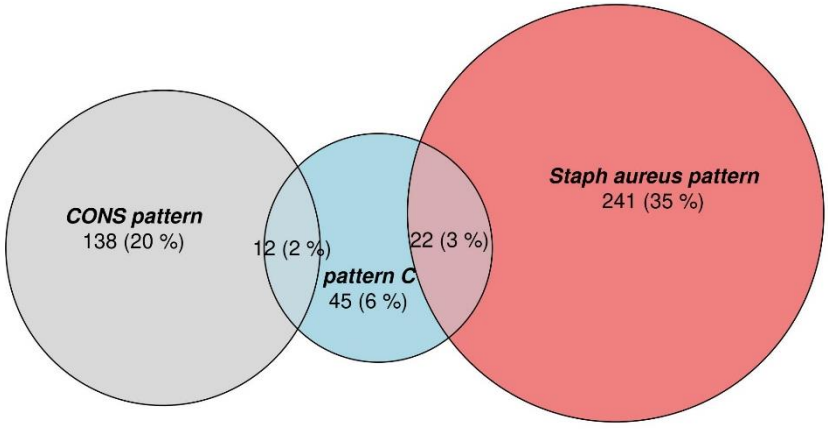
[1] Barshes NR, Mindru C, Ashong C, Rodriguez-Barradas M, Trautner BW. Treatment failure and leg amputation among patients with foot osteomyelitis. *The International Journal of Lower Extremity Wounds* 2016; 15: 303–12.

[2] Barshes NR, Clark NJ, Bidare D, Dudenhoeffer J-H, Mindru C, Rodriguez-Barradas MC. Polymicrobial foot infection patterns are common and associated with treatment failure. *Open Forum Infectious Diseases*. Oxford University Press US, 2022: ofac475.

[3] Ashong CN, Raheem SA, Hunter AS, Mindru C, Barshes NR. Methicillin-resistant staphylococcus aureus in foot osteomyelitis. *Surgical Infections* 2017; 18: 143–8.

[4] Barshes NR, Mindru C, Trautner BW, Rodriguez-Barradas MC. Discordant isolates in bone specimens from patients with recurrent foot osteomyelitis. *European Journal of Clinical Microbiology & Infectious Diseases* 2019; 38: 767–9.

We have made novel contributions to understanding the systemic impact of foot infection. Specifically, we first described acute kidney injury associated with foot osteomyelitis in 2017[5]. We use the presence of acute kidney injury as a clinical sign of foot infection, we have modified our selection of inpatient and outpatient antibiotics accordingly (selective use of vancomycin based on the aforementioned factors, minimizing use of sulfamethoxazole and trimethoprim). We have also described acute cardiac complications (new myocardial infarctions, worsening heart failure, and new arrhythmias) occurring with severe foot infections[6]. Although the prevalence was only 6.6% among the 274 patients analyzed, patients with these new cardiac events have a significantly higher one-year mortality. We therefore consult our medical teams for further cardiac workup when acute cardiac complications are seen. Lastly, we've described an unusual syndrome of severe anemia, weight loss, hyponatremia, hyopalbuminemia, and uremia and other metabolic derangements occurring in a series of patients with beta-hemolytic streptococci[7]. We are particularly aggressive in controlling infection in patients with this constellation of findings.



pattern C = two or more of "K.E.E.P.S." organisms:
Klebsiella,
Enterococcus fecalis,
Enterobacter,
Escherichia coli,
Proteus, and/or
Streptococcus (alpha-hemolytic)

NEITHER *Bacteroides*
NOR *Corynebacterium*

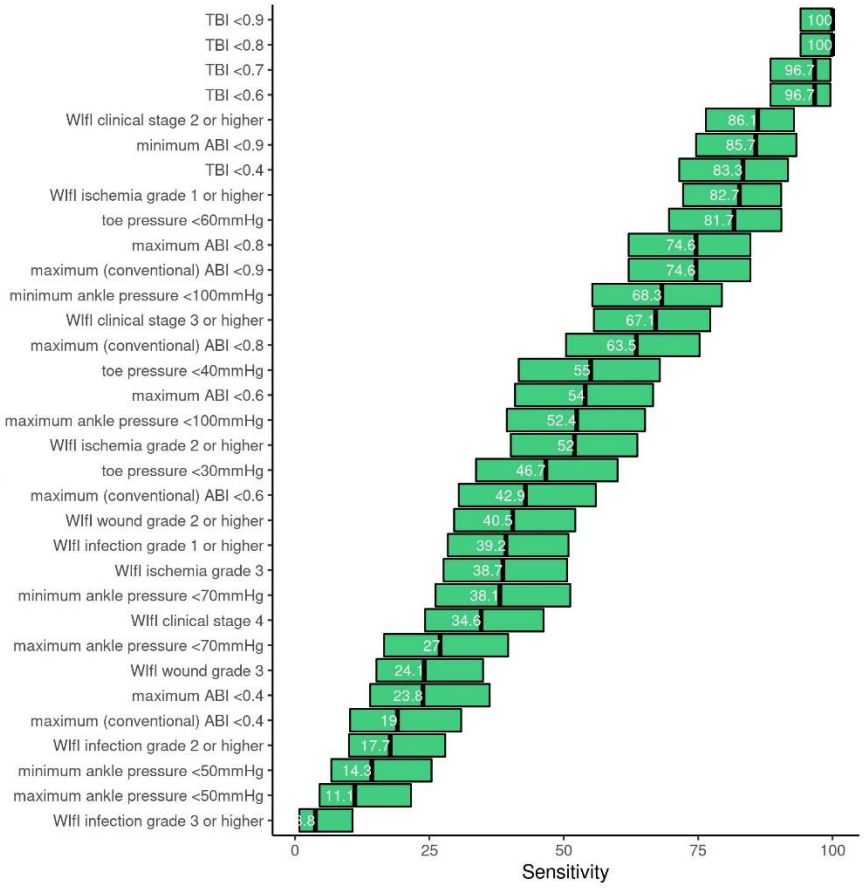
[5] Jiang BC, Cowart JB, Barshes NR. Acute kidney injury associated with foot osteomyelitis. *Clinical Medicine* 2017; 17: 376–6.

[6] Singh M, Khan K, Fisch E, Frey C, Mathias K, Jneid H, Musher DM, Barshes NR. Acute Cardiac Events in Patients With Severe Limb Infection. Acute cardiac events in patients with severe limb infection. *The International Journal of Lower Extremity Wounds* 2018; 17: 261–7.

[7] Den JL, Gay LM, Barshes NR. Severe anemia, anorexia, and uremia associated with diabetic foot infections: A case series. *The Foot* 2022; 53: 101926.

The Identification of Peripheral Artery Disease

Our approach to identifying peripheral artery disease (PAD) has also evolved based on research findings. With award funding from the Society for Vascular Surgery, we performed a formal decision analysis with a probabilistic Markov which we expected would support our approach at that time: selective angiography done based on the results of non-invasive arterial testing (specifically, toe pressure <60mmHg). Findings from the analysis, however, suggested that the sensitivity in identifying PAD might be increased by deciding on angiography simply based on weak or absent pedal pulses and using non-invasive testing to instead corroborate adequate arterial perfusion in patients with palpable pedal pulses[8]. A subsequent observational study has corroborated these findings and have suggested that a toe-brachial index of <0.7 may be even more sensitive still, especially in patients without medial artery calcification of pedal vessels as seen on plain radiography[9].

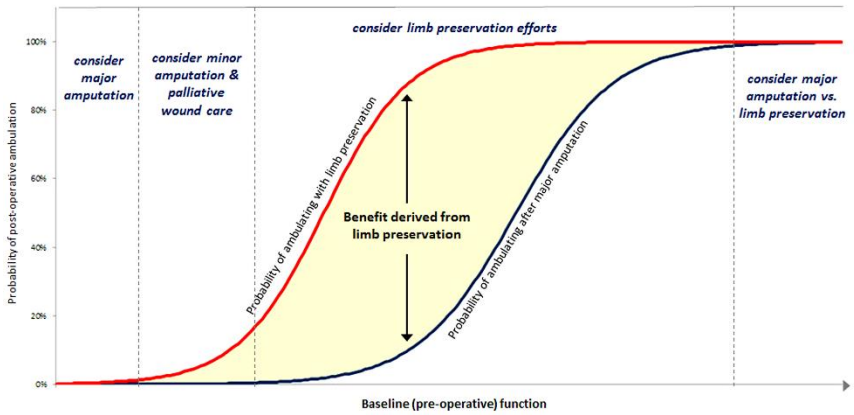


[8] Barshes NR, Flores E, Belkin M, Kougias P, Armstrong DG, Mills Sr JL. The accuracy and cost-effectiveness of strategies used to identify peripheral artery disease among patients with diabetic foot ulcers. *Journal of Vascular Surgery* 2016; 64: 1682–90

[9] Choi JC-B, Miranda J, Greenleaf E, Conte MS, Gerhard-Herman MD, Mills JL Sr, Barshes NR. Lower-extremity pressure, staging, and grading thresholds to identify chronic limb-threatening ischemia. *Vascular Medicine* 2023; 28: 45–53

Decision Making: Revascularization and Limb Salvage, Leg Amputation or Palliative Wound Care

Leg amputation is generally still the only alternative that many surgeons provide to patients who are not candidates for revascularization and limb salvage. It had been ours prior to the aforementioned cost-utility study[10]. In this study, wound care alone (i.e. without revascularization) was included as a strategy analyzed with the intent of demonstrating the clinical harms associated with missing the diagnosis of PAD. Unexpectedly, the model predicted the strategy of wound care alone would actually produce better health outcomes and lower total costs than leg amputation[11]. We subsequently reported outcomes of this "palliative wound care" alternative to leg amputation for a selected group of patients with advanced comorbid conditions; these research findings[12] and much more clinical experience since have confirmed that it is indeed a good and generally preferable alternative to leg amputation.



[10] Barshes NR, Chambers JD, Cohen J, Belkin M, Ischemic Extremities 1 (MOVIE) Study Collaborators MTOHV in, et al. Cost-effectiveness in the contemporary management of critical limb ischemia with tissue loss. *Journal of Vascular Surgery* 2012; 56: 1015–24.

[11] Barshes NR, Chambers JD, Cohen J, Belkin M, Ischemic Extremities 1 (MOVIE) Study Collaborators MTOHV in, et al. Cost-effectiveness in the contemporary management of critical limb ischemia with tissue loss. *Journal of Vascular Surgery* 2012; 56: 1015–24.

[12] Barshes NR, Gold B, Garcia A, Bechara CF, Pisimisis G, Kougias P. Minor amputation and palliative wound care as a strategy to avoid major amputation in patients with foot infections and severe peripheral arterial disease. *The International Journal of Lower Extremity Wounds* 2014; 13: 211–9.

We therefore generally pursue surgical revascularization and limb salvage – even in patients with advanced comorbidities[13] or marginal functional status[14], and especially in patients with a contralateral leg amputation[15]. We favor endovascular interventions for patients with end-stage renal disease[16].

Leg amputation is typically now recommended to patients who are not a candidate for revascularization and limb salvage but have one or more of the following characteristics: infection that is not controlled by surgical therapy (e.g. minor amputation) and limited-course antibiotics and causing secondary infection or other systemic effects (ex. weight loss, anorexia, malaise); pain that is not controlled by medications or image-guided nerve injections; wounds that patients or care providers cannot or will not manage due to voluminous fluid output or foul odor; or mobility that is impaired by the foot wound and that may improve with leg amputation.

We generally recommend and offer leg amputation at the transtibial (below-knee) level, but we may suggest more proximal levels, such as through-knee or transfemoral, for patients with ischemic pains and "no-option" peripheral artery disease because of a significantly higher rate of revision to more proximal levels following transtibial amputation in these patients[17].

[13] Barshes NR, Menard MT, Nguyen LL, Bafford R, Ozaki CK, Belkin M. Infrainguinal bypass is associated with lower perioperative mortality than major amputation in high-risk surgical candidates. *Journal of Vascular Surgery* 2011; 53: 1251–9.

[14] Barshes NR, Kougias P, Ozaki CK, Pisimisis G, Bechara CF, Henson HK, Belkin M. Cost-effectiveness of revascularization for limb preservation in patients with marginal functional status. *Annals of Vascular Surgery* 2014; 28: 10–7.

[15] Sharath S, Henson H, Flynn S, Pisimisis G, Kougias P, Barshes NR. Ambulation and independence among Veterans with nontraumatic bilateral lower-limb loss. *Journal of Rehabilitation Research & Development* 2015; 52:851-8.

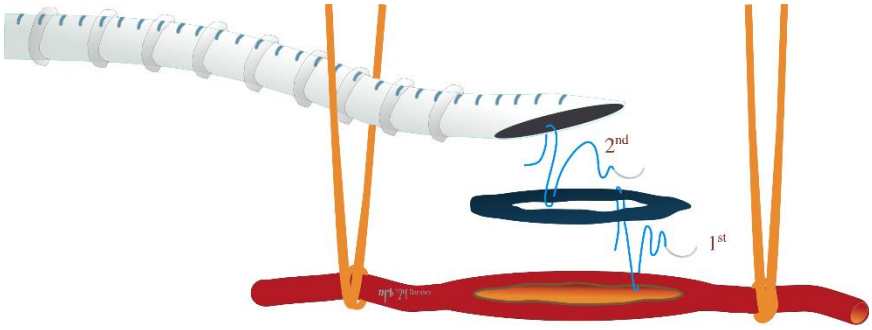
[16] Barshes NR, Kougias P, Ozaki CK, Goodney PP, Belkin M. Cost-effectiveness of revascularization for limb preservation in patients with end-stage renal disease. *Journal of Vascular Surgery* 2014; 60: 369–74.

[17] Khouqer A, Uribe-Gomez A, Sharath SS, Kougias P, Barshes NR. Wound complications and reoperations after transtibial amputation of the leg. *Annals of Vascular Surgery* 2020; 69:292-7.

Revascularization for PAD

Our approach to treating PAD has been informed by cost-utility studies that suggest infrainguinal bypass may be more clinically effective and cost-effective that endovascular intervention[13,]. Spliced vein conduits seem better in patients without adequate single-segment saphenous vein, but bypasses done with polytetrafluoroethylene (PTFE) and a distal vein patch provide good outcomes too[18,19]. In 2011, cryopreserved allograft vein was the conduit used for 9% infrainguinal bypasses, but this has been eliminated because of findings suggesting it was associated with poorer clinical outcomes and higher costs[15]. Similarly, we reduced the usage of stent-grafts used in infrainguinal endovascular interventions from 28% in 2011 to 9% in 2017 and <5% currently based on findings suggesting a significantly poorer patency and higher rate of acute limb occlusion with these devices[20]. We employ bundled interventions (pre-operative nasal and skin decontamination for methicillin-sensitive Staphylococcus aureus, routine perioperative antibiotics, chlorhexidine/alcohol skin preparation, wound closure using subcuticular sutures, and incisional negative pressure wound therapy dressings for groin wounds) that has lead to a 5-fold reduction in superficial or deep surgical site infections[21].

We have employed a strategy of surgical closure of many foot wounds early after revascularization[22]. This approach was initially based on the post-operative care of the incident foot ulcer being identified as a cost-driver for the overall strategy of revascularization and limb salvage[13].



[18] Barshes NR, Ozaki CK, Kougias P, Belkin M. A cost-effectiveness analysis of infrainguinal bypass in the absence of great saphenous vein conduit. *Journal of Vascular Surgery* 2013; 57: 1466–70.

[19] Branco BC, Kougias P, Braun JD, Mills Sr JL, Barshes NR. Distal vein patch use and limb events after infragenicular prosthetic bypasses. *Journal of Vascular Surgery* 2018; 68: 145–52.

[20] Zamani N, Sharath SE, Browder RC, Barshes NR, Braun JD, Mills JL Sr, Kougias P, Younes HK. Outcomes after endovascular stent placement for long-segment superficial femoral artery lesions. *Annals of Vascular Surgery* 2021; 71: 298–307.

[21] Zamani N, Sharath SE, Vo E, Awad SS, Kougias P, Barshes NR. A multi-component strategy to decrease wound complications after open infra-inguinal re-vascularization. *Surgical Infections* 2018; 19: 87–94.

[22] Barshes NR, Bechara CF, Pisimisis G, Kougias P. Preliminary experiences with early primary closure of foot wounds after lower extremity revascularization. *Annals of Vascular Surgery* 2014; 28: 48–52.

Ensuring Adequate Access to Timely Specialty Care

Data available through the VHA Support Service Center helped us recognize that our hospital system had half the number of podiatrists and also lower rates of podiatry clinic visits for veterans at moderate and high risk (PAVE II and III, respectively) than VHA hospitals of comparable size. We proposed an action plan that has resulted in successfully hiring two additional podiatrists, and we have a plan to increase the frequency of podiatry clinic visits for these at-risk patients.

We have done work with state-level data has helped us identify groups of people within Texas who experience high rates of leg amputation: persons categorized as black or Hispanic and persons living in specific geographic locations[23,24,25,26]. Based on findings suggesting higher rates of leg amputations and poorer access to specialty care among people in east Texas, one of the authors (N.R.B.) began seeing vascular surgery patients at VHA community-based outpatient VHA clinic in Lufkin, a town of 35,000 people located 127 miles from Houston.

Primary Prevention of Foot Ulcers

Data analyses have helped us direct our primary prevention efforts. An economic model suggested that primary prevention efforts had a much higher potential for cost-savings that limb salvage treatment, including efforts that might be low effectiveness but have low cost[27]. Based on this, we developed a 500-word plain language trifold brochure that discusses preventative care actions[28].

With the help of the information technology specialists, we generated lists of veterans of all races/ethnicity living in high amputation-rate zip codes in our region and mailed them our brochures with an explanatory cover letter, timed along with April as "Amputation Awareness & Prevention Month." We have now completed two rounds of mailings, with brochures and letters sent during the last round to 3,512 veterans. Several of our specialty clinics have in-person or video-based outpatient clinic within the identified area of high amputation rates.

[23] Barshes NR, Sharath S, Zamani N, Smith K, Serag H, Rogers SO. Racial and geographic variation in leg amputations among texans. *Texas Public Health Journal* 2018; 70: 22.

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