



Actor Portrayal

Achieving Excellence in Peripheral Artery Disease and Chronic Limb-Threatening Ischemia Care

Insights From a Center of Excellence

Johnson & Johnson

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population health decision makers, and/or similar entities.

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Executive Summary

Advice for institutions seeking to start their own Chronic Limb-Threatening Ischemia program*:



To ensure **physician buy-in** and consistent, evidence-based care across the institution, **form a CLTI committee**. This committee should define standardized policies and guidelines (eg, mandatory angiography and committee consultations before every major amputation).



To ensure comprehensive care throughout the patient's journey, **utilize Inpatient and Outpatient CLTI Navigators** to coordinate patient care across a multidisciplinary team, adopting a defined **circle of care approach** that treats **CLTI management as a continuous process** with ongoing follow-up assessments rather than a finite treatment and recovery.



Initiate structured proctoring and training programs for physicians interested in performing peripheral vascular procedures, ensuring they meet minimum case requirements and **participate in CLTI management continuing education**.



Meticulously track and analyze data on health and economic outcomes, such as amputation rates, hospital readmissions, procedure success rates, and patient satisfaction, to accurately monitor program effectiveness, identify areas for improvement, and facilitate administrative and provider buy-in.



Consider SDOH and the needs of all patient populations by engaging with community leaders and partnering with pharmaceutical companies and nonprofit organizations to raise awareness about PAD and CLTI, provide financial assistance, and ensure access to necessary resources for treatment and follow-up care.

CLTI, chronic limb-threatening ischemia; PAD, peripheral artery disease; SDOH, social determinants of health.

*The *Guideline for the Management of Lower Extremity Peripheral Artery Disease* issued in 2024, by the American College of Cardiology and American Heart Association, in partnership with multiple societies, recommends using 'chronic limb-threatening ischemia (CLTI)' and defines CLTI as "a condition characterized by chronic (>2 wk) ischemic rest pain, nonhealing wounds and ulcers, or gangrene attributable to objectively proven arterial occlusive disease. Current nomenclature has evolved from the previous commonly used term of CLI [critical limb ischemia] to reflect the chronic nature of this condition and its potentially limb-threatening nature with associated risk for amputation and to distinguish it from acute limb ischemia." The program at El Paso was developed prior to the release of the 2024 ACC/AHA/multisociety guidelines; however, the terminology has been updated to reflect current recommendations.¹

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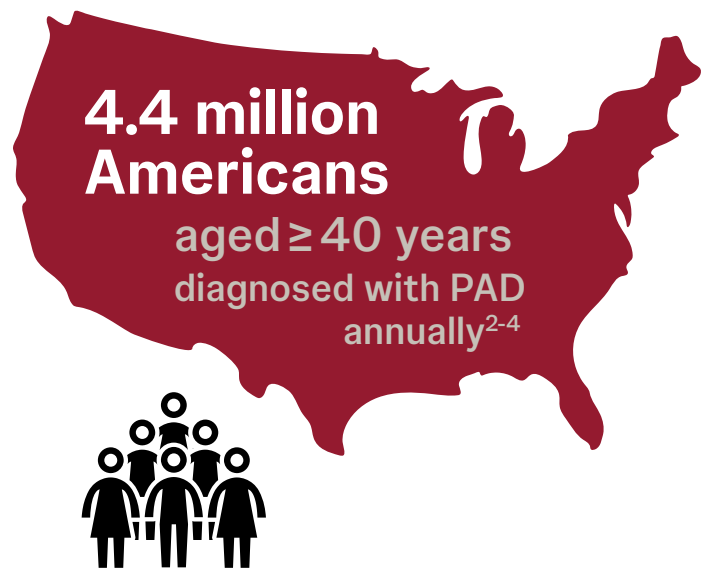
Achieving Excellence in Peripheral Artery Disease and Chronic Limb-Threatening Ischemia Care

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Approximately 4.4 million Americans 40 years or older are diagnosed with peripheral artery disease (PAD) annually.²⁻⁴ PAD often is underdiagnosed and undertreated.^{2,5,6} The severe, end-stage manifestation of PAD is chronic limb-threatening ischemia (CLTI), in which objectively proven arterial occlusive disease leads to a chronically decreased blood supply that is insufficient to meet the resting metabolic need of the limb's tissues.^{1,7,8} Over half a million US adults 40 years or older develop CLTI annually.^{3,4} Among patients with PAD, those with CLTI are more likely to eventually need an amputation than are those without CLTI.^{9*}

In the United States, approximately 150,000 nontraumatic lower extremity amputations were conducted in 2015, translating to an estimated rate of over 400 nontraumatic amputations per day.¹⁰ Approximately half of major amputations occur without any vascular procedure, including diagnostic angiography or revascularization.^{10-12†} However, among patients with CLTI, those who undergo diagnostic angiography have 90% lower odds of undergoing amputation without any lower extremity revascularization attempt.^{13§}

Many institutions have seen a substantial decrease in the rate of major lower extremity amputations since implementing a multidisciplinary model of care for PAD.^{14,15} **In 2022, the Hospitals of Providence Memorial Campus in El Paso, Texas, was 1 of only 2 hospitals in the United States accredited as a Peripheral Vascular Disease Center of Excellence by The Joint Commission.**¹⁶ Centers of Excellence have a multidisciplinary team of specialists, provide protocol-driven care, monitor and report relevant outcomes, demonstrate established methods of improvement, and serve as an educational resource.⁹ The team at the Hospitals of Providence Memorial Campus achieved this designation by demonstrating a commitment to consistent, high-quality peripheral vascular care and patient outcomes since the program's inception in 2016.



In this article, experts from El Paso Cardiology Associates and the Hospitals of Providence Memorial Campus discuss the unmet needs that led to the development of the multidisciplinary CLTI program, which treats patients from Texas, Mexico, New Mexico, and Arizona. **This actionable resource presents best practices on developing a standardized care program that includes workflow integration, provider engagement, and program assessment tools for managing PAD and CLTI.**

*Based upon results from a United Kingdom population-based analysis of 2002-2012 data on 373 incident PAD events, 202 of which were CLTI events. After 5 years, those who experienced an incident CLTI event had a significantly higher risk of amputation than did those who experienced an incident acute limb ischemia event (43.4% vs 16.9%, respectively; $P = 0.01$). Results may not be generalizable, and CLTI incidence may have been overestimated.⁹

†This analysis of 2010-2015 Medicare claims data examined health and cost outcomes among 72,199 adults with incident CLTI, of whom 46,795 (65%) underwent endovascular or surgical revascularization or major amputation. Among those who underwent major amputation, 51% had not received any previous revascularization. Limitations included the possibility of miscoding, limited data on patient characteristics, and inability to control for repeat procedures on the contralateral leg or determine the rationale for treatment procedures.¹¹

‡This analysis of 2003-2006 Medicare Part B claims data in 20,464 patients (aged ≥ 65 years) with CLTI who underwent amputation found that in the year before amputation, 54% of patients had not undergone any vascular procedure. Procedures examined included diagnostic endovascular interventions and angiographies as well as therapeutic endovascular interventions and surgical procedures. Limitations include the reliance on administrative claims data, inability to distinguish contralateral limb vascular procedures and amputations, 12-month study period, and moderate model discrimination due to lack of granular detail.¹²

§Based upon results of an analysis of 2003-2007 Nationwide Inpatient Sample data in 958,120 patients (aged ≥ 21 years) with CLTI who were treated with lower extremity revascularization and/or major amputation to identify patients who had not undergone a revascularization procedure prior to amputation. Among all included patients, 24.24% underwent major amputation, and 27.44% underwent diagnostic angiogram. Patients evaluated with an angiogram were significantly less likely to undergo amputation (odds ratio, 0.094; 95% CI, 0.088-0.101; $P < 0.0001$). Limitations included reliance on administrative data that did not include detailed information on angiography such as the availability of facilities or trained staff.¹³

Unmet Needs in Chronic Limb-Threatening Ischemia in El Paso

When **M. Laiq Raja, MD, FACC, FSCAI**, started as an interventional cardiologist in the El Paso area approximately 20 years ago, he noticed that many of his patients with coronary artery disease or myocardial infarction also had severe PAD and CLTI. He explained that the high incidence of PAD and the lack of treatment knowledge in El Paso at that time spurred him to learn about multidisciplinary management strategies for limb preservation and amputation prevention from other physicians.

According to **Rob J. Anderson, MBA**, chief executive officer at the Hospitals of Providence Memorial Campus, a Tenet hospital that treats primarily a Medicare and Medicaid population, rates of diabetes and PAD are high in the predominantly Hispanic population in El Paso and surrounding areas. Prior to development of the CLTI program, many patients in El Paso who had these conditions either went without treatment, received treatment from a primary care provider or cardiologist without expertise in PAD, or had to travel elsewhere to receive more specialized care. This highlighted the need for PAD-directed care in the El Paso area.

PAD Progression and Symptomology

PAD is a chronic and progressive peripheral vascular disease in which atherosclerosis leads to stenosis and occlusion of arteries in the lower extremities.^{2,6,7,17} Patients with PAD may experience decreased physical functioning and quality of life (QOL), and they may have reduced walking ability due to exercise-induced intermittent claudication in the limbs; however, early stages of PAD may be asymptomatic.^{6,7,17} Indeed, 20% to 50% of patients with PAD have no symptoms, and 40% to 50% present with atypical symptoms such as leg pain or discomfort that occurs in the absence of exercise, that does not resolve with rest, or that does not cause the patient to stop walking.^{5,6,18-20} In patients with CLTI, symptoms of the occlusion (eg, chronic ischemic rest pain, nonhealing ulcers, gangrene) last longer than 2 weeks.^{1,6,7}



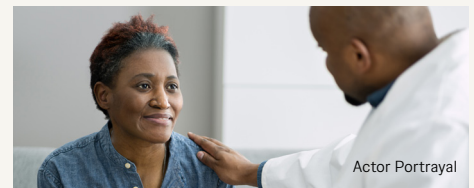
Up to 50% of patients with PAD have **no symptoms.**^{5,6,18-20}



Up to 50% of patients with PAD present with **atypical symptoms.**^{5,6,18-20}

Disparities in Risk, Prevalence, and Outcomes of PAD

Risk factors for PAD include both intrinsic and extrinsic factors (**box**).^{1,21,22} Patients with diabetes are up to 7 times more likely to develop PAD than are those without diabetes.²¹ Aspects of social determinants of health (SDOH) may predispose individuals to develop PAD and CLTI.^{1,7} SDOH are socioeconomic and structural factors that influence health outcomes; such factors may include economic stability, the neighborhood and built environment, the social and community context, and access to high-quality health care and education.²³ Disparities in healthcare access and structural racism may account for reduced management of PAD risk factors; this, in turn, contributes to a greater prevalence of PAD, delayed diagnoses, and a higher risk of sequelae such as major amputation among affected patients.^{2,6} Indeed, Black, Native American, and Hispanic patients with PAD have a greater risk of undergoing a major limb amputation than do non-Hispanic White patients.²⁴ Furthermore, the average length of stay among patients hospitalized with PAD is longer for Black, Asian/Pacific Islander, and Hispanic patients than for non-Hispanic White patients.^{24*}



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Risk Factors for PAD^{1,21,22}

- ✓ Black heritage
- ✓ Diabetes
- ✓ High body mass index
- ✓ Aged ≥ 65 years
- ✓ History of cardiovascular disease
- ✓ Hyperlipidemia
- ✓ Hypertension
- ✓ Smoking
- ✓ Use of antihypertensive agents
- ✓ Chronic kidney disease

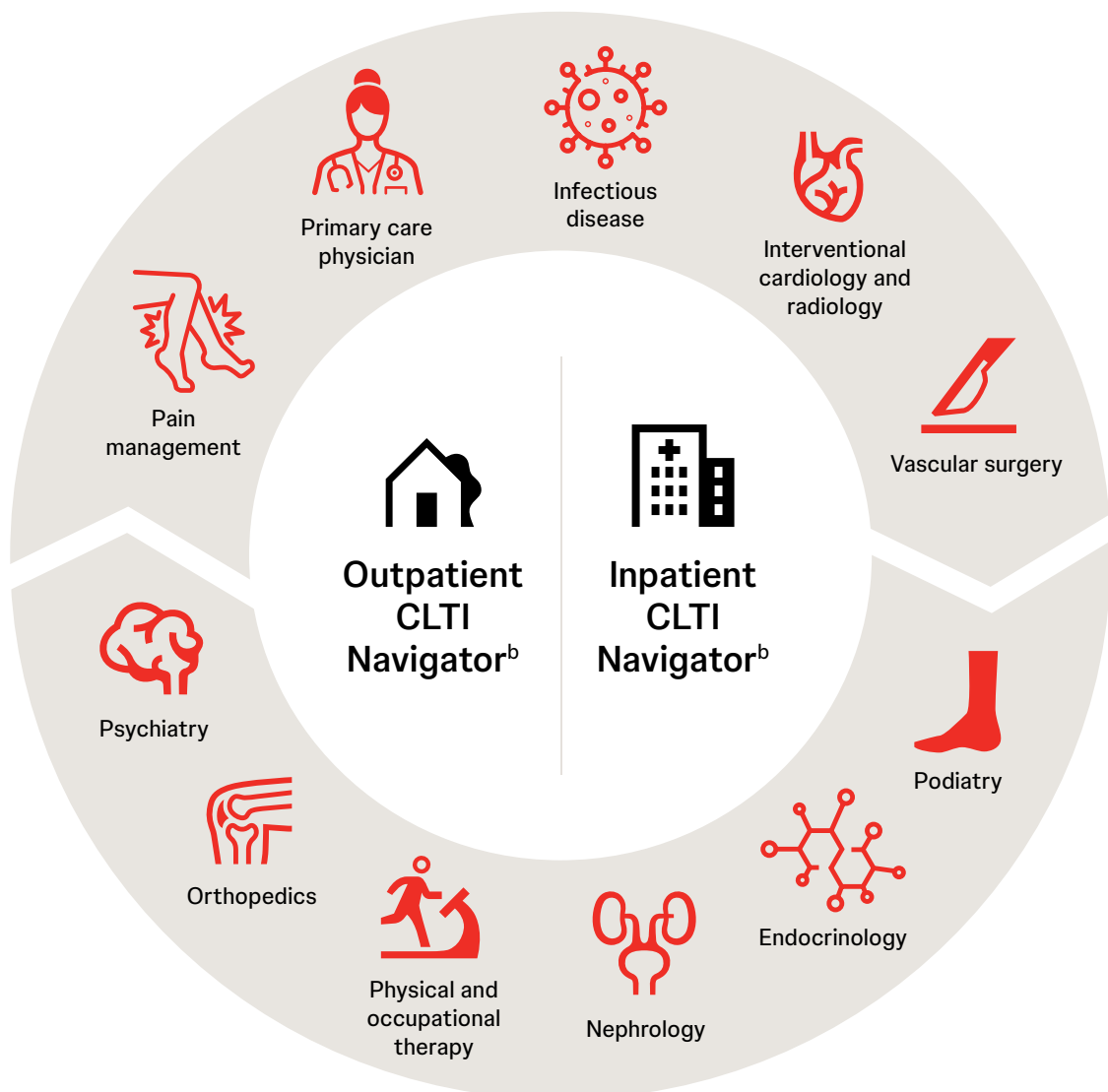
*Results of this cross-sectional analysis of 2011-2015 data from the National Inpatient Sample of 341,480 PAD-related hospitalizations showed that compared with non-Hispanic White patients, Black, Native American, and Hispanic inpatients with PAD had an increased risk of undergoing a major limb amputation (odds ratio, 1.71, 1.48, and 1.36, respectively) ($P < 0.0001$ for all). The average length of stay was 5 days; prolonged length of stay was seen in Black, Asian/Pacific Islander, and Hispanic inpatients with PAD (incidence rate ratio, 0.12, 0.14, and 0.09, respectively) ($P < 0.0001$ for all). Study limitations included risk of self-selection bias due to recruitment of patients requiring hospitalization, omission of additional healthcare outcomes from the analysis, and variability in hospitals' financial policies.²⁴

The Chronic Limb-Threatening Ischemia Program and the Circle of Care

To address these gaps in care for patients with PAD and CLTI, Dr Raja and fellow key stakeholders **Lorena C. Henderson, APRN, MSN, NP-C**, and **Rosa Marquez, MSN, FNP-C, RCIS**, developed a multidisciplinary CLTI program described as a *circle of care* that considers management of CLTI to be on a continuum, with ongoing follow-up assessments rather than finite treatment and recovery.

The multidisciplinary program includes CLTI vascular specialists (ie, an interventional cardiologist, a vascular surgeon, or an interventional radiologist), infectious disease physicians, wound management specialists, podiatrists, nephrologists, orthopedists, physical or occupational therapists, and CLTI Navigators. Patients also are referred to endocrinologists at the beginning of care; as Dr Raja explained, many of these individuals have poor glycemic control, which slows wound healing. Recent additions to the circle of care include a pain management physician to address the pain associated with any wounds patients may have and a psychiatrist to help mentally prepare patients who require limb amputation for the procedure and recovery.

Circle of Care at the CLTI Program^a



CLTI, chronic limb-threatening ischemia.

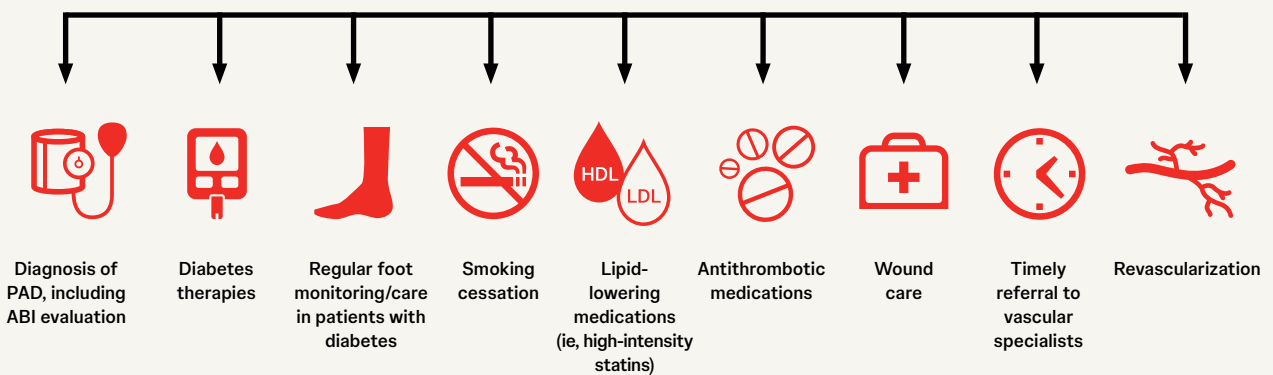
^aNote that order of flow in the circle of care is patient specific.

^bInpatient and Outpatient CLTI Navigators are crucial for ensuring seamless continuity of care for patients. Responsibilities include managing intake assessments, coordinating care among all physicians involved in the patient's care, overseeing discharge planning, providing continuous patient education, and facilitating patient support and transportation, all of which can lead to improved patient outcomes and satisfaction.

Disease Management Recommendations

An ankle-brachial index (ABI) ratio of less than 0.9 in either leg indicates the presence of PAD.¹⁸ A low ABI ratio also is associated with an increased risk for worsening symptoms in the lower limbs and for cardiovascular disease events.¹⁸ According to the 2024 Guideline for the Management of Lower Extremity Peripheral Artery Disease, goals of PAD management include reducing the risk of cardiovascular events, preventing limb events and the need for amputation, and improving QOL and functional status.¹ Achieving these goals requires a multidisciplinary team approach that may incorporate care from vascular specialists, endocrinologists, podiatrists, plastic surgeons, infectious disease specialists, wound nurses, orthotists and prosthetists, nutritionists and diabetes educators, pharmacists, and physical therapists.^{1,8,10}

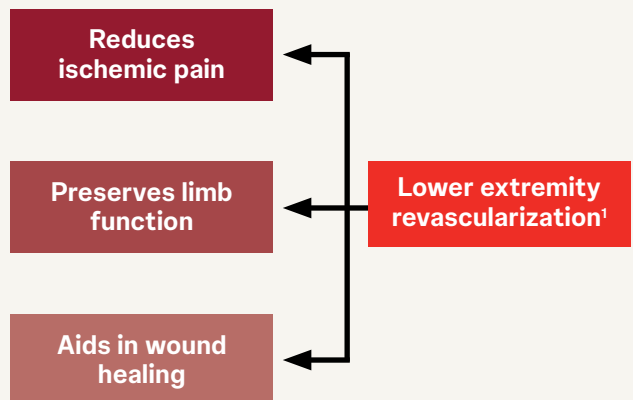
Evidence-Based Management to Decrease Lower Extremity Amputation Risk in Patients With PAD^{1,10}



ABI, ankle-brachial index; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PAD, peripheral artery disease.

Patients with PAD should be offered guideline-based pharmacotherapy and counseling to reduce the risk of cardiovascular and limb-related events and target individual patient risk factors such as diabetes or hypertension.¹ For patients with CLTI, treatment decisions should be made after comprehensive imaging (eg, ultrasonography, angiography) of the limb is completed to reveal the structure and severity of arterial stenosis; a multidisciplinary care team should then determine the possibility of limb preservation or the necessity of amputation.^{6,8,25} However, primary amputation is rarely an appropriate first-line treatment option.²⁵

In addition to medical therapy, individuals with CLTI should be offered wound healing therapy and revascularization to minimize tissue loss, reduce ischemic pain, and maintain functioning of the limb. For lower extremity revascularization in patients with CLTI, surgical, endovascular, or hybrid approaches are used to restore in-line blood flow to an artery in the foot or—for patients with CLTI-related wounds—provide direct blood flow to the wound bed (eg, angiosome).¹



According to Ms Marquez, **the key to the CLTI program is incorporation of Inpatient and Outpatient CLTI Navigators, who are essential for the successful continuity of care.**

The Inpatient Navigator is responsible for performing the intake assessment of all patients with CLTI, coordinating patient transfers from other facilities, communicating with all physicians involved in the patient's care, guiding the discharge planning and process, and keeping in contact with patients to provide education and ensure that they attend their follow-up appointments. The hospital also has a phone line that is monitored by the Navigator 24 hours per day, 7 days per week. When the Navigator is unavailable, another CLTI protocol-trained provider monitors the line. This phone line is used by physicians to quickly contact the CLTI providers and by patients to request assistance or get answers to care questions.

Ms Marquez explained that the Inpatient CLTI Navigator also educates all providers in the hospital about the CLTI program and protocols. Particularly for staff working in the emergency department—where many patients initially present—there is an emphasis on the signs and

“[CLTI management discussions] happen quickly—a lot faster than they would if we were waiting for each consultant. We wanted to ensure that we’re opening those arteries and improving the blood flow; [therefore], if we needed to amputate a toe or perform debridement, there’s already vascular flow... Having that communication has helped patients get to where they needed to go faster and better.”

— Rosa Marquez, MSN, FNP-C, RCIS

symptoms of PAD and CLTI (eg, pain while walking, variations in peripheral pulse, ulcers, and changes in appearance of the lower extremity) and the importance of initiating noninvasive studies as soon as a patient presents with those indicators. After starting the noninvasive studies, a nurse contacts the Inpatient CLTI Navigator, who confirms that the necessary tests were completed and asks that the patient be referred to an interventionalist on the call list. Nurses continue to monitor the patient to ensure that the situation is not acute. After obtaining results from noninterventional studies, the Inpatient CLTI Navigator guides the management plan by communicating with the interventional cardiologist and providers from the departments of Podiatry and Infectious Disease. “[These discussions] happen quickly—a lot faster than they would if we were waiting for each consultant,” said Ms Marquez. “We wanted to ensure that we’re opening those arteries and improving the blood flow; [therefore], if we needed to amputate a toe or perform debridement, there’s already vascular flow. If there’s no blood flow, surgery is not going to be successful, and [the wound] is going to become necrotic and is not going to heal. Having that communication has helped patients get to where they needed to go faster and better.” Once a management plan is determined, the CLTI Navigator provides the patient with education about any procedures and the importance of taking prescribed medications and managing their general health (eg, blood pressure, glycemic control). **Martha Tapia, APRN, MSN, FNP-BC**, explained that patient education begins in the inpatient setting and then continues throughout the patient’s outpatient care journey.

Patients have a follow-up appointment 1 week after any revascularization procedure to examine the wound and lower extremities. The ABI is assessed in the office at 30 days and at 3, 6, 9, and 12 months; examinations performed at 30 days and 12 months are full ABI assessments and ultrasound arterial duplex evaluations. The Outpatient Navigator in Dr Raja’s office assists the Inpatient Navigator with continuity of care into the outpatient setting; for patients seen at other healthcare offices, the Inpatient Navigator may coordinate with an office manager or other medical office staff. The Navigator will collaborate with specialists (eg, providers involved with infectious disease, wound care, or podiatry), schedule follow-up appointments, and help ensure that patients attend these appointments by calling in advance of their scheduled visits and connecting them with transportation assistance as needed. “So much of [care for patients with CLTI] is not just intervention and identifying and fixing the problem; it’s also continuing with follow-up once a patient is discharged,” explained Ms Marquez. “The [Outpatient] CLTI Navigator role is essential to ensure that patients receive education and assist with the intense follow-up that’s needed after discharge from an acute setting.”

In addition to ensuring that patients keep follow-up appointments, the Outpatient Navigator performs a needs assessment to make certain that patients have a support system at home and transportation to attend their outpatient appointments. They also can bridge patients to a long-term acute care facility, if needed. Patients are given phone numbers for the Inpatient and Outpatient CLTI Navigators, known collectively as the *amputation prevention hotline*, whom they can call, text, and send pictures of their wounds. “Communication and accessibility to our team is important for the success of the program,” said Ms Henderson.

Gaining Buy-In and Overcoming Obstacles

Prior to developing the program, Dr Raja and his colleagues brainstormed with vascular medicine experts who implemented multidisciplinary CLTI programs at their institutions. The team consulted with founders of CLTI programs at other organizations who shared their knowledge, protocols, patient education, and data. These experts included Jihad Mustapha, MD, FACC, FSCAI, cofounder of the Advanced Cardiac & Vascular Centers for Amputation Prevention in Grand Rapids, Michigan, and Craig Walker, MD, of the Cardiovascular Institute of the South in Louisiana and Mississippi. To help secure buy-in from the hospital administration for the program in El Paso, Ms Henderson presented a model of the proposed multidisciplinary CLTI program to demonstrate how it could have positive economic impact on a hospital by reducing readmissions, decreasing amputations, and improving patient satisfaction.

From an administrative perspective, Mr Anderson noted, “Having a dedicated CLTI Navigator who helps that patient through the different stages of their disease really provides the best outcomes, the best care.” He explained that the CLTI Navigator also boosts patient satisfaction. “They feel that they have someone to help them and their family through this [care journey]. And that’s what ties it all together and makes the program flow.”

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— Rob J. Anderson, MBA

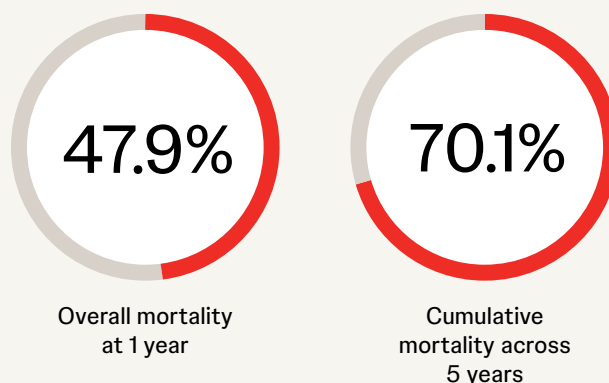
According to Ms Henderson and Ms Marquez, **choosing the right person for the CLTI Navigator role is imperative.** The ideal individual is someone who is knowledgeable about vascular anatomy and the various interventions needed for CLTI, is able to effectively communicate and build relationships with the different providers, and is invested in supporting patients through their care journey. Ms Henderson

Clinical and Economic Impact of Amputations in Patients With PAD and CLTI

The 1-year mortality rate among patients with CLTI ranges between 15% and 40% depending on factors such as disease severity, presence of diabetes, and amputation.¹⁷ Major amputation is associated with an increased risk of short- and long-term mortality in those with PAD or CLTI.¹⁷ Indeed, following major or minor amputation, the overall mortality rate among patients with PAD is 47.9% at 1 year; the cumulative mortality rate is 70.1% across 5 years after amputation.^{26*}

Among patients with CLTI, revascularization is associated with improved clinical outcomes and with lower healthcare costs than is amputation.^{11,27} Compared with surgical or endovascular revascularization, primary major amputation is associated with a higher risk for subsequent major amputation and shorter survival regardless of clinical CLTI presentation severity (ie, rest pain, ulcer, or gangrene).¹¹ Patients with CLTI who undergo revascularization experience a lower risk of major amputation or inpatient death and incur lower healthcare costs than do those who undergo major amputation.^{11,27†}

After amputation, patients with PAD experience increased rates of mortality over time.^{26*}



*Based on a systematic review and meta-analysis of global, retrospective, observational, and cohort studies of primary amputations (2005–2015) wherein 50% or more of these amputations were due to peripheral vascular disease. Nearly 100% of the participants included in the analysis had peripheral vascular disease and most (60.6%) had diabetes. Study results may be limited due to design of the analysis and reviewed studies.²⁶

†Based on the 2010–2015 Medicare claims analysis of 72,199 adults with CLTI. After propensity-score matching for baseline characteristics, among 9942 patients, the 4-year survival rates for endovascular and surgical revascularization (38% and 40%, respectively) were significantly higher (both, $P < 0.001$) than for major amputation (23%); significance vs major amputation was present within each clinical presentation category. Major amputation rates in follow-up for endovascular or surgical revascularization (6.5% and 9.6%, respectively) were significantly lower (both, $P < 0.001$) than for primary major amputation (10.6%). After adjustment for follow-up duration, the costs per patient-year (in 2016 US\$ among 9219 patients) for endovascular and surgical revascularization (\$49,700 and \$49,200, respectively) were significantly lower (both, $P < 0.001$) than for major amputation (\$55,700). Limitations included the possibility of miscoding, limited data on patient characteristics, and inability to control for repeat procedures on the contralateral leg or determine the rationale for treatment procedures.¹¹

‡Based on a retrospective analysis of 2006–2014 data from 52,527 patients with CLTI from the Truven Health MarketScan Commercial and Medicare Supplemental Databases. Patients with CLTI who experienced a major amputation (defined as amputation above the ankle) incurred an estimated additional monthly cost (US\$) of \$6000 (or \$5000 without pharmacy claims) compared with those who were managed with peripheral vascular intervention or surgery (PVI/S), minor amputation without PVI/S, or conservative therapy (patients with CLTI and gangrene and with no record of PVI/S or minor amputation). The study was limited by the use of claim-based data that lack important clinical variables, may contain errors, and do not represent the uninsured population; long-term outcomes were not assessed.²⁷

explained that a nurse often works best for this function, because nurses tend to play a neutral role in patient care. She emphasized that the Navigator has to be able to troubleshoot, have some “finesse with the doctors to be able to work through frustrations,” and help everyone to decide what is best for the patient without competing with each other.

Within the CLTI program, the various practices involved in the outpatient CLTI team use different electronic health record (EHR) systems. To overcome the EHR system obstacle among the private-practice physicians involved in the program, team members looked for creative ways to deliver information; this included using CarePICS, an application that allows all of a patient’s providers to review follow-up pictures of the wound and the results of follow-up testing.

According to Ms Henderson, many revascularization procedures used in CLTI care are not standardized, and specific training and fellowship opportunities specifically for PAD are limited. “A lot of times, it’s still left to the physician to go and seek that extra training and to learn how to do advanced procedures for peripheral vascular intervention,” she said. “The physician has to have that passion.” She emphasized that having a physician champion such as Dr Raja was essential to developing the program and maintaining the improved outcomes.

For the CLTI program to be effective, Dr Raja knew that establishing standardized policies was a necessity. All CLTI cases seen at the Hospitals of Providence Memorial Campus are reviewed by the medical director of the CLTI program. However, one of his first tasks was to invite all of the interventional cardiologists, vascular surgeons, interventional radiologists, and other physicians with an integral role in CLTI care to join a CLTI committee. The group of 15 to 20 physicians who expressed interest in participating have since collaborated to create CLTI treatment guidelines for each

Dr Raja and his colleagues instituted a policy mandating that all patients being considered for amputation are required to undergo angiograms and potentially, revascularization procedures. Additionally, all cases must be reviewed by the CLTI committee, typically via a conference call held within 24 hours.

stage of the care journey. All CLTI cases with unexpected standard outcomes or complications are reviewed by the CLTI committee.

For example, Dr Raja estimated that the majority of patients who undergo major amputation never receive an angiogram. Therefore, his colleagues and he instituted a policy mandating that all patients being considered for amputation are required to undergo angiograms and potentially, revascularization procedures. Additionally, all cases must be reviewed by the CLTI committee, typically via a conference call held within 24 hours. The call includes all physicians involved in the patient’s care, including 2 vascular physicians, 2 podiatrists, an infectious disease specialist, and the attending physician. The committee reviews the case and votes on whether an amputation can proceed or a second opinion with an additional vascular evaluation is needed. “The second opinion process is very formal, so it does not create any political unrest,” explained Ms Henderson. “You have to ensure that it is structured very diplomatically and that there’s a very clear algorithm for all the physicians to follow that explains how the process works.”

Members of the Committee of Vascular and CLTI Services include:

- Interventional cardiologists and radiologists
- Primary care providers
- Vascular surgeons
- Podiatrists
- Orthopedic surgeons
- Infectious disease specialists
- Nephrologists
- Cardiologists
- Cardiovascular services director
- CLTI Navigators
- Wound care specialists
- Quality Department staff
- Nurse practitioners with CLTI focus
- Inpatient unit directors (progressive care unit, medical/surgery unit, and intensive care unit)
- Chief operations officer/chief nursing officer



Mr Anderson and Dr Raja shared that they initially received some pushback from other physicians in the early stages of developing these processes. Some cardiologists within the hospital system had deviated from evidence-based best practices for PAD and CLTI, which made it difficult to ensure a consistent level of patient care across the hospitals. “A few cardiologists [believed that] they didn’t need to use the CLTI committee, and they didn’t need to have those patients reviewed,” said Mr Anderson. “But the rate of amputations for those providers was 20% or 30% greater [than for their colleagues].” **By reassuring providers that the intent of the CLTI program was to optimize patient outcomes, and by showing them data on the improvement in outcomes seen with program participation, Mr Anderson and Dr Raja were able to improve buy-in among these physicians.** In addition, the review policy helped encourage physicians who were previously hesitant to perform full evaluations to order the appropriate testing for the benefit of the patient.

Closing Gaps in Care and Measuring Effectiveness of Initiatives

In 2022, The Joint Commission accredited the Hospitals of Providence Memorial Campus as a Center of Excellence for PAD¹⁶; according to Dr Raja, this accreditation was based heavily on outcomes such as amputation rate, hospital readmissions, and hospital length of stay. He explained that the rate of major amputations was 5.3% in 2021-2022 and predicted that the major amputation rate in 2023 was likely to be even lower (~3.2%). He shared that since implementing the CLTI program, the hospital length of stay also decreased for all patients who underwent a procedure—from about 12 to 15 days down to 5 to 6 days.* The rate of hospital readmissions also decreased considerably to approximately 3 or fewer readmissions per month.

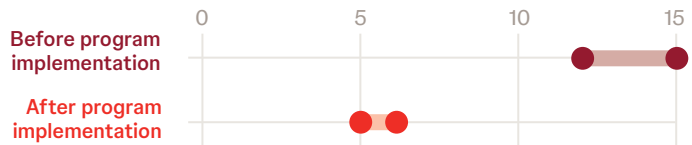


A Center of Excellence in PAD and CLTI should include^{8,10}:

- a multidisciplinary team of specialists to manage PAD and CLTI and related risks and sequelae;
- protocol-driven care based on evidence-based clinical practice procedures and pathways integrated into the EHR;
- screening for SDOH and barriers to care in populations at high risk for amputation;
- a clear process to collect data and report outcomes, and distinct procedures to continually improve services based on outcomes data and new treatments and techniques; and
- PAD and CLTI diagnosis and management education for providers, patients, and caregivers.

All physicians interested in performing peripheral vascular procedures at the Hospitals of Providence Memorial Campus must be proficient in wound-directed revascularization and the angiosome concept of foot perfusion, and they need to have performed at least 25 below-the-knee procedures within 1 year; those who do not meet this minimum are proctored until these requirements are met. After gaining privileges to perform revascularization procedures at the hospital, physicians also are required to complete continuing education courses in CLTI management and attend relevant professional conferences.

Hospital stay length following procedures has decreased since implementing the CLTI program, going from ~12-15 days down to 5-6 days.



Measuring Success

The CLTI program incorporates a multifaceted definition of successful revascularization, which includes stenosis of 50% or less following the intervention, without flow-limiting dissections; acceptable healing rates (assessed with pictures at baseline and at each follow-up visit); and absence of infection. According to Ms Henderson, a fully perfused wound will start to show improvement by about 4 to 6 weeks, and it should be fully healed by 3 months.

Successful management of patients in the CLTI program often is complex, shared Ms Tapia, because many patients have multiple comorbidities including hypertension, renal disease, and diabetes. She added that ongoing education about PAD and the CLTI program is a priority in the El Paso community because many patients among the predominantly Hispanic population tend to wholly trust doctors' opinions, and they may accept the first doctor stating that amputation is the only option without seeking a second opinion. Colleague **Pedro Medina, FNP**, also educates patients that PAD and CLTI are lifelong diseases that require ongoing management and monitoring. This emphasis on patient education is helpful to minimize loss to follow-up. Medina explained, "Our patients are great about following up with us because they are well informed as to what is going on with their disease process. And they do not want to lose their leg. They want to get better." Through the Limb Savers Society, an amputation prevention nonprofit organization created by Dr Raja and Ms Henderson,²⁸ El Paso Cardiology Associates recently hosted a health fair focused on PAD that included providers from the departments of Cardiology, Podiatry, and Infectious Disease and vendors from other health organizations. Free PAD evaluations were offered at the fair along with screenings for blood glucose and cholesterol levels. Moving forward, the plan is to continue to host these fairs annually.

*These data represent the length of hospital stay for patients when in-hospital processes and procedures occur on schedule.

Although the CLTI providers in El Paso are in relatively close geographic proximity to each other, patients often travel from long distances and from out of state to receive care. When possible, Ms Tapia and Mr Medina schedule studies and follow-up appointments with providers close to the patient's home. If the patient needs a procedure, the team then coordinates clinic visits and hospital appointments so that the patient does not have to make multiple trips to El Paso.

Financial assistance also is provided for patients who need help with co-payments, transportation, or wound care supplies. Ms Tapia explained that much of this assistance is available via the Limb Savers Society, which raises money through CLTI conferences. The CLTI program also works with the Never Too Late Foundation,²⁹ which provides clothing and food assistance for underfunded populations and groups. “We try to make it as easy as we can for the patient, because that’s where much of the loss to follow-up happens,” explained Ms Tapia. “If [patients] don’t have the access to transportation or [if they need] financial assistance, sometimes for gas or for hotels, this is where our nonprofits come in.”

“We try to make [receiving CLTI care] as easy as we can for the patient, because that’s where much of the loss to follow-up happens. If [patients] don’t have the access to transportation or [if they need] financial assistance, sometimes for gas or for hotels, this is where our nonprofits come in.”

— Martha Tapia, APRN, MSN, FNP-BC

Advice to Leaders of Other Organizations Seeking to Improve Healthcare Access

Mr Anderson advised that staff at other institutions who want to implement a CLTI program should determine the type of program needed in their community and gain the help of the medical and clinical leadership to guide the development. Furthermore, all stakeholders—CLTI providers, medical executive committee, governing board, etc.—need to agree on processes for the program. Ms Marquez emphasized the importance of administrative buy-in “to understand what the program is, how it works, and [why steps are needed in] the process. We had [the administration] very involved and part of all the CLTI meetings for that reason.”

According to Ms Henderson, meticulous tracking of data also is needed to develop the program and to demonstrate its success. “You need to have data,” she said. “You should be abstracting [data such as] how many amputations per month? How many procedures? What are the outcomes of the procedures? What is the success rate? How do you identify—and how do you define—technical success in the case?”

Dr Raja recommended that leaders of other institutions who want to implement a CLTI program should ensure that they have physician champions who are passionate about treating people with CLTI and who have top-level expertise in the field and a care team that has the patient at the center of care. “The whole objective, the concept of this program, is centered on patient outcomes—decreasing amputation, decreasing mortality,” said Dr Raja. “The business [side] will come, but that should not be the [primary goal].”

Ms Tapia emphasized that it takes time for such comprehensive multidisciplinary programs to function smoothly, noting, “There are going to be obstacles. There are going to be many things that come up that you’re going to have to work around. There are going to be a lot of patients who make it difficult. But you just have to stick with it.” She continued, “You see [the improvement in] these wounds and patients [who] are so gracious to you. It’s gratifying to stick to it and see those outcomes at the end of all the challenges.”

The cohesiveness of CLTI care from providers specializing in interventional cardiology, podiatry, wound care, and infectious disease also is key to the successful multidisciplinary program at the Hospitals of Providence Memorial Campus, said Mr Medina. “Working closely with the rest of our colleagues and specialties is really unique and what makes it successful,” he explained. “Everyone is really trying to work together for the same goal and to help the patient.”

The American Heart Association has set a goal of reducing the rate of nontraumatic lower extremity amputations by 20% by 2030.¹⁰ To help meet this goal, it is imperative that CLTI programs consider community needs, gather stakeholder consensus on treatment and program processes, and foster communication across a patient-centric multidisciplinary care team.

Resources

THE JOINT COMMISSION RESOURCES

The Joint Commission enterprise is a global driver of quality improvement and patient safety in health care. Through leading practices, unmatched knowledge and expertise, and rigorous standards, members of The Joint Commission help organizations across the continuum of care lead the way to zero harm.

<https://www.jointcommission.org>

Disease-Specific Care Certification Review Process Guide 2023

<https://www.jointcommission.org/-/media/tjc/documents/accred-and-cert/survey-process-and-survey-activity-guide/2023/2023-disease-specific-care-organization-rpg.pdf>

PROVIDER RESOURCES

2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESSE Guideline for the Management of Lower Extremity Peripheral Artery Disease

<https://www.sciencedirect.com/science/article/pii/S0735109724003814?via%3Dihub>

CardioVascular Coalition

<https://cardiovascularcoalition.com/>

The Limb Savers Society

<https://www.limbsaverssociety.com/>

PAD Toolkit for Health Care Professionals (American Heart Association)

<https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-toolkit>

Peripheral Artery Disease (PAD) National Action Plan (American Heart Association)

<https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-resources/pad-action-plan>

PATIENT RESOURCES

Never Too Late Foundation

This charity provides a community fund to assist with supplies for families and nonprofit shelters and furnishes a local pantry for people in need.

<https://www.officiallynevertoolate.org/>

Save Legs. Change Lives.

Save Legs. Change Lives. is a multiyear initiative aimed at creating urgency and action to help address the hidden threat of peripheral artery disease (PAD)-related amputation, particularly among Black Americans, who are up to four times more likely than other Americans to have a PAD-related amputation. With this critical initiative, Johnson & Johnson aims to advance equitable care for individuals affected by PAD and members of communities placed at increased risk for PAD.

<https://www.savelegschangetolives.com/patient-resources.html>

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