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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Inadequacies in Patient Safety Reporting Processes and Alleged Deficient Quality of Care Prior to a Patient's Foot Amputation at the Edward Hines, Jr. VA Hospital in Illinois

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Edward Hines, Jr. VA Hospital (facility) in Hines, Illinois, to assess an allegation that deficient quality of care resulted in the amputation of a patient's foot.[1] The OIG did not substantiate the allegation; however, the OIG found that podiatry staff missed an opportunity to provide reeducation and refit the patient with VA-issued diabetic shoes (VA-issued shoes). Additionally, the OIG found inadequacies in the patient safety reporting process related to the alleged deficient clinical care.

According to the electronic health record, in the fall of 2022, the patient temporarily stopped anticoagulation therapy for a colonoscopy; fell at home while wearing VA-issued shoes; and later developed an acute arterial occlusion that led to a left foot amputation. The facility vascular surgeon (vascular surgeon) told the OIG that the acute arterial occlusion may have been caused when the patient temporarily stopped the anticoagulant medication (prior to a bleeding-risk procedure) or possibly due to the fall.

The OIG reviewed the patient's care and found that pharmacy staff managed the patient's anticoagulation therapy in accordance with Veterans Integrated Service Network and facility guidance. The OIG found that the clinical pharmacy specialist determined that bridging was not necessary, instructed the patient to stop anticoagulation therapy prior to the scheduled colonoscopy, and resume anticoagulation medication the day after the colonoscopy.[2]

In fall 2021, the former podiatrist provided the patient with a new pair of VA-issued shoes that had known challenges related to fit and heel slippage and gave instructions about placement of the feet into the shoes.[3] The patient did not bring the VA-issued shoes to the annual evaluation in fall 2022, and the former podiatrist documented that the patient had been noncompliant with use. Despite the known challenges with the VA-issued shoes and documented noncompliance, the OIG found no documentation of refitting or reeducating the patient about placement of the feet in the shoes.

The day after the fall and three subsequent interactions (within the next week), the patient reported to clinical staff symptoms that included either pain, swelling, bruising, or trouble standing and walking. Clinical staff ordered x-rays and recommended to the patient an in-person

[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the *alt* and *left arrow* keys together.

[2] International normalized ratio is a test to evaluate blood clotting. *Mayo Clinic*, "Prothrombin time test," accessed June 5, 2023, https://www.mayoclinic.org/tests-procedures/prothrombin-time/about/pac-20384661. The patient's international normalized ratio was 1.2 on the day of the colonoscopy. The patient's international normalized ratio approximately two weeks later was 3.4.

[3] The shoes open up completely on top like a clamshell, so the foot can be inserted then secured with Velcro straps. According to the former podiatrist, heel slippage was a known issue if a person's heel was not placed against the back of the shoe and the shoe securely fastened.

evaluation at the Joliet Community Based outpatient clinic, facility main campus (main campus), or community urgent care.[4]

Eleven days after the fall, the patient called a VA clinical contact center registered nurse and reported that the left foot was colder than the right.[5] The clinical contact center registered nurse advised the patient to go to an emergency department; however, the patient declined and chose to see the primary care provider at a scheduled appointment the next day.[6] At the appointment, the primary care provider assessed the patient, found that the left leg was colder to touch than the right, ordered stat doppler studies to evaluate for an arterial occlusion, and told the patient to go to the main campus Emergency Department. The patient elected to wait until the following day due to transportation concerns.[7] Although not documented, the primary care provider told the OIG that the patient was informed of the risks associated with not receiving immediate emergency care and provided transportation options; however, the patient told the OIG the risk of losing a limb was not discussed.

The following day, the patient underwent doppler studies at the main campus that revealed no arterial flow in the dorsalis pedis and the left posterior tibial arteries of the affected leg. A computed tomography angiogram showed a left distal iliac artery aneurysm and "complete left superficial femoral and popliteal artery occlusion." The vascular surgeon, who cared for the patient, explained to the patient the need for emergent revascularization of the left leg and the high probability for amputation. The patient underwent an open thrombectomy of the left common femoral artery and its branches and the external iliac artery to withdraw the blood clot. Surgery staff performed a left foot amputation because the muscle tissue appeared nonviable.

Veterans Health Administration policy notes that "for incidents involving patient safety, patient advocates should work with their local [facility] patient safety officers to insure documentation and oversight."[8] In late 2022, the patient reported to a patient representative (patient advocate) that the primary care provider neglected to provide medical attention for the left foot after the fall at home. The patient advocate provided the patient with tort claim and provider change forms but

[4] The patient received primary care and podiatry services at the Joliet Community Based outpatient clinic (Joliet clinic), 37 miles from the main campus. The patient reported to staff that an x-ray was completed at a community hospital; however, due to the wait time, the patient did not receive the results of the x-ray and clinical evaluation.

[5] VHA Directive 1006.04(1), *Clinical Contact Centers*, May 16, 2022, 1–3. The directive further notes VHA provides daily 24-hour access to clinical triage via telephone, video, chat, and other modalities. Patients can call clinical contact centers and speak to a registered nurse for an evaluation of their symptoms.

[6] The clinical contact center registered nurse also alerted the primary care provider by placing the provider as an additional signer on the note.

[7] The primary care provider reported also discussing transportation options that included self-transportation, an ambulance, or a "medicar" (medical transportation) to take the patient to the main campus.

[8] VHA Directive 1003.04, *VHA Patient Advocacy*, February 7, 2018, was in effect at the time of the events discussed in this report. The directive was rescinded and replaced by VHA Directive 1003.04, *VHA Patient Advocacy*, November 9, 2023. The 2023 directive requires patient advocates to document patient safety allegations in the joint patient safety reporting system.

did not report the incident or consult with the patient safety staff. The patient advocate told the OIG this was due to a lack of training. However, the OIG found the patient advocate received training on patient safety reporting prior to the patient reporting the incident.

The OIG made one recommendation to the Veterans Integrated Service Network Director related to the need for patient advocacy staff to consult with the patient safety staff regarding patient safety concerns, and one recommendation to the Facility Director related to the missed opportunities referenced in this report regarding refitting and reeducating patients on VA-issued shoes.

VA Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

EHR	electronic health record
INR	international normalized ratio
JPSR	joint patient safety reporting
OIG	Office of Inspector General
PACT	patient aligned care team
RN	registered nurse
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Edward Hines, Jr. VA Hospital (facility) in Hines, Illinois, to assess an allegation that deficient quality of care resulted in the amputation of a patient's foot.[1] The OIG evaluated a related concern regarding patient safety reporting.

Background

The facility, part of Veterans Integrated Service Network (VISN) 12, consists of a hospital (main campus) in Hines, Illinois, and six community-based outpatient clinics. The Veterans Health Administration (VHA) rates the facility as 1a, the highest complexity level.[2] From October 1, 2021, through September 30, 2022, the facility treated 58,171 patients and had 473 operating beds, including of 238 hospital beds, and 210 community living center beds. Patients may receive outpatient services such as pharmacy, radiology, surgery, emergency care, and other specialty services at the main campus.

Joliet Community Based Outpatient Clinic

The Joliet Community Based outpatient clinic (clinic) is located in Joliet, Illinois, 37 miles from the main campus, and provides outpatient services, including primary care, podiatry, laboratory, and other specialty health services. For urgent health issues, the clinic offers same day appointments, telehealth visits, or walk-in express care. Clinic hours are Monday through Thursday from 7:30 a.m. to 6:30 p.m. and Friday from 7:30 a.m. to 4:30 p.m.; the clinic is closed on Saturdays and Sundays. Although the clinic is closed Saturdays and Sundays, VHA requires VISNs offer patients 24/7 access to clinical triage through a clinical contact center.[3] From October 1, 2021, through September 30, 2022, the clinic treated 8,822 unique patients and completed 49,191 outpatient visits.

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[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] VHA Office of Productivity, Efficiency, and Staffing, "Fact Sheet: Facility Complexity Model." The VHA Facility Complexity Model categorizes medical facilities by complexity level. Complexity levels include 1a, 1b, 1c, 2, or 3, with 1a being the most complex. Facilities with a Level 1a complexity level rating are described as having "high volume, high risk patients, most complex clinical programs, and large research and teaching programs."

[3] VHA Directive 1006.04(1), *Clinical Contact Centers*, May 16, 2022, 1–3. The directive further notes VHA provides daily 24-hour access to clinical triage via telephone, video, chat, and other modalities. Patients can call clinical contact centers and speak to a registered nurse for an evaluation of their symptoms. A clinical contact center registered nurse uses an algorithm (a set of questions) to determine presenting symptoms and provide advice on medical care needs, to include an emergency department evaluation and treatment; Julie Briggs, "Introduction: Practicing Telephone Triage Safely," *Telephone Triage Protocols for Nurses*, 6th ed. (Lippincott Williams & Williams, 2021), 1–9.

Allegations and Related Concerns

On February 24, 2023, the OIG received an allegation regarding deficient quality of care that resulted in the amputation of a patient's foot. The OIG opened a hotline on March 23, 2023, to evaluate the allegation. Specifically, the OIG evaluated whether

- patient aligned care team (PACT) staff and a clinical contact center registered nurse (RN) referred the patient to an emergency department for evaluation and treatment upon identifying symptoms of an arterial occlusion,
- staff communicated risks associated with not immediately seeking treatment,
- pharmacy staff managed the patient's anticoagulation therapy adequately, and
- podiatry staff previously provided deficient quality of care that could have prevented the patient's fall.

Additionally, the OIG evaluated a concern identified during the inspection regarding patient safety reporting related to both the patient's fall and the alleged deficient quality of care.

Scope and Methodology

The OIG completed a site visit at the facility from April 24 through 27, 2023. Additional virtual interviews were conducted prior to and after the site visit.

The OIG interviewed VISN leaders, facility senior leaders, service chiefs and supervisory staff, quality management staff, frontline clinical and nonclinical staff, the patient, and the patient's family members.[4]

The OIG reviewed VHA, VISN, and facility policies and standard operating procedures; external standards and literature reviews; email correspondence and the patient's electronic health record (EHR); patient advocate tracking system reports and a non-OIG complaint; personnel, credentialing and privileging records; a staff member's training records; and quality management reviews relevant to this inspection.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take

[4] The OIG interviewed a former podiatrist as part of frontline clinical staff. The former podiatrist referenced in this report retired in early 2023 prior to this inspection.

place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

Patient Case Summary

The patient, in their 80s, had a history of type 2 diabetes mellitus, hypertension, obesity, edema, blood clots, atrial fibrillation, diabetic neuropathy, a left total knee arthroplasty, and coronary artery disease; and used a walker.[5] The patient started on a long-term anticoagulation therapy medication (warfarin) in summer 2007.

In late spring 2019, the patient received a new pair of VA-issued diabetic shoes (VA-issued shoes) and reported being "happy with the fit and comfort." At the same appointment, podiatry staff provided the patient with "written and oral break-in instructions."

In mid-fall 2021, the patient presented for a scheduled appointment at the facility's podiatry clinic with complaints of long, thickened toenails and increased foot swelling causing difficulty with the fit of the VA-issued shoes. Podiatry staff refitted and provided the patient with another style of VA-issued shoes to accommodate for swelling.[6] The former podiatrist provided the patient with "written and oral break-in instructions" for the new shoes and education on the patient's heels being positioned against the back of the shoes and securing the straps to prevent the feet from slipping. The patient reported being "happy with the fit and comfort of the shoes."

In spring 2022, during a scheduled appointment, the former podiatrist documented that the patient's pedal pulses in the feet were not palpable, likely due to edema. The patient's feet were warm to the touch and pink in color, with a capillary refill time of three seconds to all toes.[7] The

[5] The OIG uses the singular form of they, *their* in this instance, for privacy purposes.

[6] According to the former podiatrist, the shoe is deeper than a normal shoe to accommodate swelling of the feet. The shoes opens up completely on top like a clamshell so the foot can be inserted and secured with Velcro straps.

[7] "Capillary refill time assesses blood circulation in your arms and legs." Normal capillary refill time in adults is three seconds and sometimes longer for older adults. Capillary refill is tested by applying pressure to a finger or toe for up to 10 seconds making the skin turn pale in color. The pressure is then released, and the time before the skin returns to the same color as the surrounding tissue is measured. *Cleveland Clinic*, "Capillary Refill," accessed March 27, 2023, https://my.clevelandclinic.org/health/diagnostics/23376-capillary-refill-time.

former podiatrist documented the lower extremity edema as 2+ in the ankles and legs.[8] The neurological examination revealed diminished touch sensation of the toes.

In fall 2022, anticoagulation clinic staff instructed the patient to temporarily stop taking warfarin before a scheduled colorectal surveillance colonoscopy. One week later, the morning of the colonoscopy, the patient had an international normalized ratio (INR) of 1.2.[9] The gastroenterology provider documented the patient's positioning was on the left side for the colonoscopy and completed without any reported complications.

Six days later, during a scheduled appointment, the former podiatrist documented no clinical changes from the spring 2022 podiatry visit and instructed the patient to wear the 2021 VA-issued shoes. The next day, the patient walked into the clinic for an unscheduled visit and reported to the PACT RN of falling out of the shoe while walking downstairs the day before and landing on the left knee, causing pain and difficulty standing and walking. The PACT RN noted the "leg appear[ed] bruised and slightly swollen" and advised the patient to go to an urgent care clinic to be evaluated. The patient went to a community hospital emergency department where x-rays of the painful knee and ankle were completed, but the patient left prior to being evaluated by a provider due to waiting for five hours.

Three days later, the patient called and informed the former podiatrist of the fall with reported complaints of pain to the knee, and mentioned that x-rays were completed at the community hospital emergency department. The patient reported falling while wearing the VA-issued shoes. The former podiatrist advised the patient to call the primary care provider and request the x-rays from the community hospital. The next day, the PACT RN called the patient and the patient reported continued leg pain. The PACT RN documented the intent to request the community hospital records. The following day, the primary care provider documented being unsure if doppler ultrasound studies had been completed, needing to get the x-ray and report from the community hospital, and recommending the patient see a provider or go to the main campus Emergency Department. Later that day, the primary care provider ordered a repeat x-ray of the left ankle. There is no record of the patient completing the left ankle x-ray on that date.[10]

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[8] The Cleveland Clinic webpage notes the edema grading scale is used to determine how much fluid has built up in the tissues. The edema scale is rated Grade 1–Grade 4. A provider will gently press their finger on the swollen area of the skin and after the pressure is released, a dimple in the skin will appear. How quickly the dimple goes back to normal will determine the grade of edema. *Cleveland Clinic*, "edema," accessed July 11, 2023, https://my.clevelandclinic.org/health/diseases/12564-edema.

[9] "In healthy people, an INR of 1.1 or below is considered normal. An INR range of 2.0 to 3.0 is generally an effective therapeutic range for people taking warfarin for certain disorders. These disorders include atrial fibrillation or a blood clot in the leg or lung." *Mayo Clinic*, "Prothrombin time test," accessed June 5, 2023, https://www.mayoclinic.org/tests-procedures/prothrombin-time/about/pac-20384661. The gastroenterology provider stated the patient discontinued taking the anticoagulant prior to the procedure as instructed.

[10] The provider ordered an x-ray for the left ankle secondary to continued complaints of pain from the patient and questionable results from the community hospital x-ray results.

The following week, the patient called a clinical contact center RN and reported the fall due to the VA-issued shoes, with injury to the left knee and ankle. The patient reported severe pain and swelling in the calf down to the ankle and indicated that the foot was red and cold compared to the other foot. The clinical contact center RN advised the patient to get an emergency department evaluation "now." The patient declined and was informed that delaying care could result in a "worsening medical condition." Instead, the patient agreed to attend the scheduled appointment with the PACT team the next day.

The primary care provider saw the patient in the clinic the next day and the left ankle x-ray was completed, which revealed no fracture. The primary care provider documented the presence of pedal pulses in both feet and both legs were red from the calves to feet. The primary care provider ordered stat bilateral venous and left arterial doppler studies to be completed at the main campus. The primary care provider instructed the patient to go the same day for the ordered doppler studies or go to the main campus Emergency Department for further evaluation. The patient elected to go the following day to the main campus for the doppler studies.

On the next day, doppler studies were done at the main campus and revealed no arterial flow in the dorsalis pedis and the left posterior tibial arteries of the affected leg. A computed tomography angiogram showed a left distal iliac artery aneurysm and "complete left superficial femoral and popliteal artery occlusion." The physical exam of the left leg revealed "no sensation below mid-calf, no motor function of the foot," and "discoloration to foot and ankle." The patient's INR was 3.1, in therapeutic range for indefinite duration anticoagulation. The facility vascular surgeon (vascular surgeon) who cared for the patient explained the need for emergent revascularization of the left leg and of a high probability for amputation to the patient.

On the same day, the patient underwent an open thrombectomy of the left common femoral artery and its branches and the external iliac artery, withdrawing the blood clot. Surgery staff performed a left foot amputation because the muscle tissue appeared nonviable (see appendix A).

Inspection Results

1. Alleged Deficient Quality of Care

The OIG did not substantiate that facility staff provided deficient quality of care related to the patient's arterial occlusion or prevention of the arterial occlusion that resulted in the patient's left foot amputation. However, the OIG identified a missed opportunity to provide reeducation and refit the patient with new VA-issued shoes.

Patient's Arterial Occlusion

The OIG did not substantiate that PACT staff and the clinical contact center RN provided deficient quality of care resulting in the patient's left foot amputation. The OIG found the primary care provider and the clinical contact center RN recommended that the patient seek

emergency care upon identifying symptoms of the acute arterial occlusion. The OIG was unable to determine if the primary care provider discussed the associated risks of not seeking emergency department evaluation and treatment with the patient when the acute arterial occlusion symptoms presented due to conflicting recollections of the conversation between the primary care provider and the patient.

An acute arterial occlusion is a sudden blockage or closing of an artery, occurs abruptly within two weeks of symptom onset and is considered a medical emergency. Symptoms include pain, numbness, and coldness of the affected limb.[11] Permanent damage can result within four to six hours from when an acute arterial occlusion occurs, requiring a prompt, accurate diagnosis.[12] Bone fractures are caused by traumas such as a fall; symptoms include pain, swelling, tenderness, and limited movement.[13]

Patients have the right to collaborate with medical providers on medical care concerns and to have access to the necessary information, including potential risks, benefits, and consequences of refusing treatment when making care decisions.[14] Patients also have the right to refuse care.[15]

In fall 2022, diagnostic imaging identified the acute arterial occlusion. The vascular surgeon stated there was no definitive way to determine when the acute arterial occlusion occurred; it likely happened greater than 12 to 24 hours prior to the imaging but needed to be recognized and treated within 6 to 12 hours of the event. During an interview, the PACT RN reported suspecting a fracture when the patient initially presented to the clinic after the fall. The OIG reviewed the patient's EHR and confirmed that after the fall, the patient presented and reported to PACT staff clinical symptoms that were more consistent with a suspected fracture, as opposed to an acute arterial occlusion.

The OIG reviewed documentation from the patient's initial visits after the fall and determined that the PACT RN, former podiatrist, and primary care provider offered appropriate clinical recommendations to the patient, consistent with a suspected fracture, after interactions on four separate occasions in fall 2022. The actions included ordering x-rays and recommending the

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[11] *Cleveland Clinic*, "Acute Arterial Occlusion," accessed March 27, 2023, https://my.clevelandclinic.org/health/diseases/23491-acute-arterial-occlusion; Hideaki Obara, Kentaro Matsubara, and Yuko Kitagawa, "Acute Limb Ischemia," *Annals of Vascular Diseases*, no. 4 (October 20, 2018): 443–448, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6326052/pdf/avd-11-4-ra.18-00074.pdf.

[12] *Cleveland Clinic*, "Acute Arterial Occlusion."

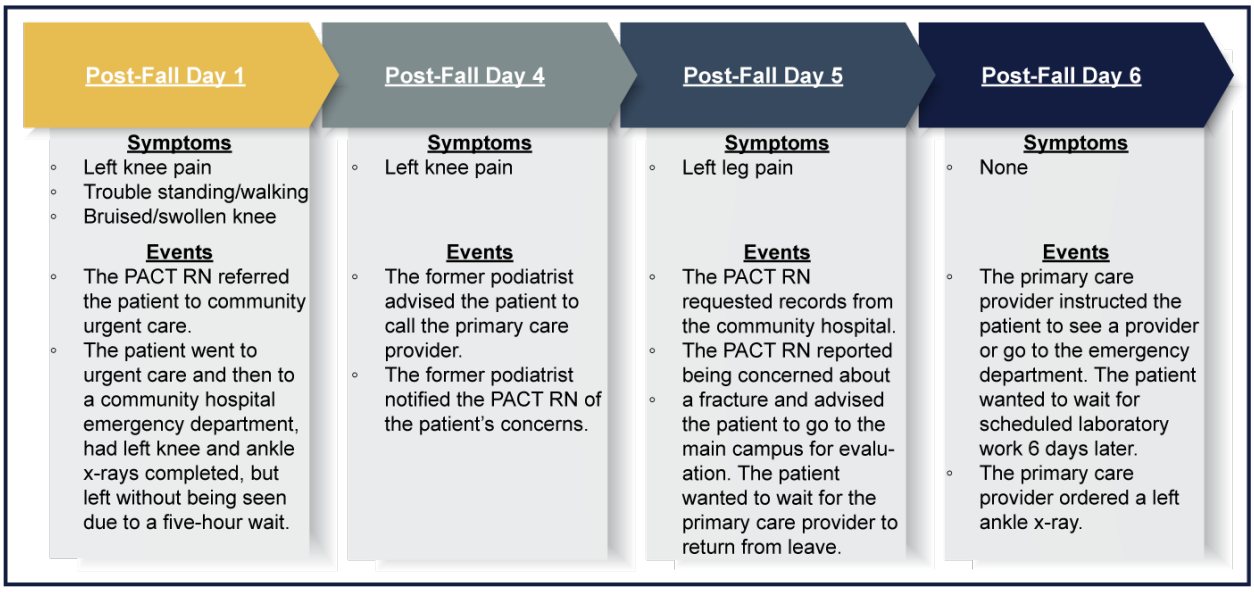
[13] *Cleveland* Clinic, "Bone Fractures," accessed July 24, 2023, https://my.clevelandclinic.org/health/diseases/15241-bone-fractures. Bone fractures are commonly diagnosed through diagnostic imaging that includes x-rays.

[14] "Bylaws and Rules and Regulations of the Medical Staff of the Department of Veterans Affairs Edward Hines Jr., VA Hospital Hines, Illinois 60141," October 2022. Through EHR review and interviews with the patient and clinical staff, the OIG found that the patient had decision-making capacity.

[15] American Medical Association, *Code of Medical Ethics September 2016,* accessed May 17, 2023, https://code-medical-ethics.ama-assn.org/ethics-opinions/patient-rights; Journal of the American Medical Association, *Professing the Values of Medicine, The Modernized AMA Code of Medical Ethics*, accessed November 21, 2023.

patient call or be seen in-person for further evaluation at the clinic, main campus, or community urgent care. See figure 1 for a summary of the patient's visits, presenting symptoms, and actions the initial days after the fall.

Figure 1. Timeline of the Patient's Initial Visit and Events After the Fall



Source: OIG analysis of the patient's EHR, and OIG interviews.

Eleven days after the fall, the patient reported to the clinical contact center RN that the left foot was colder than the right, a symptom commonly present for an acute arterial occlusion, but not common for fall injuries, such as a fracture. The clinical contact center RN documented advising the patient to go to an emergency department; however, the patient declined and chose to see the primary care provider the next day.[16] The clinical contact center RN documented informing the patient of the risks of developing a worsening medical condition if not seen emergently, but did not specifically document the possibility of loss of limb. In response to a related complaint, the clinic director documented, that the patient acknowledged being made aware of the risks of not going to an emergency department.

Twelve days after the fall, the primary care provider assessed the patient and documented that the left leg was colder to the touch than the right.[17] According to the EHR, the primary care

[16] The clinical contact center RN also alerted the primary care provider by placing the primary care provider as an additional signer on the note.

[17] The primary care provider documented feeling pulses but told the OIG the pulses were weak. The primary care provider explained that a handheld doppler was not used due to the presence of pedal pulses and explained that deficits potentially found from a handheld doppler examination would not have changed the recommendation to go to the Emergency Department; A handheld doppler is an ultrasonic device that allows a provider to assess blood flow through vessels and localizing arterial occlusions. A provider uses a doppler to take weak pulses if needed. *ClinicalKey*, "doppler," accessed May 18, 2023, https://www.clinicalkey.com/nursing/#!/content/book/3-s2.0-B9780323761833000036?scrollTo=%23hl0000934.

provider documented telling the patient to go to the main campus Emergency Department or vascular clinic for stat doppler studies. The primary care provider told the OIG the patient was offered multiple transportation options if needed and was also informed of the risks of not receiving immediate emergency care, including loss of life or limb.[18] The primary care provider reported that the patient elected to wait until the next day to be able to take the VA shuttle to the main campus for the ordered doppler studies due to not wanting to drive in traffic and not having family available to provide transport.[19] However, contrary to the primary care provider's report, the patient told the OIG the risk of losing a limb was not discussed.

The primary care provider told the OIG that the following day, the patient took the VA shuttle to the main campus and underwent doppler studies that revealed an acute arterial occlusion resulting in the patient's left foot amputation.

The OIG concluded that once symptoms of an arterial occlusion presented, the primary care provider and the clinical contact center RN recognized the signs and referred the patient to emergency care. The OIG was unable to determine whether the primary care provider explained to the patient the associated risks of not seeking an emergency department evaluation and treatment due to the conflicting recollections of the conversation.

Prevention of the Patient's Arterial Occlusion

The vascular surgeon told the OIG that the acute arterial occlusion may have been caused when the patient stopped anticoagulant medication or possibly due to the fall. Therefore, the OIG reviewed anticoagulation therapy management and podiatry care to determine if the patient's arterial occlusion may have been prevented.

Anticoagulation Therapy Management

The OIG did not substantiate that pharmacy staff provided deficient quality of care resulting in the patient's left foot amputation. Pharmacy staff managed the patient's anticoagulation therapy in accordance with VISN and facility guidance.

Anticoagulants are a group of medications that decrease the blood's ability to clot and may reduce the likelihood of patients experiencing life-threatening medical conditions.[20] Providers use VISN periprocedural guidelines to determine whether bridging is necessary for patients experiencing interruptions in anticoagulation therapy.[21] VISN guidelines recommend that prior

[18] The discussion was not documented in the patient's EHR.

[19] The primary care provider reported also discussing other transportation options that included self-transportation, an ambulance, or a "medicar" (medical transportation) to take the patient to the main campus.

[20] Cleveland Clinic, "anticoagulation," accessed June 5, 2023, https://my.clevelandclinic.org/health/treatments/22288-anticoagulants.

[21] "VA Anticoagulation Management Service Guidelines for Peri-procedural Management of Direct Acting Oral Anticoagulants and Warfarin VISN 12," March 2021.

to performing procedures that have a risk for bleeding, such as colonoscopies, anticoagulation medications be temporarily stopped to achieve an INR range of less than or equal to 1.5.[22] Facility policy establishes a therapeutic INR range of 2.5–3.5 for all patients on indefinite duration anticoagulation therapy.[23] The vascular surgeon told the OIG there is a known potential risk of developing a blood clot after temporarily stopping anticoagulation medications, but the risk is an appropriate one to take when performing a colonoscopy.

According to the EHR, the patient underwent a colonoscopy in fall 2022. The clinical pharmacy specialist reported using the VISN periprocedural guidelines, determined bridging was not necessary, and instructed the patient to stop anticoagulation therapy prior to the scheduled colonoscopy. The patient's INR was 1.2 on the day of the colonoscopy, and the patient was instructed to resume anticoagulation medication the following day. The patient's INR approximately two weeks later was 3.4.

The OIG concluded that the clinical pharmacy specialist properly managed the patient's anticoagulation therapy prior to and following the colonoscopy.

Issuance of Diabetic Shoes

The OIG was unable to determine whether the patient's fall could have been prevented; however, the OIG found that podiatry staff missed an opportunity to provide reeducation and refit the patient with new VA-issued shoes.

Emerging evidence suggests that podiatry care, when accompanied by footwear education, may play a vital role in fall prevention.[24] VHA policy requires VA prescribing providers to conduct a foot examination when providing VA-issued shoes.[25] Providers must schedule annual follow-up appointments with patients, or sooner at the patient's request, and the follow-up appointment must include an inspection and evaluation of the patient's footwear.[26]

Facility podiatry staff described a facility process for ensuring the appropriate fit of newly provided VA-issued shoes that included use of a foot-measuring device (Brannock Device) and clinical examination, followed by patient education regarding the placement of the feet into the newly provided shoes and breaking-in of footwear.[27] The podiatrist employed at the facility

[22] "VA Anticoagulation Management Service Guidelines for Peri-procedural Management of Direct Acting Oral Anticoagulants and Warfarin VISN 12."

[23] VA Hospital Hines, Illinois Policy Memorandum 578-03-111-024 (R-4), "Anticoagulation Clinic," April 4, 2018.

[24] Anna L. Hatton and Keith Rome, "Falls, Footwear, and Podiatric Interventions in Older Adults," *Clinics in Geriatric Medicine*, no. 35 (2019): 161–171, https://doi.org/10.1016/j.cger.2018.12.001.

[25] VHA Directive 1173.9, *Therapeutic Footwear and In-shoe Orthoses*, October 22, 2021.

[26] VHA Directive 1173.9.

[27] The podiatrist, podiatry RN, and podiatry licensed practical nurse reported to the OIG that patients are instructed to bring newly provided VA-issued shoes to subsequent appointments.

during the time of this inspection (podiatrist) told the OIG that standard practice is to provide VA-issued shoes to patients annually.

The OIG reviewed the patient's EHR and found that in fall 2021, the former podiatrist provided a new pair of VA-issued shoes to the patient. Additionally, the patient received written instructions and education on placement of the feet into the newly provided VA-issued shoes, and reported satisfaction with the fit and comfort.

During the annual examination in fall 2022, the former podiatrist documented the patient's noncompliance with use of the VA-issued shoes. The patient did not wear the VA-issued shoes to the visit; therefore, the former podiatrist was unable to determine the fit and appropriateness of the shoes provided to the patient in 2021. The former podiatrist encouraged the patient to resume use of the previously provided shoes and return to the clinic in one year. The next day, the patient notified the PACT RN of a fall occurring the previous evening while wearing the VA-issued shoes.

The former podiatrist told the OIG that the style of VA-issued shoes provided to the patient in fall 2021 was "probably the trickiest one to fit and I have had complaints of heel slippage in that shoe because [of] not being careful about having the heel in the back of the shoe and then making sure that the Velcro is tight." The OIG reviewed the EHR and found no documentation of refitting or reeducating the patient regarding placement of the feet into the VA-issued shoes. During interviews, the former podiatrist, patient, and patient's family could not recall if reeducation was provided.

The OIG concluded that the former podiatrist missed an opportunity to refit the patient with a new pair of VA-issued shoes. However, the OIG was unable to determine whether reeducating the patient about the placement of the feet or refitting the patient into new VA-issued shoes would have prevented the patient's fall. The OIG would have expected the former podiatrist to either provide reeducation or to refit the patient into new shoes, based on the documented noncompliance combined with the known difficulty of the VA-issued shoes provided in 2021.

2. Inadequacies in Patient Safety Reporting

The OIG determined that although the patient attributed the fall to VA-issued shoes, VHA does not require the event to be reported to patient safety staff or a review conducted because the event occurred at the patient's home. The OIG determined that the facility patient advocate did not consult with the facility patient safety staff after receiving the patient's clinical care concerns, as recommended by VHA policy.[28]

[28] VHA Directive 1003.04, *Patient Advocacy*, February 7, 2018, was in effect at the time of the events discussed in this report. The directive was rescinded and replaced by VHA Directive 1003.04, *VHA Patient Advocacy*, November 9, 2023. The 2023 directive requires patient advocates to document patient safety allegations in the joint patient safety reporting system.

VHA's National Center for Patient Safety learns of system vulnerabilities primarily through the reporting of adverse events and close calls.[29] VHA's vision for a high reliability organization is a system "that experiences fewer than anticipated accidents or events of harm."[30] VHA requires adverse events or close calls to be reported to the facility's patient safety manager.[31] Any staff member should report these events through locally-accepted methods, including the electronic Joint Patient Safety Reporting (JPSR) system. Once reported, the patient safety manager analyzes the event and assigns a risk level that may indicate a requirement to initiate a root cause analysis.[32]

Reporting the Fall

The OIG reviewed facility documents and found that initially there were no documented JPSR events regarding the patient's fall. The OIG consulted with a VA Central Office patient safety analyst (a subject matter expert) who stated that "There is no requirement or expectation a fall in the veteran's home (who is not part of the HBPC [Home Based Primary Care] program) would be entered in the JPSR system. Outpatient falls occurring on facility grounds/clinic areas would be appropriate for reporting."

Although a patient safety report for this event was not required according to the subject matter expert, a facility staff member later entered a JPSR event during the OIG's inspection.[33] A root cause analysis was not required (based on the facility's JPSR analysis); however, the VISN 12 quality management officer told the OIG the event was included in the facility's annual aggregate root cause analysis (aggregate review) process.

Reporting Deficient Quality of Care

According to the World Health Organization, patient safety is defined as "the prevention of errors and adverse effects to patients associated with health care."[34] VHA policy notes that "for incidents involving patient safety, patient advocates should work with their local [facility] patient

[29] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011, was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The two policies contain the same or similar language related to patient safety reporting and root cause analyses.

[30] "VHA's Vision for a High Reliability Organization," Health Services Research and Development, accessed July 25, 2023, https://www.hsrd.research.va.gov/publications/forum/summer20/default.cfm?ForumMenu=summer20-1.

[31] VHA Handbook 1050.01. The requirement is noted in *VHA National Patient Safety Improvement Handbook*, March 4, 2011, but is not noted in VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023.

[32] VHA Handbook 1050.01; VHA Directive 1050.01.

[33] VHA Directive 1050.01.

[34] Rene Kuriakose et al., "Patient Safety in Primary and Outpatient Health Care," *Journal of Family Medicine and Primary Care*, January 2020.

safety officers to ensure documentation and oversight."[35] VHA requires the facility patient advocate to address patient complaints that cannot be resolved at the point of service.[36]

The OIG reviewed patient advocate tracking system reports documentation and found that the patient reported clinical care concerns to a patient representative (patient advocate) in late fall 2022. Specifically, the documentation included a summary of the patient's allegation that the primary care provider neglected to provide medical attention for the left foot after the patient fell at home. The documentation also included a description that the patient had an emergency amputation because of the "said negligence."

Once received, the patient advocate reported providing the patient with tort claim and provider change forms. The patient advocate explained that not reporting the incident or consulting with the patient safety staff regarding the patient's concerns was due to a lack of training on "situations like this." However, the OIG reviewed facility documents and found that the patient advocate received training on patient safety reporting prior to the patient reporting the incident. The facility patient safety managers reported being new and unfamiliar with the patient advocate's role and processes but informed the OIG that in general, staff are encouraged to use the JPSR system to enter patient safety concerns.

The VISN 12 patient safety officer reported that all employees are taught how to enter events into the JPSR system. The patient advocate manager and chief patient experience officer reported agreeing with how the patient advocate handled the situation and noted that the patient's needs were met by providing education and resources for further recourse (file a tort claim and request to change primary care providers).[37] In contrast, a program manager with VHA Office of Patient Advocacy (a subject matter expert) told the OIG the patient advocate should have sent the complaint to the patient safety and the risk management staff.

The patient advocate did not consult with patient safety staff after receiving the patient's allegation that staff negligence led to the amputation. The OIG found that the patient's expressed concerns should have prompted the patient advocate to consult with the patient safety office.

Conclusion

Once made aware of the symptoms for an arterial occlusion, the primary care provider and the clinical contact center RN recognized the signs and referred the patient to emergency care. The OIG was unable to determine whether the primary care provider explained to the patient the

[35] VHA Directive 1003.04, February 7, 2018; VHA Directive 1003.04, November 9, 2023.

[36] VHA Directive 1003.04, February 7, 2018; VHA Directive 1003.04, November 9, 2023.

[37] The veteran experience officer reported being the direct supervising official for the patient advocate who managed the patient's complaint.

associated risks of not seeking an emergency department evaluation and treatment due to the conflicting recollections of the conversation.

The clinical pharmacy specialist properly managed the patient's anticoagulation therapy prior to and following the colonoscopy. The former podiatrist was not able to assess the fit of the patient's VA-issued shoes because the patient did not bring the shoes to the fall 2022 annual appointment. The OIG concluded that the former podiatrist missed an opportunity to refit the patient with a new pair of VA-issued shoes. The OIG was unable to determine whether reeducating had occurred regarding the placement of feet for the VA-issued shoes provided in 2021, or if issuing a new pair would have prevented the patient's fall.

The patient advocate did not consult with patient safety staff after receiving the patient's report that negligence led to the left foot amputation. The OIG concluded that these complaints were concerns that should have prompted the patient advocate to consult with the patient safety office.

Recommendations 1–2

1. The Veterans Integrated Service Network Director ensures that patient advocacy staff within Veterans Integrated Service Network 12 are educated on the need to consult with patient safety staff when complaints involve patient safety concerns.
2. The Edward Hines, Jr. VA Hospital Director ensures a review is completed of the missed opportunities referenced in this report related to refitting and reeducating patients on VA-issued shoes, determines the need to create a related standard operating procedure or facility policy, and takes action as necessary.

Appendix A: Principal Arteries of The Lower Limb

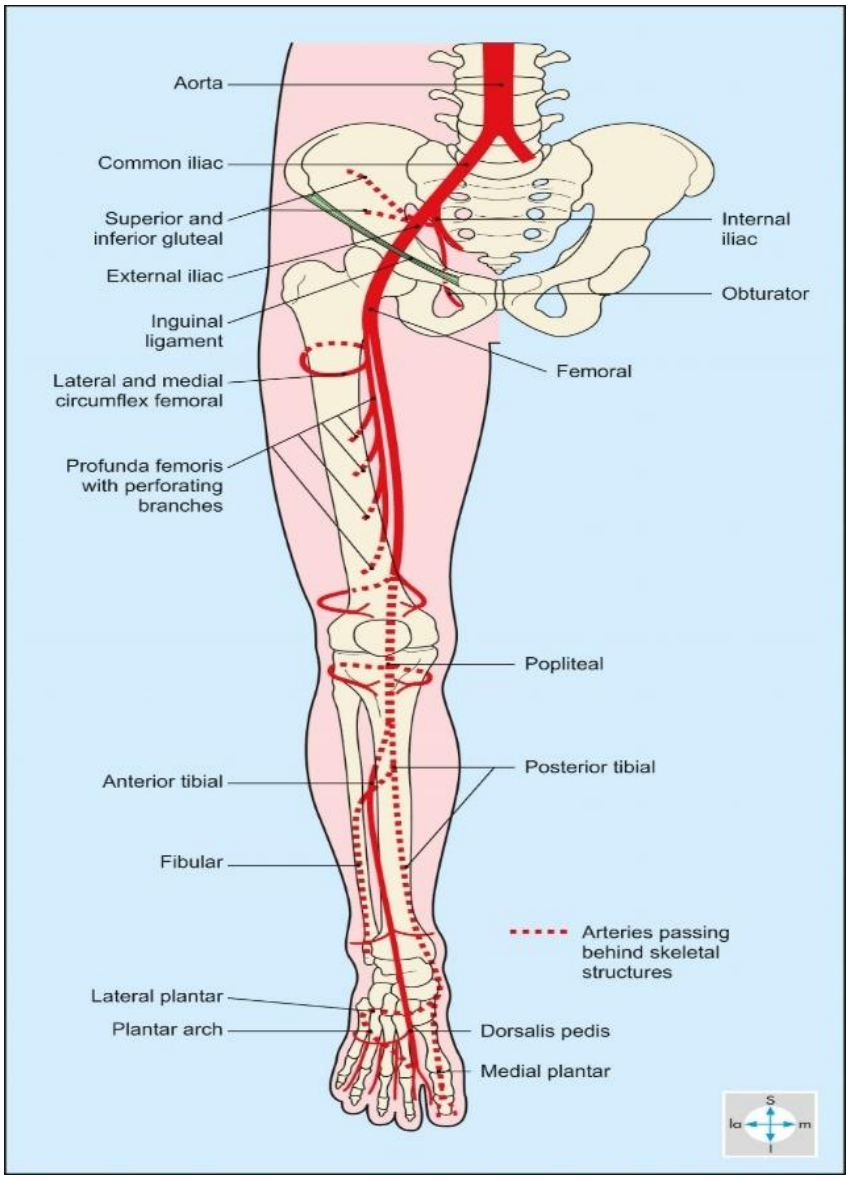


Figure 1. *Principal arteries of the lower limb.*
Source: Human Anatomy, Color Atlas and Textbook, Sixth Edition.[38]

[38] John A. Gosling et al., "Lower Limb," chap. 6 in *Human Anatomy, Color Atlas and Textbook*, 6th ed., (Elsevier, 2017), 253–319.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 26, 2024

From: Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Inadequacies in Patient Safety Reporting Processes and Alleged Deficient Quality of Care Prior to a Patient's Foot Amputation at the Edward Hines, Jr. VA Hospital in Illinois

To: Director, Office of Healthcare Inspections (54HL10)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review the Department of Veterans Affairs (VA) Office of Inspector General (OIG) draft report "Inadequacies in Patient Safety Reporting Processes and Alleged Deficient Quality of Care Prior to a Patient's Foot Amputation at the Edward Hines, Jr. VA Hospital in Illinois."

2. We thank the OIG Inspection team for their thorough review and concur with the report and conclusions.

(*Original signed by:*)

Daniel S. Zomchek, Ph.D., FACHE
Network Director, VISN 12

VISN Director Response

Recommendation 1

The Veterans Integrated Service Network Director ensures that patient advocacy staff within Veterans Integrated Service Network 12 are educated on the need to consult with patient safety staff when complaints involve patient safety concerns.

_X _Concur

____Nonconcur

Target date for completion: June 1, 2024

Director Comments

The VISN 12 Network Director reviewed this finding and identified there was variability in processes for communicating concerns reported through the Patient Advocate Office to the Patient Safety Service and this contributed to non-compliance. All Patient Advocate Staff in VISN 12 were trained on the Joint Patient Safety Reporting System (JPSR) during New Employee Orientation (NEO). To ensure ongoing compliance, the training is included in mandatory training during NEO for Patient Advocate employees at all VISN 12 facilities. The training includes which types of concerns to enter into the JPSR.

In January 2024, all facility Patient Advocate staff were briefed on November 2023 updates to VHA Directive 1003.04: VHA Patient Advocacy which includes how to manage Veteran's reported safety concerns.

Measures:

Evidence of Patient Advocate Training compliance by facility will be reported to the VISN 12 Quality Safety Committee (QPS) until all sites are compliant at >90%.

OIG Comments

The OIG recommendation refers to VHA Directive 1003.04, *VHA Patient Advocacy*, February 7, 2018, that was in effect at the time of the event and required patient advocates to consult with patient safety staff when made aware of patient safety concerns.

The OIG will review the training material provided to ensure that it addresses the VHA Directive 1003.04, *VHA Patient Advocacy*, November 9, 2023, requirement that patient advocates specifically refer patient safety allegations to patient safety officers through the Joint Patient Safety Report System.

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: January 29, 2024

From: Director, Edward Hines, Jr. VA Hospital (578)

Subj: Healthcare Inspection—Inadequacies in Patient Safety Reporting Processes and Alleged Deficient Quality of Care Prior to a Patient's Foot Amputation at the Edward Hines, Jr. VA Hospital in Illinois

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the Department of Veterans Affairs (VA) Office of Inspector General (OIG) draft report "Inadequacies in Patient Safety Reporting Processes and Alleged Deficient Quality of Care Prior to a Patient's Foot Amputation at the Edward Hines, Jr. VA Hospital in Illinois."
2. We thank the OIG Inspection team for their thorough review and concur with the report and conclusions.

(*Original signed by*:)

James Doelling
Hospital Director

Facility Director Response

Recommendation 2

The Edward Hines, Jr. VA Hospital Director ensures a review is completed of the missed opportunities referenced in this report related to refitting and reeducating patients on VA-issued shoes, determines the need to create a related standard operating procedure or facility policy, and takes action as necessary.

_ X _Concur

____Nonconcur

Target date for completion: August 2024

Director Comments

The Edward Hines, Jr. VA Hospital Chief of Staff reviewed the incident and determined that noncompliance occurred due to low volume of these cases at the Joliet CBOC [community based outpatient clinic] and lack of standard work regarding patient education. The medical center is in the process of developing a standard work document that captures the current workflow and provides instructions on refitting and reeducating patient on VA-issued shoes. Upon the completion of the document, process compliance will be monitored and reported to Quality Board monthly until three consecutive months of 90% or greater compliance is achieved.

Glossary

To go back, press "alt" and "left arrow" keys.

aggregate review. A way of "analyzing a group of similar incidents or event types to determine common causes, thereby facilitating coordinated actions to prevent recurrences."[39]

amputation. A "surgery to remove all or part of a limb extremity."[40]

aneurysm. "A bulge in the wall of an artery. Aneurysms form when there's a weak area in the artery wall. Untreated aneurysms can burst open, leading to internal bleeding. They can also cause blood clots that block the flow of blood in your artery. Depending on the location of the aneurysm, a rupture or clot can be life-threatening."[41]

anticoagulation. "A family of medications that stop your blood from clotting too easily. They can break down existing clots or prevent clots from forming in the first place. These medications can help stop life-threatening conditions like strokes, heart attacks and pulmonary embolisms, all of which can happen because of blood clots."[42]

arterial occlusion. "A blockage in one of the peripheral arteries that prevents blood from flowing to" a limb or extremity. "It usually occurs in the legs and blood clots are the most common cause." An arterial occlusion is a life-threatening medical emergency that requires prompt care to decrease the risk for loss of limb or death.[43]

atrial fibrillation. "An irregular and often very rapid heart rhythm (arrhythmia) that can lead to blood clots in the heart."[44]

blood clots. Formation of gel-like collections of blood within the veins or arteries. Blood clots are usually in response to an injury, however, can be dangerous when formed in some places and then do not dissolve.[45]

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[39] VHA Handbook 1050.01.

[40] Cleveland Clinic, "amputation," accessed March 23, 2023, https://my.clevelandclinic.org/health/treatments/21599-amputation.

[41] Cleveland Clinic, "aneurysm," accessed July 12, 2023, https://my.clevelandclinic.org/health/diseases/22769-aneurysm.

[42] Cleveland Clinic, "anticoagulation," accessed June 5, 2023, https://my.clevelandclinic.org/health/treatments/22288-anticoagulants.

[43] Cleveland Clinic, "arterial occlusion," accessed June 12, 2023, https://my.clevelandclinic.org/health/diseases/23491-acute-arterial-occlusion.

[44] Mayo Clinic, "atrial fibrillation," accessed March 27, 2023, https://www.mayoclinic.org/diseases-conditions/atrial-fibrillation/symptoms-causes/syc-20350624.

[45] Cleveland Clinic, "blood clots," accessed March 27, 2023, https://my.clevelandclinic.org/health/body/17675-blood-clots.

bridging. Refers to giving a short-acting blood thinner around the time of a procedure.[46]

capillary refill. A quick, reliable method for detecting changes in blood flow that assesses blood circulation in your arms and legs. **"**Healthcare providers apply pressure to a finger to empty the blood vessels. After releasing the pressure, they time how long it takes them to refill with oxygen-rich blood."[47]

colonoscopy. "An examination of the inside of your large intestine (colon). It's helpful for diagnosing gastrointestinal diseases, such as inflammatory bowel disease and colon cancer. It can also help treat and prevent colon cancer."[48]

computed tomography angiogram. A non-invasive test used to diagnose various heart conditions that looks at arteries in the heart using x-ray imaging of the heart and its blood vessels.[49]

coronary artery disease. A common heart condition in which the "major blood vessels that supply the heart (coronary arteries) struggle to send enough blood, oxygen, and nutrients to the heart muscle." "Cholesterol deposits (plaques) in the heart arteries and inflammation are usually the cause of coronary artery disease."[50]

diabetic neuropathy. "A type of nerve damage that can occur if you have diabetes. High blood sugar (glucose) can injure nerves throughout the body. Diabetic neuropathy most often damages nerves in the legs and feet. Depending on the affected nerves, diabetic neuropathy symptoms include pain and numbness in the legs, feet, and hands."[51]

distal. "Situated away from the point of attachment or origin or a central point especially of the body."[52]

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[46] "Bridging Anticoagulation: Is it Needed When Warfarin is Interrupted Around the Time of a Surgery or Procedure?," *Circulation,* (2012); 125:e496–e498, https://www.ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.111.084517.

[47] Cleveland Clinic, "capillary refill time," accessed March 27, 2023, https://my.clevelandclinic.org/health/diagnostics/23376-capillary-refill-time.

[48] Cleveland Clinic, "colonoscopy," accessed July 12, 2023, https://my.clevelandclinic.org/health/diagnostics/4949-colonoscopy.

[49] Mayo Clinic, "CT coronary angiogram," accessed June 15, 2023, https://www.mayoclinic.org/tests-procedures/ct-coronary-angiogram/about/pac-20385117.

[50] Mayo Clinic, "coronary artery disease," accessed March 27, 2023, https://www.mayoclinic.org/diseases-conditions/coronary-artery-disease/symptoms-causes/syc-20350613.

[51] Mayo Clinic, "diabetic neuropathy," accessed March 27, 2023, https://www.mayoclinic.org/diseases-conditions/diabetic-neuropathy/symptoms-causes/syc-20371580.

[52] *Merriam-Webster.com Dictionary*, "distal," accessed July 12, 2023, https://www.merriam-webster.com/dictionary/distal.

doppler ultrasound. Used to detect heart and blood vessel problems. "It can identify blood clots, narrowed arteries and other problems that affect the heart and blood vessels in the legs, arms and stomach."[53]

dorsalis pedis artery. "An artery of the upper surface of the foot that is a direct continuation of the anterior tibial artery. The dorsalis pedis artery runs along the line between the first and second toe, and its pulse point is felt in the mid foot."[54]

edema. "Occurs when fluid builds up in [the] tissues, often in [the] feet, legs, and ankles.[55]

femoral artery. The main artery of the thigh, positioned toward the inner part.[56]

gastroenterology. "A branch of medicine concerned with the structure, functions, diseases, and pathology of the stomach and intestines."[57]

Home Based Primary Care. "Comprehensive, longitudinal, in-home primary care provided by a VA interdisciplinary team with physician oversight in the homes of Veterans with a complex, chronic, and disabling disease for whom routine clinic-based care is not effective."[58]

hypertension. Also known as high blood pressure. "The pressure against the blood vessel walls in [the] body is consistently too high." "Blood pressure is the measurement of the pressure or force of blood pushing against blood vessels walls." [59]

iliac artery. Blood vessel that carries "blood to the lower extremities, including the legs, reproductive organs, and pelvic region." The "one on the left (called the left common iliac artery)."[60]

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[53] Cleveland Clinic, "doppler ultrasound," accessed July 20, 2023, https://my.clevelandclinic.org/health/diagnostics/22715-doppler-ultrasound.

[54] *Merriam-Webster.com Dictionary*, "dorsalis pedis artery," accessed July 12, 2023, https://www.merriam-webster.com/medical/dorsalis%20pedis%20artery.

[55] Cleveland Clinic, "edema," accessed July 11, 2023, https://my.clevelandclinic.org/health/diseases/12564-edema#:~:text=Edema%20is%20swelling%20that%20is%20caused%20by%20fluid,Cleveland%20Clinic%20is%20a%20non-profit%20academic%20medical%20center.

[56] *Merriam-Webster.com Dictionary,* "femoral artery," accessed June 15, 2023, https://www.merriam-webster.com/dictionary/femoral%20artery.

[57] *Merriam-Webster.com Dictionary*, "gastroenterology," accessed July 26, 2023, https://www.merriam-webster.com/dictionary/gastroenterology.

[58] VHA Directive 1411(1), *Home-Based Primary Care Special Population Patient Aligned Care Team Program*, June 5, 2017, p. 3.

[59] Cleveland Clinic, "High Blood Pressure (Hypertension)," accessed March 27, 2023, https://my.clevelandclinic.org/health/diseases/4314-hypertension-high-blood-pressure.

[60] Cleveland Clinic, 'iliac artery," accessed March 27, 2023, https://my.clevelandclinic.org/health/body/21681-iliac-artery.

International Normalized Ratio. Sometimes referred to as prothrombin time, it is a test to evaluate blood clotting.[61]

joint patient safety reporting. A web-based patient safety reporting system used in the VHA to capture real time incident reporting data.[62]

knee arthroplasty. A surgical procedure, also known as total knee replacement, resurfacing the damaged knee using metal and plastic parts to cap the ends of the bones creating the knee joint.[63]

neurological examination. Evaluates brain and nervous system functioning." Consists of physical examination to identify signs of disorders affecting your brain, spinal cord, and nerves (nervous system)."[64]

nonviable. "Not capable of living, growing, developing, or functioning successfully."[65]

obesity. "A condition characterized by the excessive accumulation and storage of fat in the body."[66]

pedal pulse. "A complete physical examination includes the assessment and recording of arterial pulses" in the foot. "While examining the pulse, the observer should note its intensity, rate, rhythm, and if any blood vessel tenderness, tortuosity, or nodularity exists." The pulse is examined with "the patient in the recumbent position and the ankle relaxed." The observer places their "fingertips transversely across the dorsum of the forefoot near the ankle."[67]

periprocedural. "Occurring soon before, during, or soon after the performance of a medical procedure."[68]

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[61] Mayo Clinic, "Prothrombin time test," accessed June 5, 2023, https://www.mayoclinic.org/tests-procedures/prothrombin-time/about/pac-20384661.

[62] VHA National Center for Patient Safety JPSR Guidebook, December 2022, pp.2.

[63] Johns Hopkins Medicine, "knee replacement surgery procedure," accessed June 15, 2023, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/knee-replacement-surgery-procedure.

[64] Cleveland Clinic, "neurological exam", accessed July 25, 2023, https://my.clevelandclinic.org/health/diagnostics/22664-neurological-exam.

[65] *Merriam-Webster.com Dictionary*, "nonviable," accessed July 12, 2023, https://www.merriam-webster.com/dictionary/nonviable.

[66] *Merriam-Webster.com Dictionary*, "Obesity," accessed July 12, 2023, https://www.merriam-webster.com/dictionary/obesity.

[67] R. Dean Hill, Robert B Smith III, "Examination of the Extremities: Pulses, Bruits, and Phlebitis," chap. 30 in *Clinical Methods: The History, Physical, and Laboratory Examinations*, 3rd ed. HK Walker, WD Hall, and JW Hurst (Boston: Butterworths, 1990).

[68] *Merriam-Webster.com Dictionary*, "Periprocedural," accessed June 15, 2023, https://www.merriam-webster.com/medical/periprocedural.

revascularization. "A surgical procedure for the provision of a new, additional, or augmented blood supply to a body part or organ."[69]

root cause analysis. "A comprehensive team-based, systems-level investigation with a formal charter for review of health care adverse events and close calls."[70]

stat. "Without delay, immediately."[71]

thrombectomy. "A thrombectomy is a surgery to remove a blood clot from an artery or vein."[72]

tibial artery. "Either of the two arteries of the lower leg formed by the bifurcation of the popliteal artery." "A larger posterior artery that divides between the medial malleolus and heel into the lateral and medial plantar arteries."[73]

warfarin. An anticoagulation medication used to prevent blood clots. Also known as Coumadin.[74]

x-ray. A type of medical imaging using safe amounts of radiation that creates pictures of the body to include bones and soft tissue. Medical professionals use the images to diagnose conditions such as diseases and injuries.[75]

[69] *Merriam-Webster.com Dictionary*, "Revascularization," accessed July 12, 2023, https://www.merriam-webster.com/dictionary/revascularization.

[70] VHA, National Center for Patient Safety JPSR Guidebook, December 2022, p. 5.

[71] *Merriam-Webster.com Dictionary*, "Stat," accessed July 18, 2023, https://www.merriam-webster.com/dictionary/stat.

[72] Cleveland Clinic, "Thrombectomy," accessed March 23, 2023, https://my.clevelandclinic.org/health/treatments/22897-thrombectomy.

[73] *Merriam-Webster.com Dictionary*, "*Tibial artery*," accessed July 12, 2023, https://www.merriam-webster.com/medical/tibial%20artery.

[74] Mayo Clinic, "Warfarin," accessed October 2, 2023, https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/in-depth/warfarin-side-effects/art-20047592.

[75] Cleveland Clinic, "X-Ray," accessed June 13, 2023, https://my.clevelandclinic.org/health/diagnostics/21818-x-ray.

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