

**PAD PARADOX:**  
**Simultaneous Overuse and Undertreatment of Patients with PAD and CLTI:**  
**Why do they co-exist and can the issue be fixed ?**

**VEITH SYMPOSIUM** 2024  
 Connecting The Vascular Community

20 November 2024

Joseph L. Mills, MD  
 Reid Professor and Chief, Division of Vascular Surgery & Endovascular Therapy  
 Michael E. DeBakey Department of Surgery  
 Baylor College of Medicine  
 Houston, Texas USA

Baylor College of Medicine

### Conflict of Interest

- I have no conflicts of interest related to this presentation.
- Member of IWGDF Classification Working Group
- Co-Chair of IWGDF/ESVS/SVS PAD and DFU Working Group
- Scientific Advisor, Biogen (consultant fees to BCM, not personal)
- Scientific Advisor, Humacyte bypass graft (fees to BCM)
- Consultant: Angec
- Immediate Past President of the Society for Vascular Surgery (SVS)

### The Over-Under Paradox

- **PAD and claudication**, atypical leg pain - Emphasis on testing to identify early PAD is a double-edged sword
  - Slippery slope to over-intervention
- **CLTI and DFU**
  - **INEQUITY** - Lack of access to care for many
  - Fragmented care
  - Failure to classify or follow algorithms based on guidelines and best practices

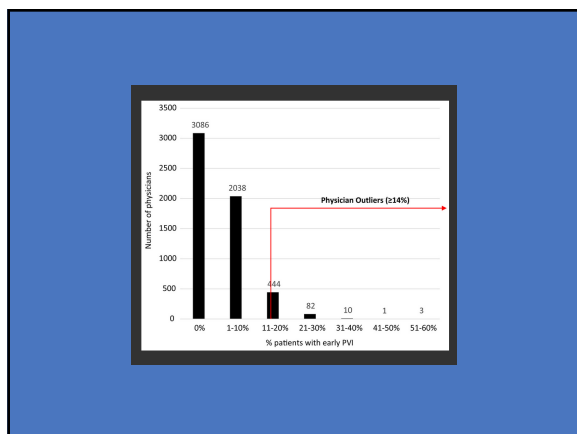
### Overuse of early peripheral vascular interventions for claudication

Guidelines from the Society for Vascular Surgery and the Choosing Wisely campaign recommend that peripheral vascular interventions (PVI) be limited to claudication patients with lifestyle-limiting symptoms only after a failed trial of medical and exercise therapy. We sought to explore practice patterns and physician characteristics associated with early PVI offer of a new claudication diagnosis to evaluate adherence to these guidelines.

**Methods**  
 We used 100% Medicare fee-for-service claims to identify patients diagnosed with claudication for the first time between 2015 and 2022. Early PVI was defined as an aortic/bifemoral/popliteal PVI performed within 6 months of initial claudication diagnosis. A physician-level PVI utilization rate was calculated for physicians who diagnosed new claudication patients and performed at least one PVI (regardless of indication) during the study period. Hierarchical multivariable logistic regression was used to identify physician-level factors associated with early PVI.

**Results**  
 Of 154,824 patients who had a first-time diagnosis of claudication during the study period, 4,886 (3.2%) underwent early PVI. Among the 154,824 physicians included in the analysis, the median physician-level early PVI rate was low at 0% (range, 0%-38.9%). However, there were 310 physicians (1.9%) who had an early PVI rate 2.14% (2 standard deviations above the mean). After accounting for patient characteristics, a higher percentage of services delivered in ambulatory surgery center or office settings was associated with higher PVI utilization (OR, 1.17; 95% adjusted odds ratio [OR], 1.12-1.24; OR, 1.48; 95% adjusted OR, 1.32-1.67; P < .05). Other non-calculated physician factors independently associated with high PVI utilization included male sex (OR, 2.04), fewer years in practice (≤ 20 years: OR, 1.12; 11-20 years: OR, 1.13; ≥ 30 years: OR, 1.13), rural location (OR, 1.23), and lower volume claudication practice (≤ 99 patients diagnosed during study period, 277 patients: OR, 1.30; 100-99 patients: OR, 1.11; all P < .05).

**Conclusions**  
 Outlier physicians with a high early PVI rate for patients newly diagnosed with claudication are identifiable using a claims-based practice pattern measure. Given the shared Society for Vascular Surgery and Choosing Wisely initiative goal to avoid interventions for first-line treatment of claudication, confidential data-sharing programs using national benchmarks and educational guidance may be useful to address high utilization in the management of claudication.



### Poor Outcomes for People with Diabetic Foot Ulcers (DFU)

Estimated > 540 million people with diabetes worldwide

18.6 million DFU worldwide  
 1.6 million DFU in USA  
 Lifetime risk for DFU: ~ 34%

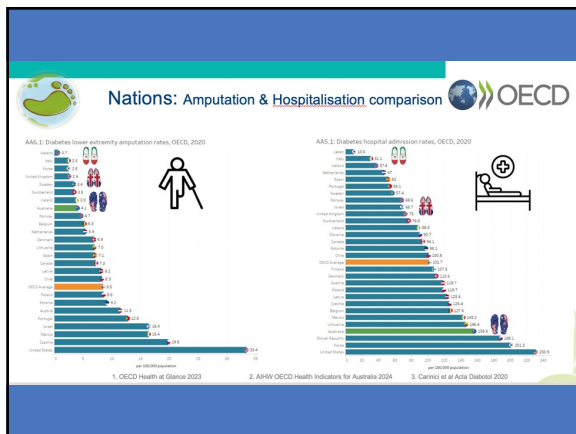
More than 50% of DFUs become infected

20% of DFU result in amputation

85% non-traumatic amputations are due to diabetes

Every 3 mins in America, a limb is amputated due to diabetes!

Amstrong et al. NEJM 2017  
 Lipsky et al. Clin Infect Dis 2012  
<https://diabetes.org/get-involved/advocacy/amputation-prevention-alliance>



### I. The Health Care Terrain: *the root cause of unrest*

- Profit driven, neither patient care nor outcome driven and is characterized by:
  - Fragmentation and lack of integration
  - Lack of broad access to care
  - Health care disparities: race, gender, age geography
  - Dysfunctional delivery system
  - Progressive loss of physician autonomy
  - No increase in physician reimbursement

### Private Equity Debacle

According to the Private Equity Stakeholder Project, 21% of all healthcare bankruptcies in 2023 involved organizations owned by financial firms.

**Vascular Specialist**

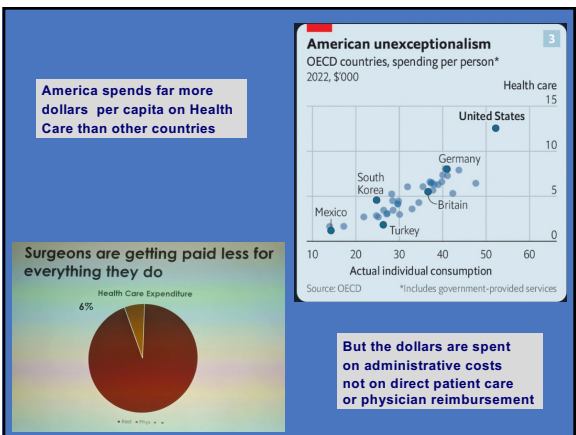
The American Medical Association found that the top reason physicians sell their practices (to any entity) is that they need higher reimbursement rates to remain financially viable. On their own, they find that they cannot negotiate those rates effectively with insurers. Physicians also need access to capital to keep up with the high costs of doing business, from legal compliance to technological investments, such as complex electronic health records.

**The devil we don't know: The case against private equity in medicine**

Other studies have sounded the alarm over worrisome decreases in quality of care. For example, a study published in *The BMJ* uncovered a link between private-equity investment and cost increases for payers and patients as high as 32%. Another study reported that nursing homes owned and operated by private-equity firms were associated with 20,000 additional deaths over a 12-year period.

**Private equity bankruptcies in healthcare explode 112% in 5 years**

Chad Van Alstin | April 18, 2024 | Health Exec | Economics



### LOWE INSTITUTE HOSPITALS INDEX

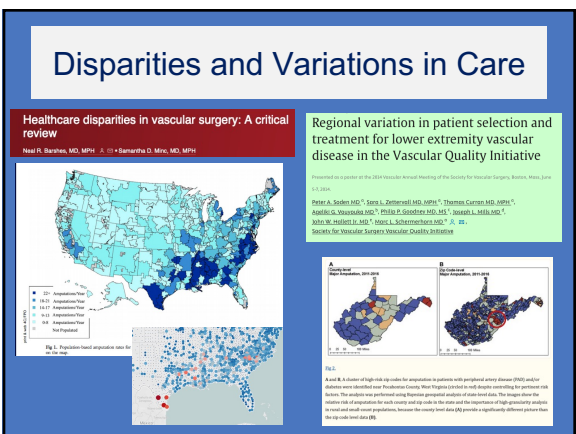
#### 2023 RESULTS

## Avoiding Overuse: Coronary Stents

How professional inertia harms patients and wastes billions of dollars

**KEY TAKEAWAYS**

- U.S. hospitals performed over 229,000 unnecessary coronary stents from 2019-2021. That's a rate of one every seven minutes.
- Of the approximately 1 million stents placed by hospitals, 22 percent met criteria for overuse.
- Medicare wasted as much as \$2.44 billion on unnecessary stents from 2019-2021.
- Rates of overuse varied widely: at some hospitals, more than 50 percent of all stents met criteria for overuse, while at others, fewer than 5 percent were unnecessary.



**1. Educate patients and others via press when possible**

- Some recommended questions:
- Could anything else be causing my symptoms?
  - What are the different ways to treat my illness?
  - Can I make any lifestyle changes before undergoing invasive treatments?
  - What are the risks and side effects of the treatment?
  - Is there a simpler, safer way to treat my illness?
  - What is a good outcome? What is a poor outcome?
  - What happens if I don't receive any treatment?
  - If the procedure is not being done in a hospital, can the doctor take me to a hospital if complications arise, and do they have privileges at a nearby hospital?
  - Will the procedure require any follow-up procedures?

**2. AUC**

**Society for Vascular Surgery appropriate use criteria for management of intermittent claudication**

**Abstract**

The Society for Vascular Surgery appropriate use criteria (AUC) for the management of intermittent claudication were created using the RAND appropriateness method, a validated and standardized method that combines the best available evidence from medical literature with expert opinion, using a modified Delphi process. These criteria serve as a framework on which individualized patient and clinician shared decision-making can occur. These criteria are not definitive. AUC should not be interpreted as a requirement to administer treatments listed as appropriate (benefit outweighs risk), nor should AUC be interpreted as a prohibition of treatments listed as inappropriate (no meaningful benefit). Clinical situations will occur in which modifying factors, not included in these AUC, will shift the appropriateness level of a treatment for an individual patient. Proper interpretation of AUC requires a description of these modifying patient factors. For scenarios with an intermediate rating, clinician judgment combined with the best available evidence should determine the treatment strategy. These scenarios require mechanisms to track the treatment decisions and outcomes. AUC should be modified periodically to ensure that they remain relevant. The committee used 2007 clinical guidelines for the treatment of intermittent claudication (IC) as the scientific, current best, and noncontroversial evidence on the management of IC. The committee used 2007 clinical guidelines as a representative range of clinical practice, including an intentionally high degree of controversy among the guidelines. Post hoc, the term "appropriate use" replaced with the phrase "use whenever benefit." The term "appropriate" was also replaced with "benefit outweighs risk." The key rationale for the management of IC is unclear within these AUC as follows. First, vascular therapy in IC patients may be more beneficial for all patients with IC, because for patients who have not completed vascular therapy, invasive therapy might provide net a benefit for selected patients with IC who are cardiovascularly at high risk. Second, for patients who have a low physiologic and technical risk, and who are experiencing severe therapy limitations and/or a short walking distance. Third, considering the long-term disability of the currently available noninvasive medical interventions for intermittent claudication should be reserved for patients with severe therapy limitations and/or a short walking distance. Fourth, in the current best available expert, open access medical interventions will provide greater net benefit than endovascular intervention for the treatment of IC. Finally, the endovascular approach, unlike intervention for the treatment of IC is of unclear benefit and could be harmful.

**3. Verification Program SVS with ACS**

**The time is now**

- Promote MD led Teams
- Verify quality
- Regionalize efforts
- Improve access

By Beth Bales • 23rd March 2023 • 100

Anton Sibilly, R. Clement Darling III, and Michael C. Darling

The Society for Vascular Surgery (SVS) and the American College of Surgeons (ACS) have launched the "Vascular Verification Program (Vascular-VP)," an ACS Quality Program developed in partnership with the SVS.

**4. Track Outcomes**

- Vascular Quality Initiative (VQI)
  - SVS started a PSO (Patient Safety Organization) in 2011 and has since collected the outcomes of over 1,000,000 interventions within the VQI
  - CMS removed this requirement for CAS

**Presidential address: Outcome assessment in vascular surgery — Results mean everything**

Norman R. Hartzler, MD From the Department of Vascular Surgery, The Cleveland Clinic Foundation, Cleveland.

**5. CPGs - Clinical Practice Guidelines**

**CLINICAL PRACTICE GUIDELINE DOCUMENT**

**The Intersocietal IWGDF, ESVS, SVS Guidelines on Peripheral Artery Disease in People With Diabetes Mellitus and a Foot Ulcer**

Robert Friddle<sup>1,2</sup>, Vivienne Chuter<sup>3</sup>, Joseph Mills<sup>4</sup>, Robert Hinchliffe<sup>5</sup>, Nobuyoshi Azuma<sup>6</sup>, Christian-Alexander Behrendt<sup>7</sup>, Edward J. Boyle<sup>8</sup>, Michael S. Conte<sup>9</sup>, Misty Humphries<sup>10</sup>, Lee Kirksey<sup>11</sup>, Katherine C. McGlinchey<sup>12</sup>, Sigrid Nilak<sup>13</sup>, Joakim Nordstrand<sup>14</sup>, Vincent Rowe<sup>15</sup>, David Russell<sup>16</sup>, Sus C. van den Berg<sup>17</sup>, Masaru Venema<sup>18</sup>, Nicolas Schaper<sup>19</sup>

