

Closing the Racial Disparity in PAD Care and Amputations

Paradigm for Parity



Cardiovascular Solutions of
Central Mississippi

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Interventional Cardiologist

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Follow us on Instagram @ padadvocate

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria

- Ownership/Founder

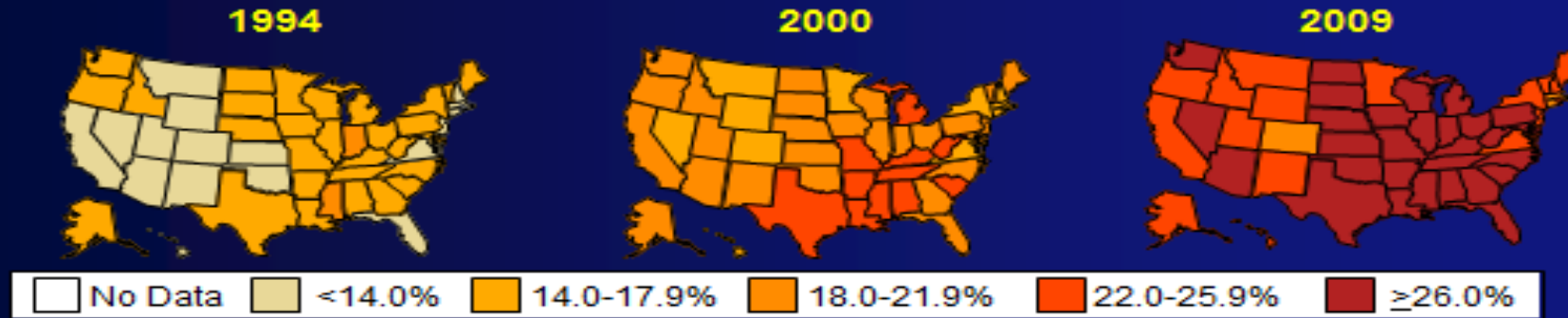
Company

- Medicure Pharma, Inc
- Association of Black Cardiologist, Inc
- Bard Peripheral Vascular, Inc
- Biotronik, Inc
- BlackHagen Design
- Cardiovascular Systems, Inc;
- Janssen Scientific Affairs, LLC
- Cardiovascular Solutions of Central Mississippi, LLC
- Fusion Vascular LLC

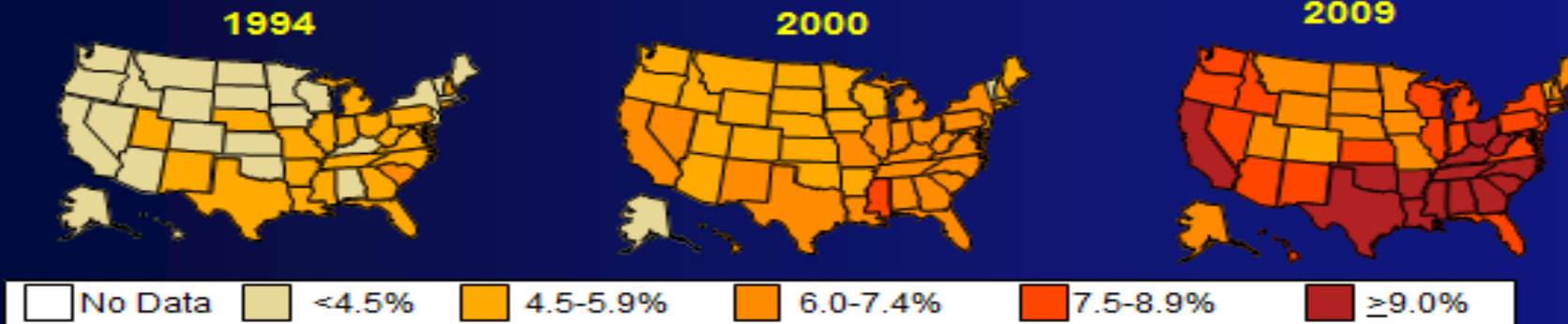
The Perfect Storm

Age-adjusted Percentage of U.S. Adults Who Were Obese or Who Had Diagnosed Diabetes

Obesity (BMI ≥ 30 kg/m²)



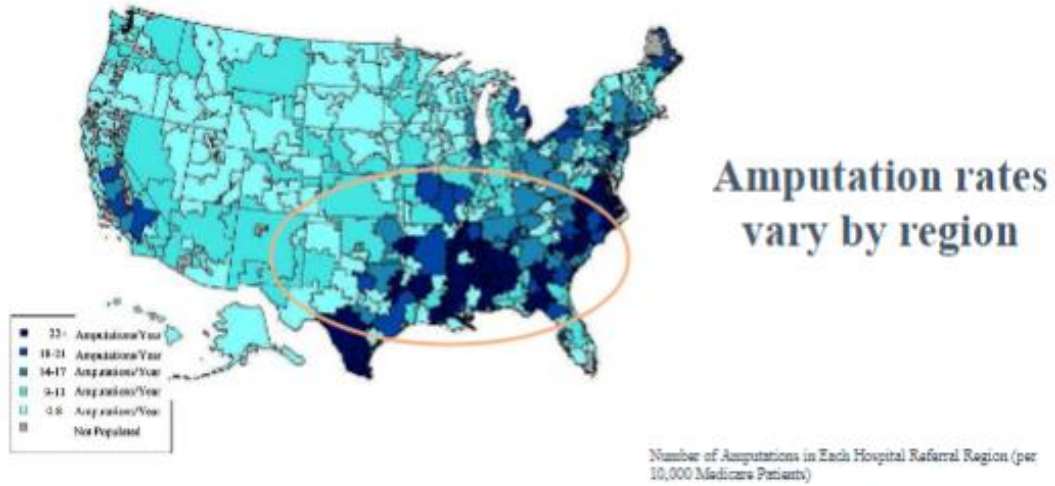
Diabetes



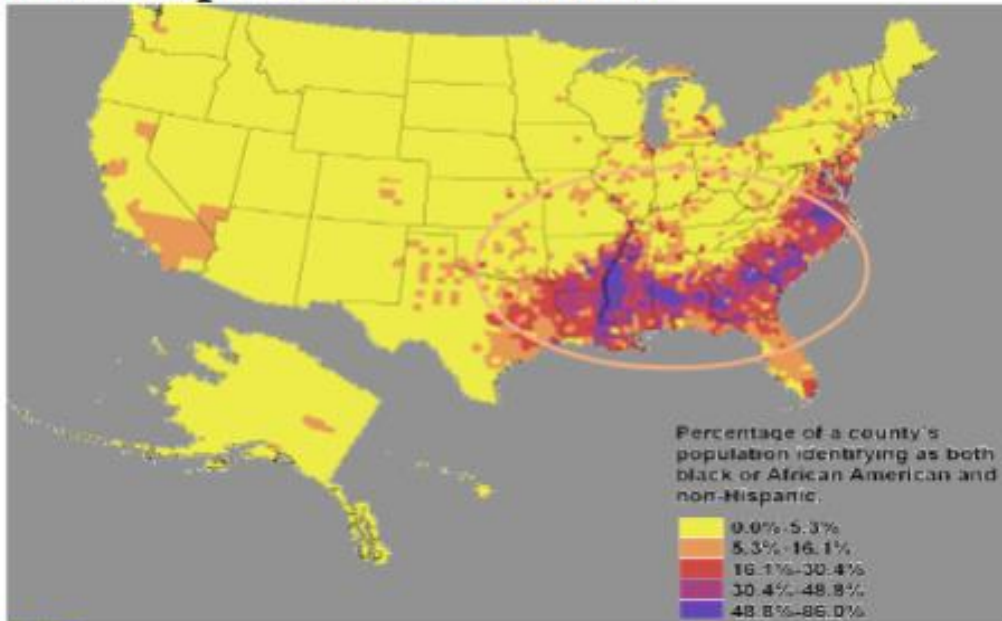
CDC's Division of Diabetes Translation. National Diabetes Surveillance System available at <http://www.cdc.gov/diabetes/statistics>



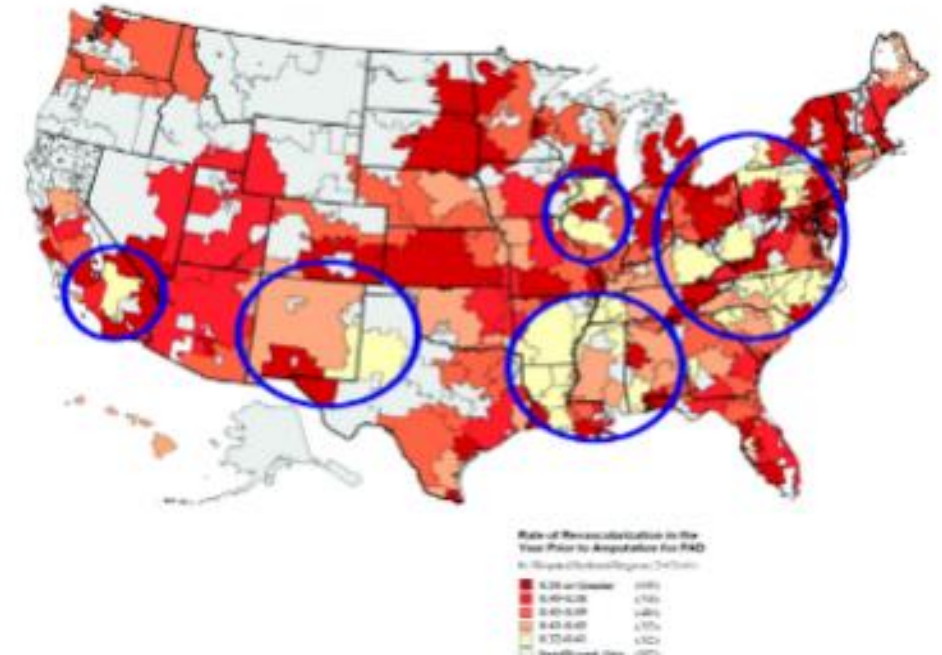
Amputation Rates per State in Medicare Patients

Goodney, Holman, Worley, et al. Regional intensity of vascular care and lower extremity amputation rate. *J Vasc Med* 2012

CensusScope- Black America



Revascularization: Low in Specific US Regions



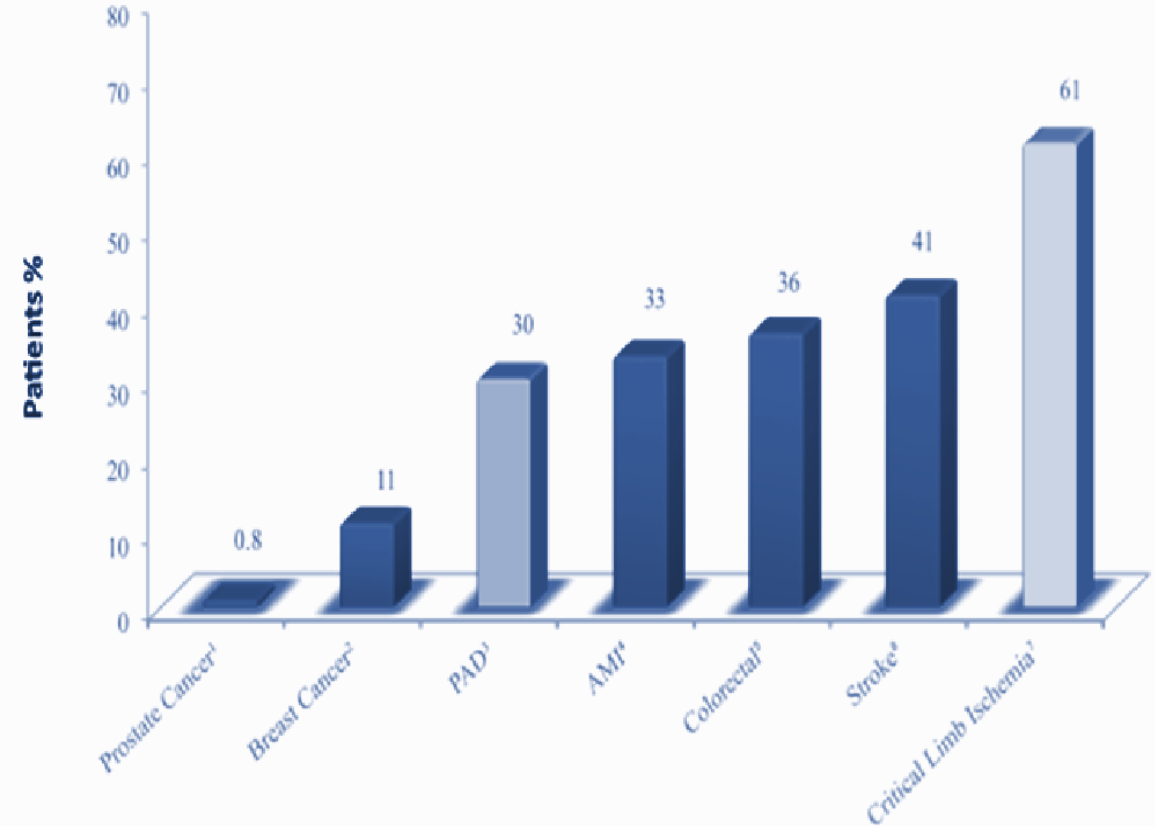
REGIONAL VARIABILITY IN DELIVERY OF CARE



Amputation Lottery: It's not a game

- Probability of major amputation depends on:
 - Who you are and where you live
 - Race/Ethnicity
- Hospital-related costs account for the majority of total costs
- Majority undergoing amputations are Medicaid/Medicare recipients
- Economic burden of PAD / CLI exceeds diabetes and all cancers

5 Year Morality Rates for PAD and CLI





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USPSTF SCREENING AND RISK ASSESSMENT- (I) NO TO ASYMPTOMATIC SCREENING!

Comments also raised concern that an I statement could have a negative effect on health care disparities for PAD. These comments cited evidence that the prevalence of PAD is disproportionately higher among racial/ethnic minorities and low-socioeconomic populations, and noted that the I statement could discourage testing and perpetuate disparities in treatment and outcomes. The USPSTF recognizes these well-established disparities in care. However, the evidence on screening and treatment in these groups is currently lacking, and the USPSTF was unable to determine the overall balance of benefits and harms. Future research should include diverse populations and report on their outcomes. The USPSTF added language to the “Research Needs and Gaps” section to clarify this point.

Whence We Have Come: Continued Lack of Diversity in Clinical Trials

African-Americans: 12% of U.S. → 5% of clinical trials.¹

Hispanics: 16% of U.S. → 1% of clinical trials.²

Elderly (>75) yrs: 40% of MIs → 12% of MI clinical trials.³

Women: 51% of CV deaths → 33% of CV trials.⁴

1. Data presented by P. Sanders in "Dialogues on Diversifying Clinical Trials," Washington, D.C., 2011 Sept 22. http://www.womenshealthresearch.org/site/PageServer?pagename=events_clinicaltrials.

2. Data presented by J. Tierney in "Dialogues on Diversifying Clinical Trials," Washington, D.C., 2011 Sept 22. http://www.womenshealthresearch.org/site/PageServer?pagename=events_clinicaltrials.

3. <https://www.nytimes.com/2018/04/13/health/elderly-clinical-trials.html>

4. Dhruva S. S., et al. Gender Bias in Studies for Food and Drug Administration Premarket Approval of Cardiovascular Devices. *Circulation: Cardiovascular Quality and Outcomes*. 2011 Mar 1; 4(2):165-71.

CLINICAL TRIALS ≠ U.S. DEMOGRAPHICS

Table 1. Baseline Characteristics of the Participants.*

Characteristic	Rivaroxaban plus Aspirin (N=9152)	Rivaroxaban Alone (N=9117)	Aspirin Alone (N=9126)
Age — yr	68.3±7.9	68.2±7.9	68.2±8.0
Female sex — no. (%)	2059 (22.5)	1972 (21.6)	1989 (21.8)
Body-mass index†	28.3±4.8	28.3±4.6	28.4±4.7
Blood pressure — mm Hg			
Systolic	136±17	136±18	136±18
Diastolic	77±10	78±10	78±10
Cholesterol — mmol/liter	4.2±1.1	4.2±1.1	4.2±1.1
Tobacco use — no. (%)	1944 (21.2)	1951 (21.4)	1972 (21.6)
Hypertension — no. (%)	6907 (75.5)	6848 (75.1)	6877 (75.4)
Diabetes — no. (%)	3448 (37.7)	3419 (37.5)	3474 (38.1)
Previous stroke — no. (%)	351 (3.8)	346 (3.8)	335 (3.7)
Previous myocardial infarction — no. (%)	5654 (61.8)	5653 (62.0)	5721 (62.7)
Heart failure — no. (%)	1963 (21.4)	1960 (21.5)	1979 (21.7)
Coronary artery disease — no. (%)‡	8313 (90.8)	8250 (90.5)	8261 (90.5)
Peripheral arterial disease — no. (%)§	2492 (27.2)	2474 (27.1)	2504 (27.4)
Estimated GFR — no. (%)¶			
<30 ml/min	77 (0.8)	80 (0.9)	86 (0.9)
30 to <60 ml/min	1977 (21.6)	2028 (22.2)	2028 (22.2)
≥60 ml/min	7094 (77.5)	7005 (76.8)	7012 (76.8)
Race — no. (%)			
White	5673 (62.0)	5672 (62.2)	5682 (62.3)
Black	76 (0.8)	94 (1.0)	92 (1.0)
Asian	1451 (15.9)	1421 (15.6)	1397 (15.3)
Other	1952 (21.3)	1930 (21.2)	1955 (21.4)
Geographic region — no. (%)			
North America	1304 (14.2)	1305 (14.3)	1309 (14.3)
South America	2054 (22.4)	2036 (22.3)	2054 (22.5)
Western Europe, Israel, Australia, or South Africa	2855 (31.2)	2845 (31.2)	2855 (31.3)
Eastern Europe	1607 (17.6)	1612 (17.7)	1604 (17.6)
Asia-Pacific	1332 (14.6)	1319 (14.5)	1304 (14.3)
Medication — no. (%)			
ACE inhibitor or ARB	6475 (70.7)	6581 (72.2)	6462 (70.8)
Calcium-channel blocker	2413 (26.4)	2374 (26.0)	2482 (27.2)
Diuretic	2727 (29.8)	2666 (29.2)	2746 (30.1)
Beta-blocker	6389 (69.8)	6401 (70.2)	6394 (70.1)
Lipid-lowering agent	8239 (90.0)	8204 (90.0)	8158 (89.4)
NSAID	531 (5.8)	466 (5.1)	473 (5.2)
Nontrial PPI	3268 (35.7)	3266 (35.8)	3264 (35.8)

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The NEW ENGLAND
JOURNAL of MEDICINE

Mississippi Delta Miracle

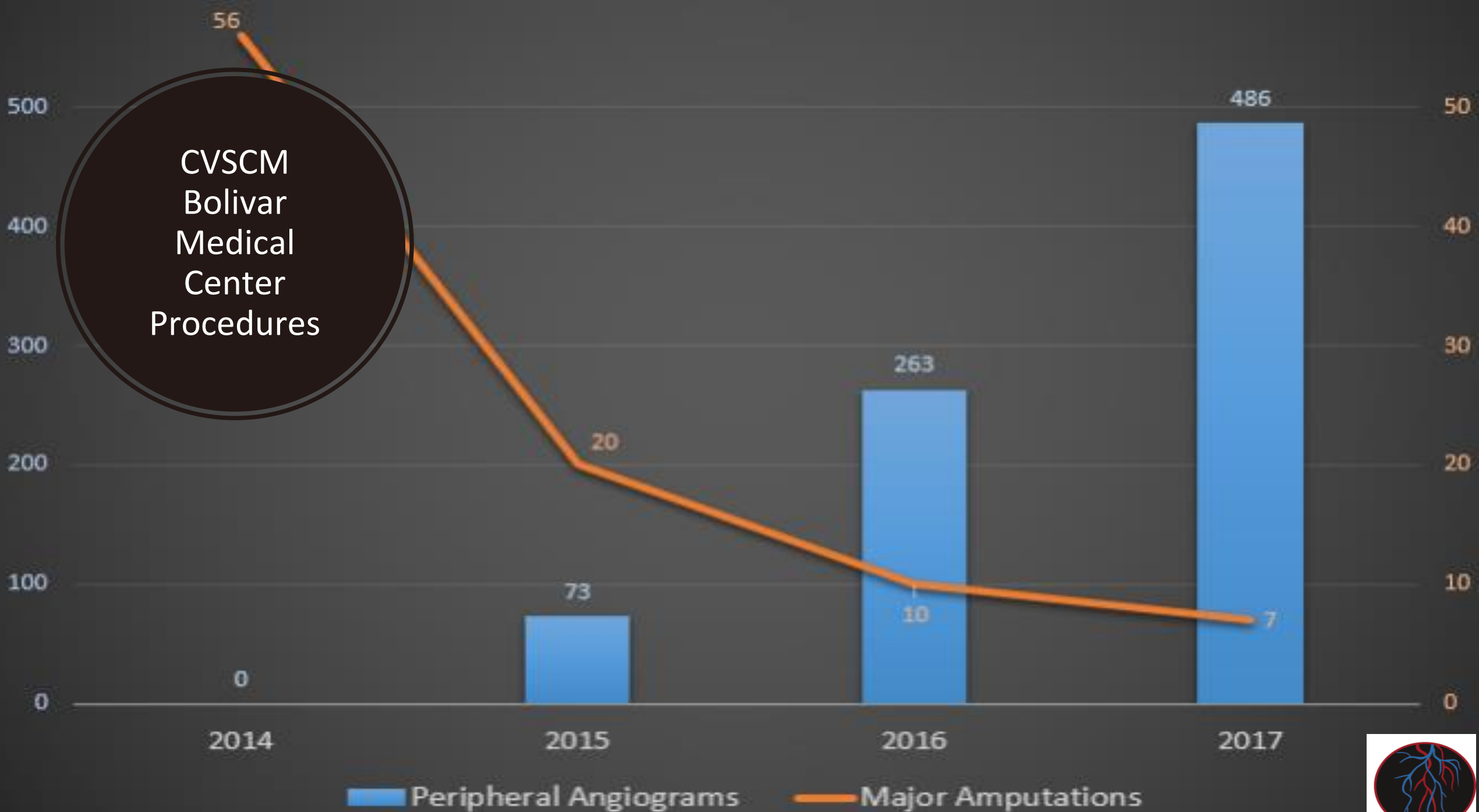
Angiographic Screening Yields Dramatic
Reduction in Amputations

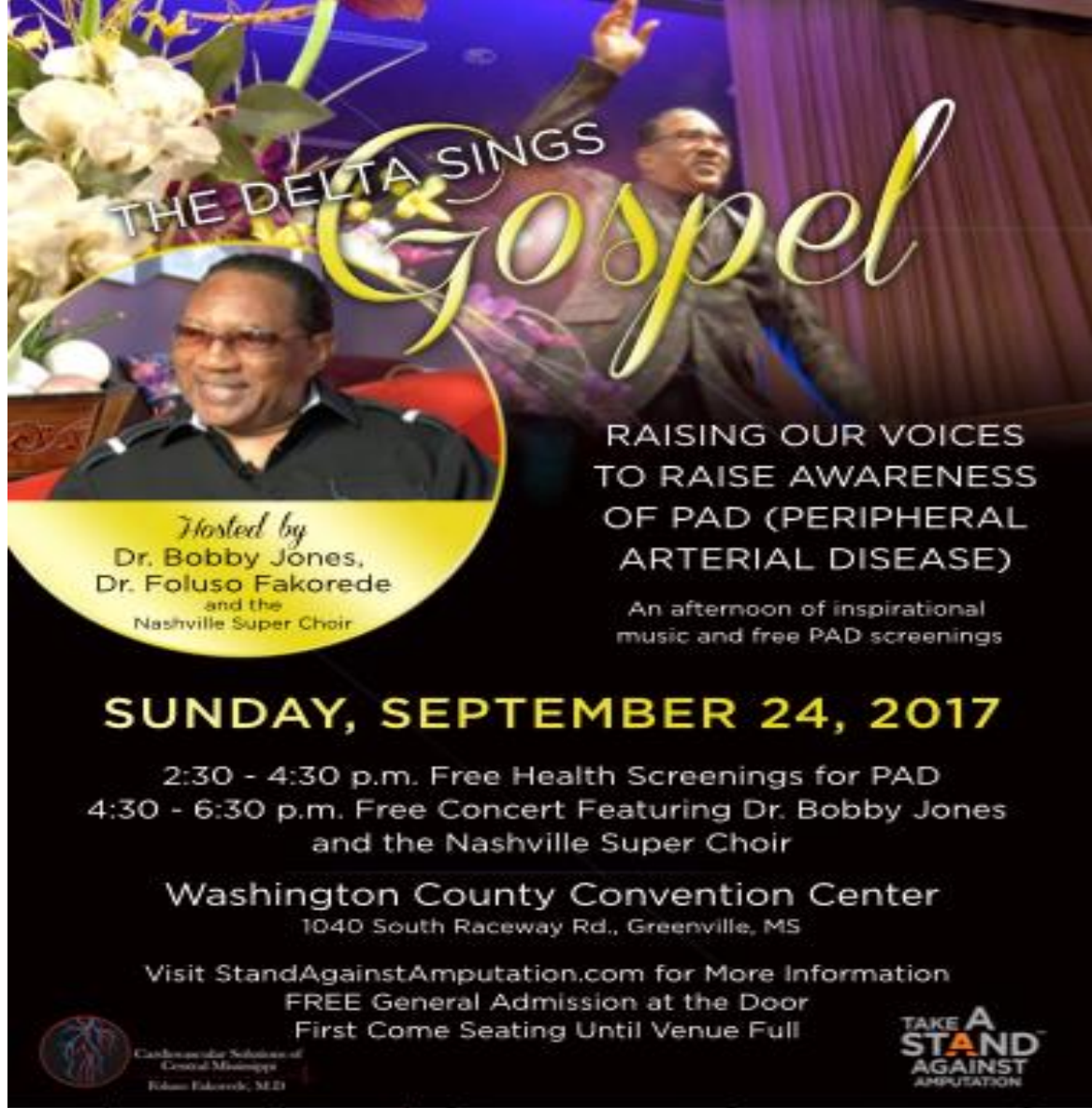
- Foluso A. Fakorede, MD; Bynthia M. Anose, PhD; Mary L. Yost, Brad J. Martinsen, PhD
- Goal: avoid amputation as first-line treatment for CLI patients. To facilitate this goal, it is necessary to:
 - elucidate the predictors of amputation risk
 - design an effective, alternative treatment algorithm
 - take a holistic approach to identifying such risk factors, both physiological and socioeconomic (address biases and misconceptions)
- Cardiovascular Solutions of Central Mississippi
 - Our treatment approach and results

in conjunction with CSI



CVSCM
Bolivar
Medical
Center
Procedures





THE DELTA SINGS
Gospel

Hosted by
Dr. Bobby Jones,
Dr. Foluso Fakorede
and the
Nashville Super Choir

RAISING OUR VOICES
TO RAISE AWARENESS
OF PAD (PERIPHERAL
ARTERIAL DISEASE)


An afternoon of inspirational
music and free PAD screenings

SUNDAY, SEPTEMBER 24, 2017

2:30 - 4:30 p.m. Free Health Screenings for PAD
4:30 - 6:30 p.m. Free Concert Featuring Dr. Bobby Jones
and the Nashville Super Choir

Washington County Convention Center
1040 South Raceway Rd., Greenville, MS

Visit StandAgainstAmputation.com for More Information
FREE General Admission at the Door
First Come Seating Until Venue Full

 Catheter-based Solutions of
Central Mississippi
Foluso Fakorede, M.D.

**TAKE A
STAND
AGAINST
AMPUTATION**



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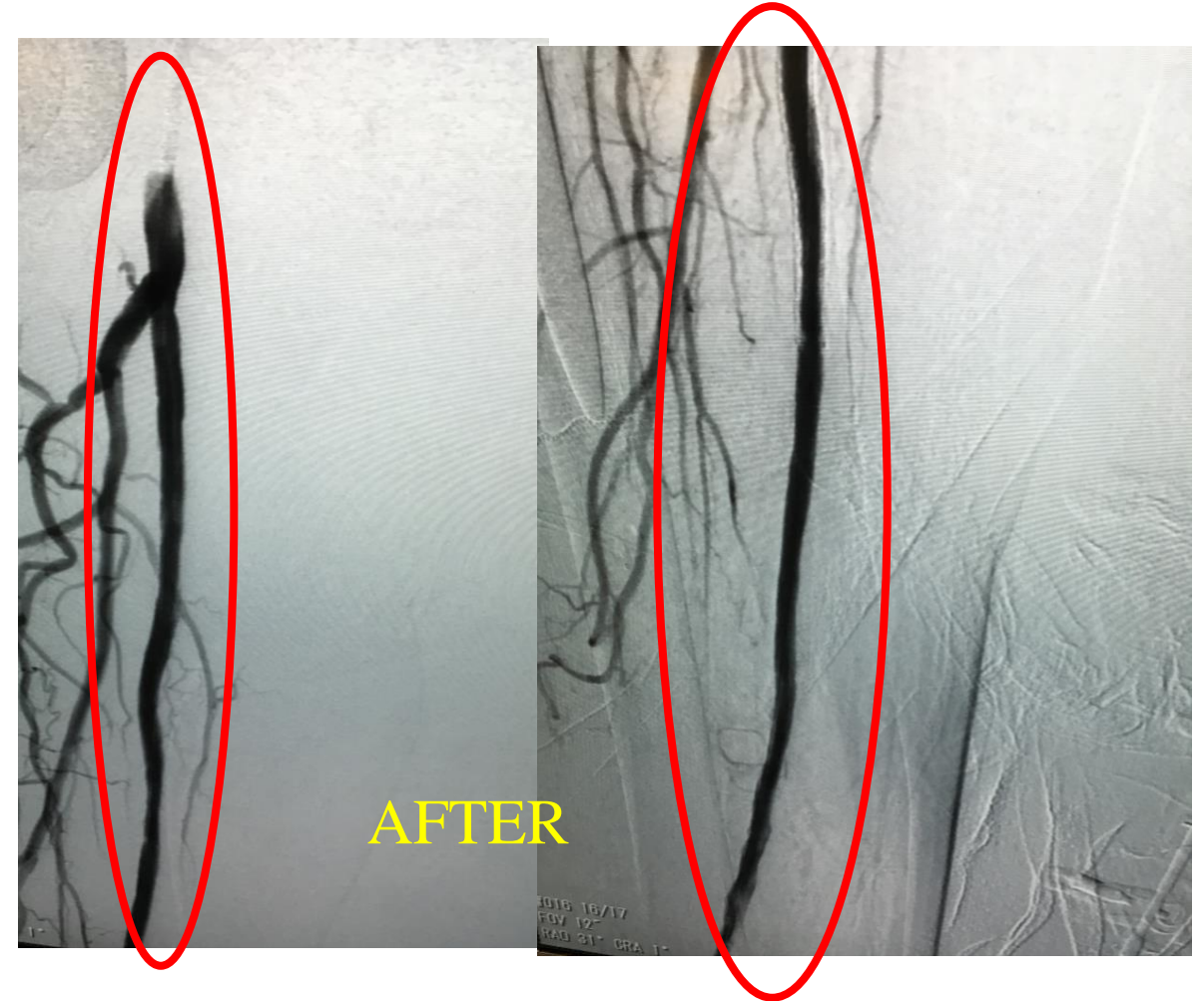
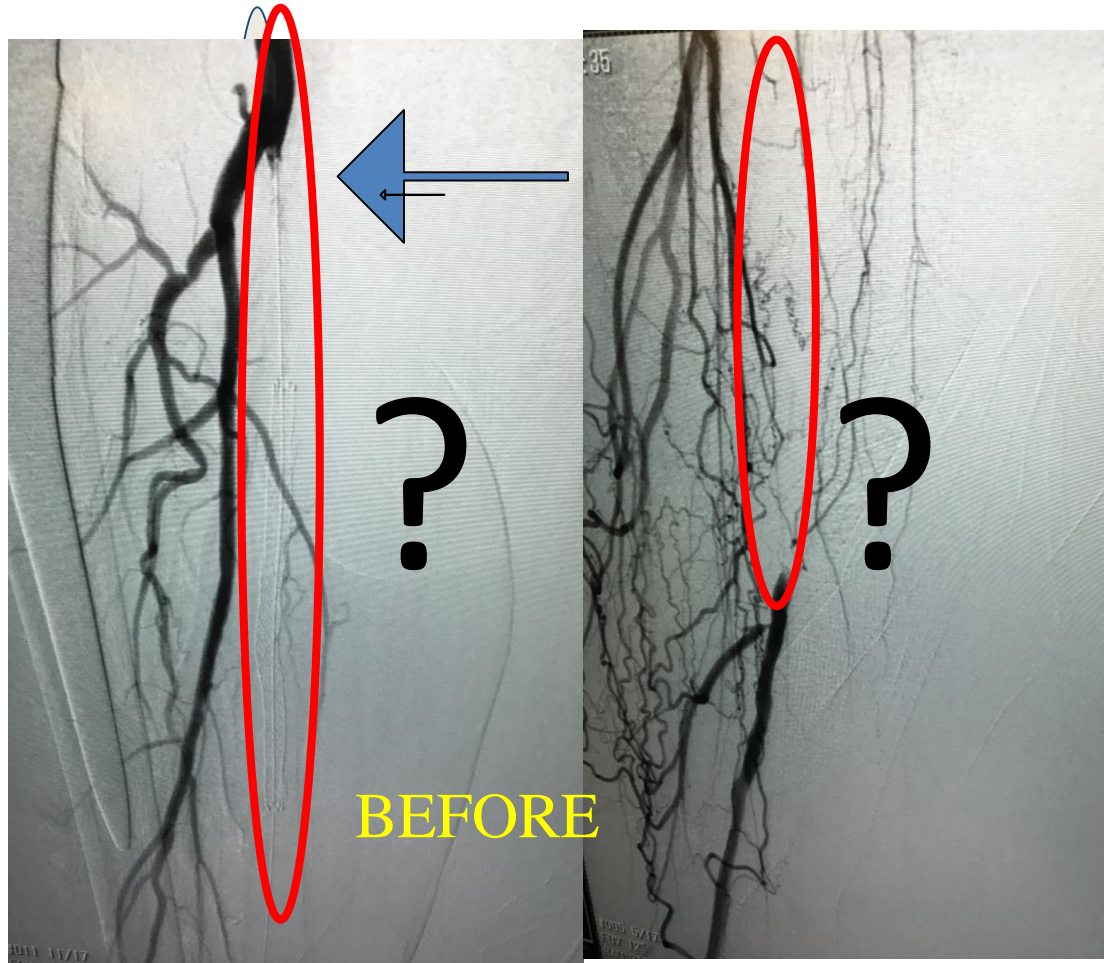
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POPULATION SCREENING/EDUCATIONAL AWARENESS

- Ms. Gwendolyn Hughes
- Military wife for 40 years and worked as a technician for the pentagon. Husband retired from service to care for her.
- Diagnosed with CVA & diabetes, but wheelchair bound due to undiagnosed PAD.
- Screened in August 2017 (despite USPSTF saying not to screen “atypical” patients)



TIMELY SCREENING AND INTERVENTION IS KEY



2 WEEKS POST REVASCULARIZATION



PAD POLICY ACTION

OVERVIEW	<p>According to the CDC, more than 100 million American are living with prediabetes or diabetes. While these numbers are staggering, proactive action is being taken:</p> <ul style="list-style-type: none"> • <u>Prediabetes.</u> In 2017, CMS finalized the Medicare Diabetes Prevention Program to promote healthy living and lower the rate of progression to type 2 diabetes. • <u>Diabetes.</u> The Diabetes Caucus is one of the largest caucuses in the U.S. Congress with over 300 Members and was instrumental in passing the National Clinical Care Commission Act of 2017 to create a commission to make recommendations on intragovernmental action relating to diabetes care and insulin. <p>BUT important sequelae (secondary diseases) of diabetes such as peripheral artery disease (PAD) are not getting equal attention, and minorities are suffering as a result.</p> <ul style="list-style-type: none"> • Today, 20 million Americans have PAD and an estimated 200,000 of them – disproportionately minorities – suffer avoidable amputations every year. • The VA has a comprehensive amputation prevention program – Preventing Amputations in Veterans Everywhere (PAVE) – but Medicare and Medicaid do not.
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LEGISLATIVE OPTIONS	<p>H. Res. [__]</p> <ul style="list-style-type: none"> • Congressional Resolution expressing concern about and vision for PAD and amputation prevention, including (1) formation of intragovernmental work group, (2) USPSTF review of at-risk screening for PAD, (3) multidisciplinary review of PAD patients, and (4) no non-emergent amputation without prior arterial testing. <p><u>PAD Caucus</u></p> <ul style="list-style-type: none"> • Congressional PAD Caucus formed to heighten attention to and pave the way for statutory action on PAD and amputation prevention. <p><u>Legislation</u></p> <ul style="list-style-type: none"> • In coordination with Reps. John Lewis and Danny Davis of W&M, a bill to ensure multidisciplinary review of PAD patients, no amputations without arterial testing.
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TASK FORCE	<p><u>Current</u></p> <ul style="list-style-type: none"> • Association of Black Cardiologists • CardioVascular Coalition (American Vascular, Azura Vascular, CSI, Janssen, Lifeline Vascular, National Cardiovascular Partners, OEIS, Vascular Access Centers, Philips) • Preventive Cardiovascular Nurses Association • Society for Cardiovascular Angiography and Interventions <p><u>Prospective</u></p> <ul style="list-style-type: none"> • American Heart Association • Other Industry (drug and device manufacturers)
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Conclusion

- Research should be done to incorporate a higher representation of minorities/women regarding best evidence-based treatment and longitudinal community research.
- Awareness campaigns that parallel that of oncology/celebrity-led messages at appropriate scientific literacy levels
- **DIS-INCENTIVIZE** amputations and publicize amputation rates in all hospitals-Policy action.
- Revamping our PAD curriculums in all professional and allied professional training programs.
- Patient, providers, policy and community navigators understand social determinants of health, loss of productivity to society and economic cost of death.
- Recruitment and retention of multi-disciplinary specialists to the epicenters of PAD/CLI. Benefit of regionalized centers to address fragmentation of protocols?