Department of Surgery, Division of Vascular Surgery

Exploring the Path from Basic Science to Clinical Outcomes Research: Unveiling Multiple Avenues for Quality Improvement

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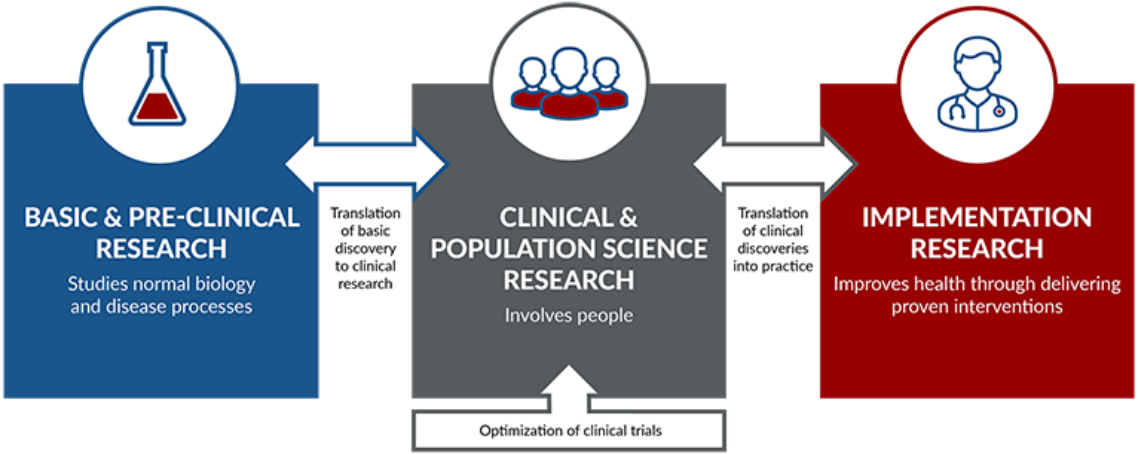
The Cryptic Masons Research Fellow in Clinical Outcomes

From Bench To Bedside

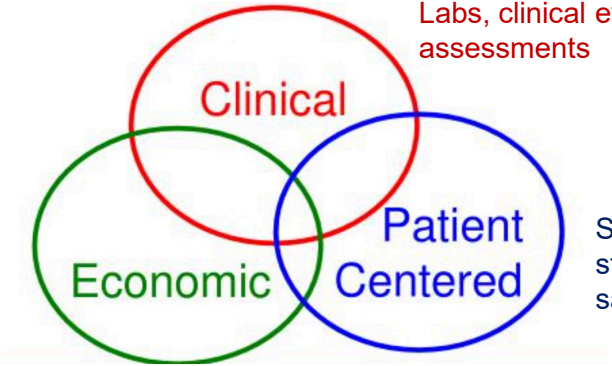


https://www.nhlbi.nih.gov/science/research-spectrum

Health Outcomes Research

Scientific inquiry used to provide information on healthcare services and determine how they influence the probability of optimal patient outcomes in terms of physiologic status, physical function, emotional and intellectual performance and comfort

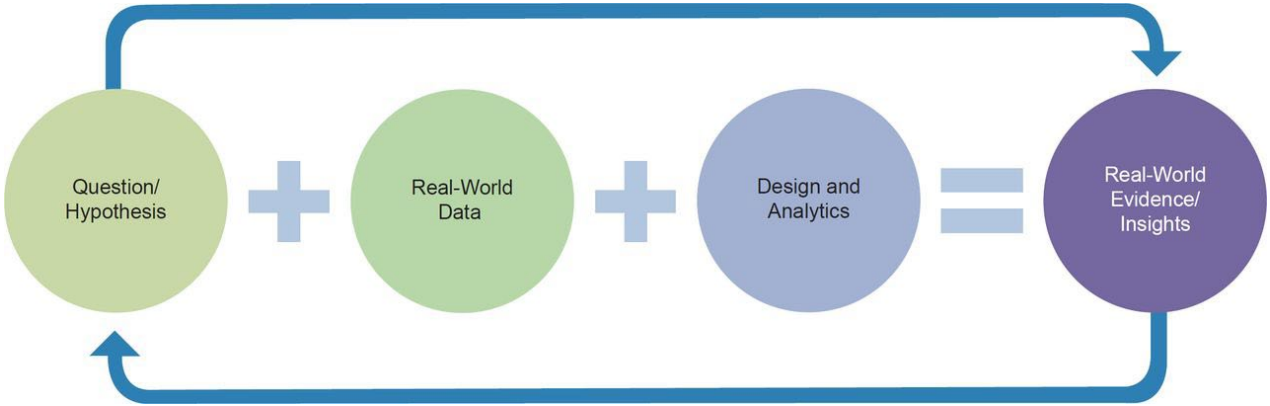
Labs, clinical events, physician assessments



Productivity, costs, healthcare utilization

Symptoms report, health status, quality of life, patient satisfaction

Health Outcomes Research



Real-world data help supplement randomized clinical trials to Help Inform Clinical Decision-Making

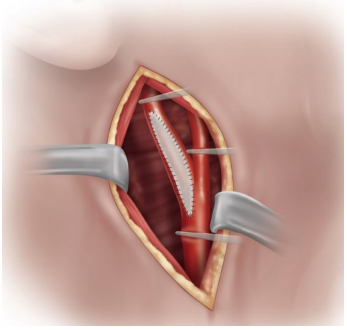
2023 Clinical Outcomes Projects

1. Carotid Artery Disease
2. Peripheral Artery Disease

Carotid Artery Disease

Carotid artery stenosis is a major risk factor for stroke, the **fifth** leading cause of death in the United States.

Carotid Artery Disease

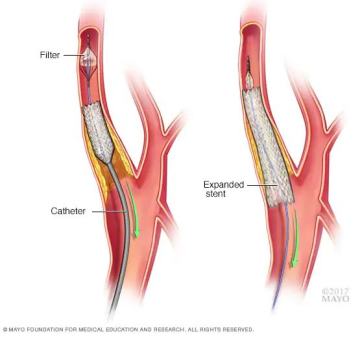


Carotid stenosis for revascularization

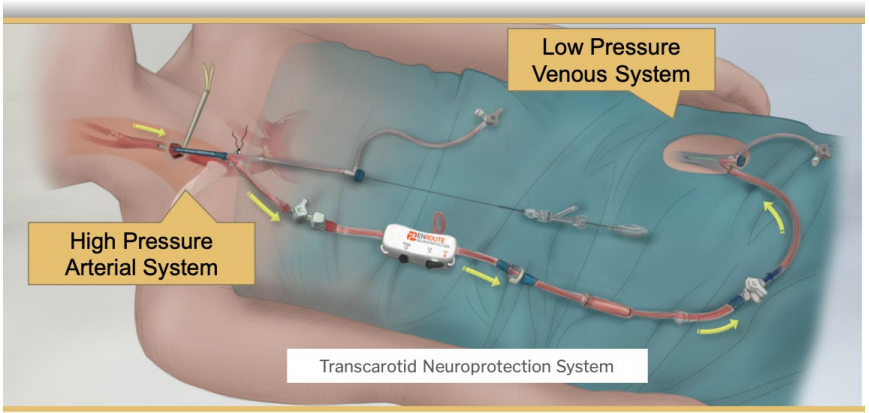
Carotid Endarterectomy

Carotid Artery Stenting

- previous neck irradiation
- hostile neck
- “high carotid” bifurcation
- previous neck surgical access
- other severe systemic comorbidities



TransCarotid Stenting with Dynamic Flow Reversal (TCAR)



- Avoid the arch
- "CEA-like" Neuroprotection
- Less manipulation

Carotid Artery Disease Projects

1. Association between Physicians' Preference and Stroke/Death Outcomes after Carotid Revascularization
2. Perioperative Use of Antiplatelets after TCAR
3. Contemporary Trends and Age-Based Outcomes of Carotid Revascularization for Asymptomatic Carotid Artery Stenosis
4. Predictors of Prolonged Length of Stay after Elective Carotid Revascularization

Carotid Artery Disease Projects

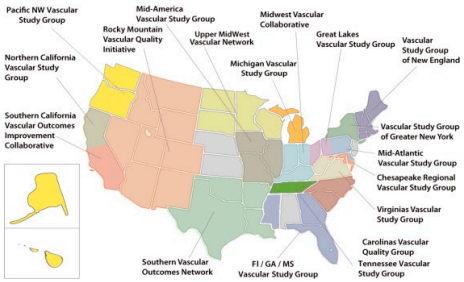
THE SVS VASCULAR QUALITY INITIATIVE

SVS | VQI

In collaboration with NCDR®

- 14 registries contain demographic, clinical, procedural and outcomes data from more than a million vascular procedures performed across the United States, as well as Canada and Singapore.

18 Regional VQI Groups



- Improving the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information

Carotid Artery Disease Projects

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1. Association between Physicians' Preference and Stroke/Death Outcomes after Carotid Revascularization

- A total of 104,925 carotid revascularization procedures performed by 1,433 physicians

- Physician's preference has a bearing on their overall stroke/death rates and that physicians relying solely on TFCAS as the minimally invasive procedure of choice have worse outcomes.

- Important finding in light of CMS's decision memo proposing expanded coverage for transfemoral Carotid artery stenting (CAS) for Medicare beneficiaries under specified conditions.

Physician Experience	CEA+TCAR	CEA+TFCAS		CEA, TFCAS and TCAR	
		OR (95%CI)	*P*	*OR (95%CI)*	*P*
In-Hospital Outcomes					
Death	Ref.	1.42 (1.04-1.04)	.03	1.12 (0.88-1.43)	.36
Any Stroke	Ref.	1.28 (0.98-1.69)	.07	1.04 (0.90-1.20)	.63
Stroke/Death	Ref.	1.31 (1.03-1.66)	.03	1.05 (0.92-1.20)	.44
One-Year Outcomes		*HR (95%CI)*	*P*	*HR (95%CI)*	*P*
Stroke	Ref.	1.51 (1.2-1.9)	0.001	1.3 (1.1-1.6)	0.01
Death	Ref.	1.1 (0.6-2.0)	0.68	1.3 (0.9-1.9)	0.18
Stroke/Death	Ref.	1.45 (1.1-1.9)	0.01	1.1 (0.9-1.4)	0.17

Carotid Artery Disease Projects

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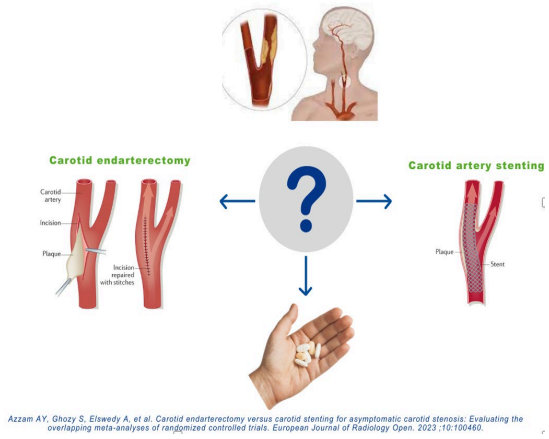
2. Contemporary Trends and Age-Based Outcomes of Carotid Revascularization for Asymptomatic Carotid Artery Stenosis

- Prognosis and management of patients with asymptomatic carotid artery stenosis remains controversial.
- Remains a significant contributor to stroke especially with the aging of the population and the increasing prevalence of risk factors.
- Almost 70% of carotid revascularization procedures in the United States are performed on asymptomatic patients, with almost 18% performed on patients older than 80 years.
- Older age is significantly associated with increased in-hospital mortality and stroke/death outcomes extending up to 1-year of follow up.



Azzam AY, Ghozy S, Elswedy A, et al. Carotid endarterectomy versus carotid stenting for asymptomatic carotid stenosis: Evaluating the overlapping meta-analyses of randomized controlled trials. European Journal of Radiology Open. 2023 ;10:100460.

When considering revascularization for aCAS, careful patient selection, medical optimization, and avoidance of the transfemoral approach are warranted to improve outcomes in this patient population.

Carotid Artery Disease Projects

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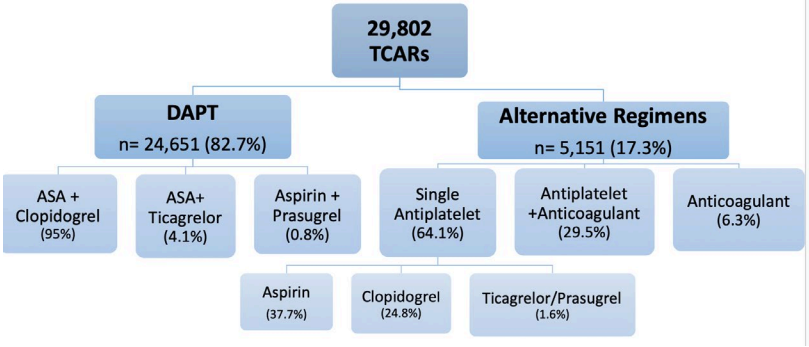
3. Perioperative Use of Antiplatelets after TCAR

- Current guidelines recommend dual-antiplatelets (DAPT) in the peri-operative period after Transcarotid Artery Revascularization (TCAR)

- Inadequate compliance with DAPT is often encountered due to poor tolerance, bleeding or need for concomitant anticoagulation



- ~17% of patients undergoing TCAR are not maintained on DAPT

- Significant increase in in-hospital stroke/death and stroke in patients on alternative regimens compared to DAPT

Carotid Artery Disease Projects

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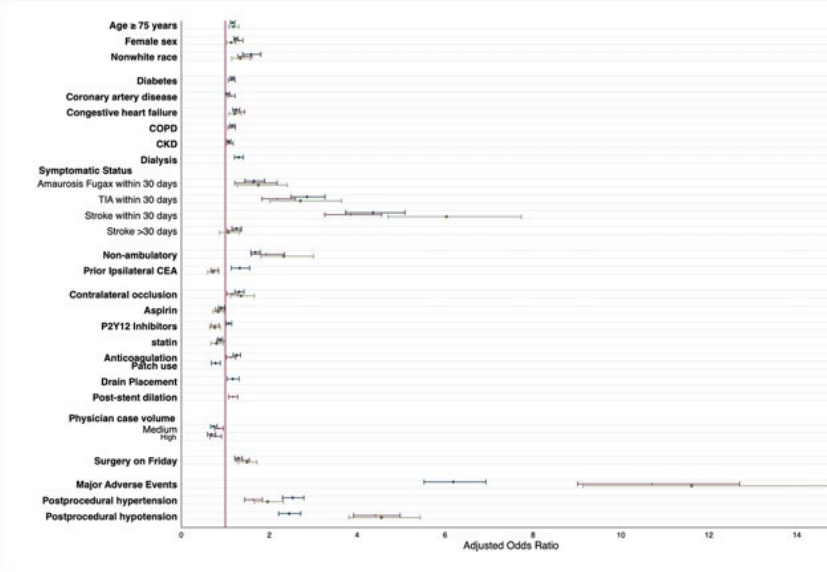
- Hospitals are encouraged to strive for a postoperative day one discharge after carotid revascularization

- Aimed to Identify predictors of prolonged length of stay (pLOS) after elective carotid endarterectomy (CEA), Transcarotid artery revascularization (TCAR) and transfemoral carotid artery stenting (TFCAS).



4. Predictors of Prolonged Length of Stay after Elective Carotid Revascularization

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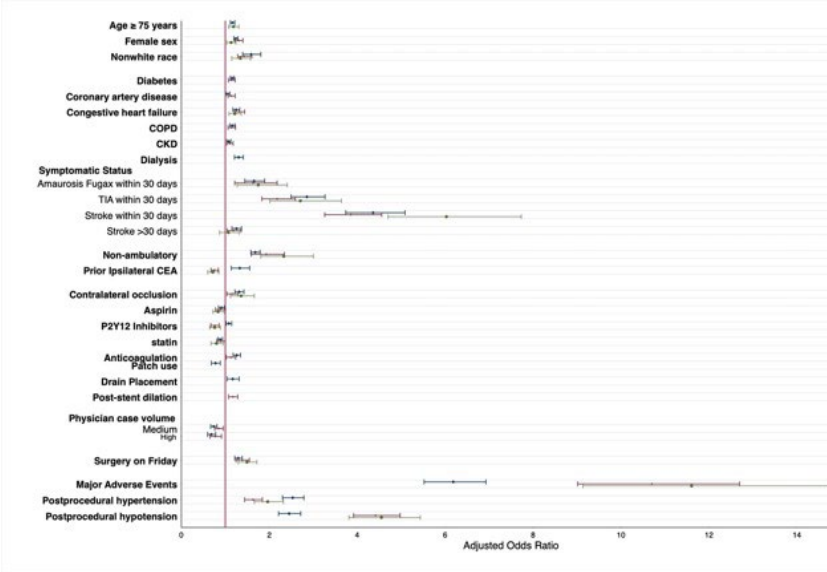
- Aimed to Identify predictors of prolonged length of stay (pLOS) after elective carotid endarterectomy (CEA), Transcarotid artery revascularization (TCAR) and transfemoral carotid artery stenting (TFCAS).

- Several modifiable predictors for prolonged length of stay after CEA, TCAR and TFCAS : Patching during CEA, intraoperative protamine use, avoiding post-stent ballooning and interventions on non-ambulatory patients

- Represent quality improvement opportunities to reduce the incidence of prolonged LOS and improving care in patients undergoing carotid revascularization



Carotid Artery Disease Clinical Outcomes Research

SVS | VQI
In collaboration with NCDR®

FELLOWSHIP IN TRAINING

"Designed to introduce residents and fellows in vascular programs to the patient safety organization (VQI/PSO).

FIT applicants will work closely with their VQI mentor on participation in regional biannual meetings and review of comparative data including center level quality improvement processes."

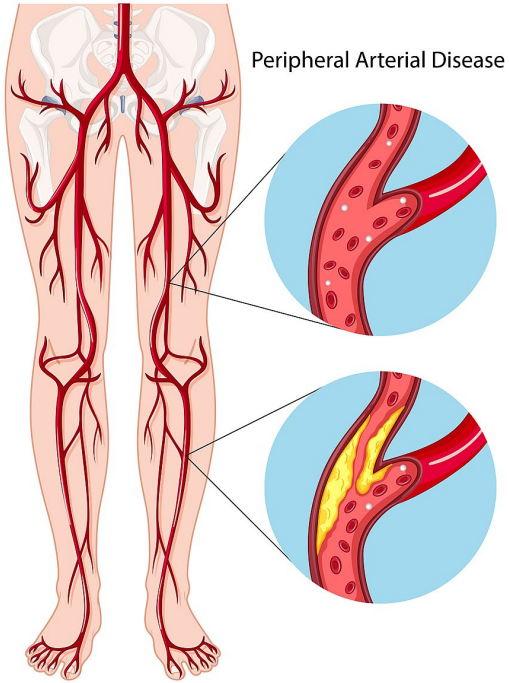
2023 Clinical Outcomes Projects

1. Carotid Artery Disease
2. **Peripheral Artery Disease**

Peripheral Arterial Disease (PAD)

- PAD affects 200 million people worldwide and ~ 8.5 million in the United States

- ~11% are likely to develop critical limb threatening ischemia (CLTI)

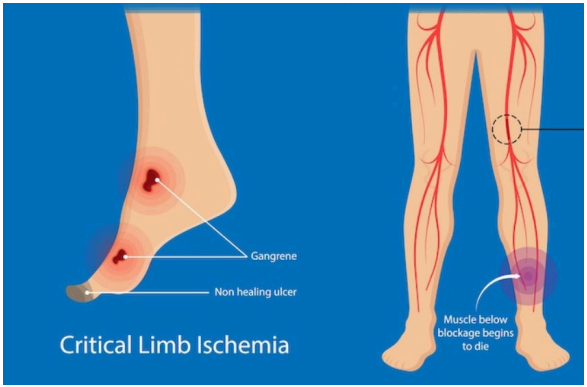


https://www.carolinaheartandleg.com/peripheral-arty-disease/

AMPUTATIONS

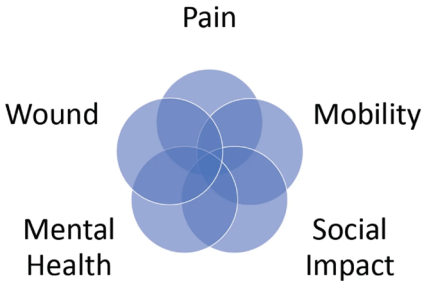
- There are ~150 000 nontraumatic leg amputations every year in the US, mostly in patients with diabetes.
- Although amputation is an important and potentially lifesaving treatment option for some patients, it is often **preventable,** even among patients with advanced PAD.
- Annual cost of amputation is ~6.5 billion dollars
- Amputation further increases the rate of mortality and disability

  > 50% people with a major amputation will be dead in 5 years



Psychological Impact of Amputations

- Quality of life scores significantly drop for amputees compared to non-amputees
- Changes in employment status and the use of prosthetic devices correlates with more negative scores
- Amputees have higher of depression, anxiety, and negative body image.



Goodney P et al. Journal of Vascular Surgery. 2022 Jan 24.

Race and PAD

- Race is consistently the determining risk factor for CLTI-related major limb amputation and underutilization of limb salvage techniques

- African Americans (AA) were shown to have:
  - Higher rates of PAD and diabetes
  - More severe disease at time of presentation
  - Less likely to be treated with optimal medical therapy or to undergo limb salvage therapy

→*Non-White race alone* ***more than doubles the risk of primary amputation*** *in patients with CLTI* ***and lowers the rate of utilization of limb salvage techniques*** *by at least 28%"* *(Anjorin AC et al, J. Vasc Surg 2022;75(6):e77-8)*

Circulation
Volume 143, Issue 17, 27 April 2021; Pages e875-e891
https://doi.org/10.1161/CIR.0000000000000967

American Heart Association.

AHA POLICY STATEMENT

Reducing Nontraumatic Lower-Extremity Amputations by 20% by 2030: Time to Get to Our Feet: A Policy Statement From the American Heart Association

Mark A. Creager, MD, FAHA, Chair, Kunihiro Matsushita, MD, PhD, FAHA, Vice Chair, Shipra Arya, MD, SM, Joshua A. Beckman, MD, FAHA, Sue Duval, PhD, FAHA, Philip P. Goodney, MD, MS, J. Antonio T. Gutierrez, MD, MHS, John A. Kaufman, MD, MS, Karen E. Joynt Maddox, MD, MPH, FAHA, Amy W. Pollak, MD, Aruna D. Pradhan, MD, MPH, FAHA, Laurie P. Whitsel, PhD, FAHA, and On behalf of the American Heart Association Advocacy Coordinating Committee

Special Communication

Closing the Gaps in Racial Disparities in Critical Limb Ischemia Outcome and Amputation Rates: Proceedings from a Society of Interventional Radiology Foundation Research Consensus Panel

Yolanda Bryce MD [a], Barry Katzen MD [b], Parag Patel MD, MS [c], Carla C. Moreira MD [d], Foluso A. Fakorede MD [e], Shipra Arya MD [f], Melissa D'Andrea MD [g], Jihad Mustapha MD [h], Vincent Rowe MD [i], Kenneth Rosenfield MD [j], Suresh Vedantham MD [k], Nadine Abi-Jaoudeh MD [l], Paul J. Rochon MD [m]

Call to Action: Structural Racism as a Fundamental Driver of Health Disparities: A Presidential Advisory From the American Heart Association

Keith Churchwell, Mitchell S.V. Elkind, Regina M. Benjamin, April P. Carson, Edward K. Chang, Willie Lawrence, Andrew Mills, Tanya M. Odom, Carlos J. Rodriguez, Fatima Rodriguez, Eduardo Sanchez, Anjail Z. Sharrief, Mario Sims, Olajide Williams and **On behalf of the American Heart Association**

Originally published 10 Nov 2020 | https://doi.org/10.1161/CIR.0000000000000936 | Circulation. 2020;142:e454–e468

Published in final edited form as:
Semin Vasc Surg. 2022 June ; 35(2): 141–154. doi:10.1053/j.semvascsurg.2022.05.003.

Disparities in peripheral artery disease care: A review and call for action

Reasons of Racial Disparity

Underlying reasons for these disparities are multifactorial

- Differences in comorbidities (smoking status, diabetes, hypertension, body mass index, glomerular filtration rate, and hypercholesterolemia**)**
- Anatomic factors
- Socioeconomic status
- Type or lack of insurance
- Lack of access to quality health care, capacity and expertise of local hospitals
- Implicit bias and lack of Trust

Determining Influences on Racial Disparity in Non-traumatic Lower Extremity Amputation in Patients with Critical Limb Threatening Ischemia.

“DISCOVER-CLTI”

DISCOVER-CLTI

***Aim*:** Identify barriers associated with increased risk of non-traumatic lower extremity amputations in African Americans versus White patients with CLTI

Study Population: Patients with CLTI in Indiana in the past 5 years

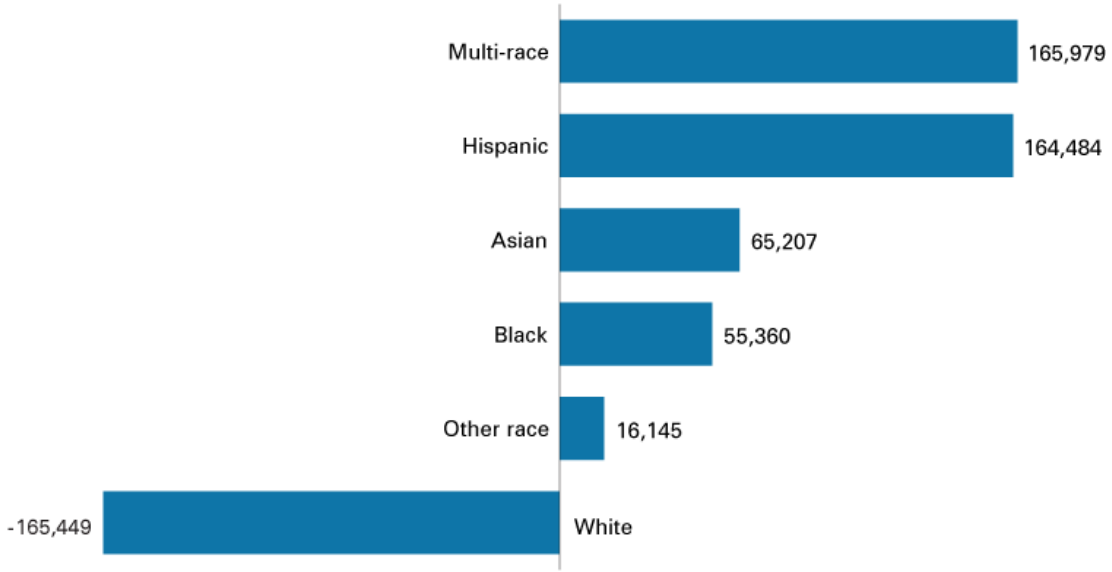
Methods:

1) A retrospective analysis of patients with CLTI across 3 different healthcare systems (IU Hospital, Eskenazi Hospital, and Veterans Affairs)

- Modifiable and non-modifiable risk factors associated with increased rates of lower extremity amputation in AA with CLTI will be evaluated and validated across the 3 different healthcare systems

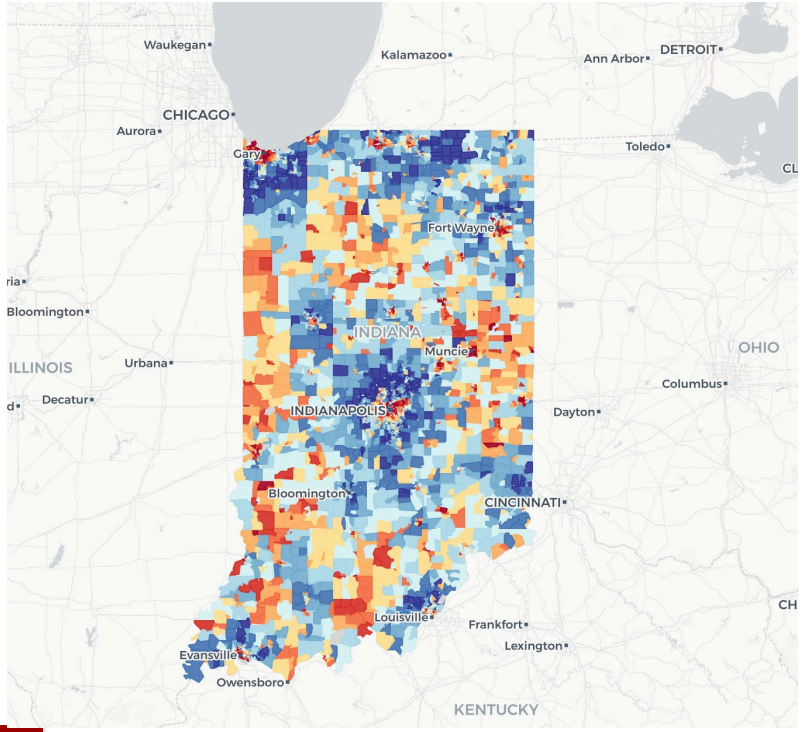
2) Qualitative research (Semi-structured interviews and surveys) for a number of patients, and providers in the 3 different healthcare systems to assess perception and assess health literacy, knowledge of PAD and its management strategies

Difference in Indiana population by race and ethnic group, 2010 to 2020



The number of Hoosiers who identified as being multiracial had a 167% increase. White declined by 165,449 (-3.1% difference), Asian and Black increased by 65,207 (64.3%) and 55,360 (9.5%), respectively.

Area Deprivation Index

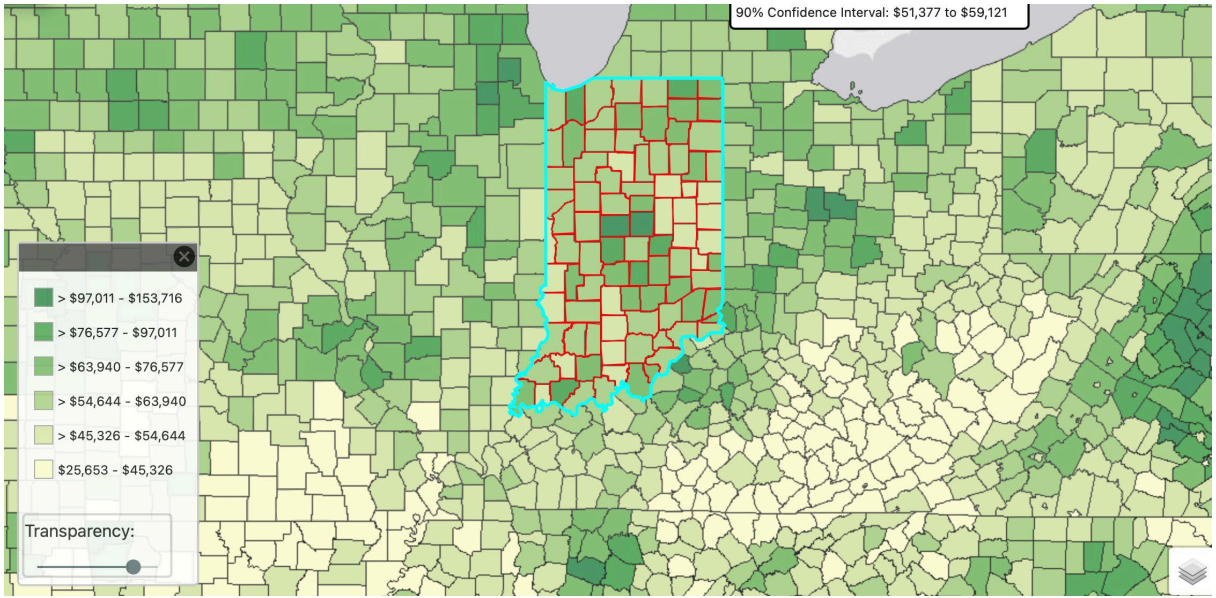


ADI scores from within this state alone are ranked from lowest to highest, then divided into deciles (1–10).

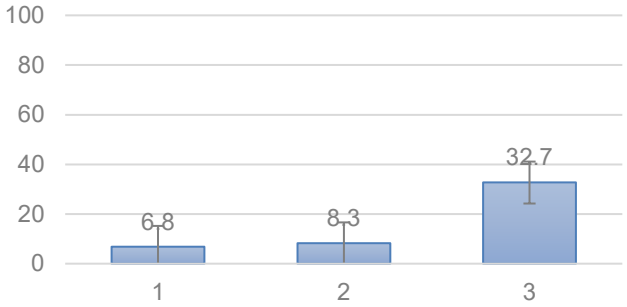
least disadvantaged block groups – most disadvantaged block groups

1 2 3 4 5 6 7 8 9 10

Household Income



Amputation rates at different institutions between 2018-2023



Data collection (ongoing)

Demographics: age, sex, insurance status, intitial encounter

Comorbidities:

Diabetes
Diabetes Meds
HBA1C
Hyperten
Coronary
Congesti
Atrial Fib
Stroke
Chronic Kidney disease
Creatinine levels
Dilaysis
Hyperlipidemia
Hyperlipidemia Meds
COPD/Emphysema
BMI
Depression/anxiety
Smoking
Antiplatelets
Anticoagulants
Cilostazol

Dis

WIfI Staging
Glass Anatomic Staging
Revascularization attempts

Socioeconomic Fact

Educational Level
PCP Available
Podiatry/Wound clinic Available
Specialty referral to vascular surgery
Care Giver Available
Median income in residential ZIP codes (See references)
Neighborhood poverty (<=20%, or>20%)
Area deprivation index (ADI)
Number of Post-Diagnosis ABIs
Number of Post-diagnosis Vascular Surgery Visits

This granular data will allow comparison of different patient populations and identifying key risk factors associated with increased amputation rates

Project 2: **Exploring Perceptions, Knowledge, and Barriers to Timely Management and Prevention of Peripheral Artery Disease/CLTI**

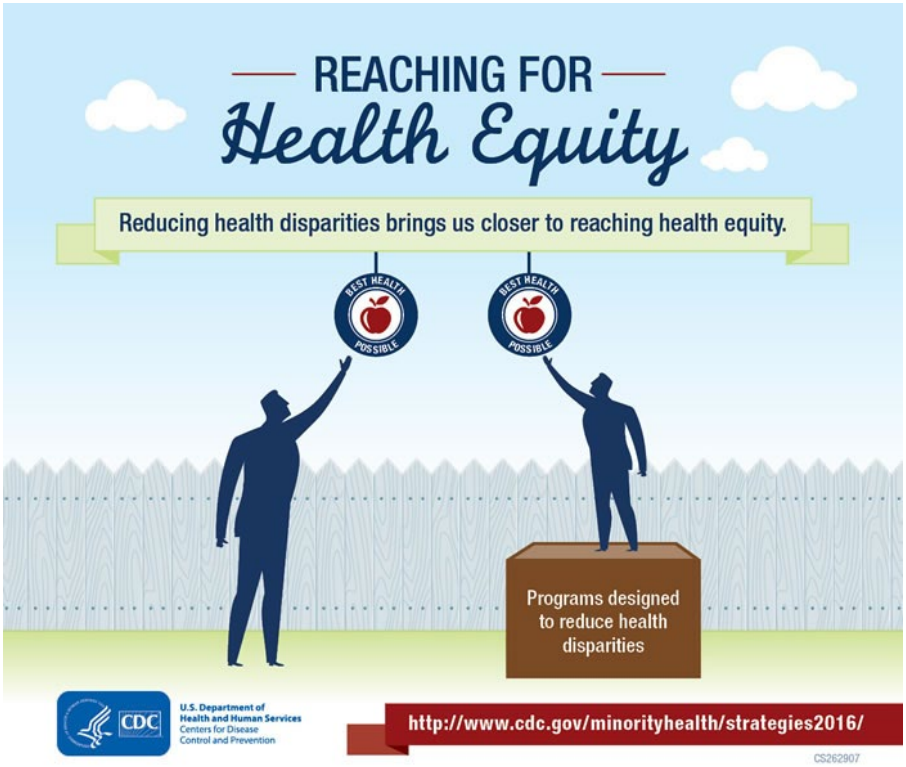
- A combination of semi-structured interviews and surveys will be conducted with patients presenting with critical limb ischemia (with or without a history of lower extremity amputation) to gain insights into their health literacy and the perceived barriers that limit timely access to care.
    - It will directly engage patients in the decision-making process and provide a safe and trustful environment within the health care system to underserved populations.
- Primary care physicians at all three institutions will also participate in the study to assess their knowledge of critical limb ischemia, referral strategies, and their perspectives on the gaps and challenges in providing care for these patients.
- Currently awaiting IRB review and approval
- Targeted sample: N=150

Implications

By identify the barriers contributing to disparities in PAD management and increased amputation rates in certain populations, we can then partner with community organizations to design interventions that:

1. Improve PAD awareness among patients and providers
2. Increase timely access to high-quality vascular care
3. Ensure early diagnosis and evidence-based management
4. Improve risk factor modification
5. Reinforce patients' expectations and their adherence to management strategies

Findings can be replicated on a larger regional and national scale


REACHING FOR
Health Equity
Reducing health disparities brings us closer to reaching health equity.
BEST HEALTH POSSIBLE
BEST HEALTH POSSIBLE
Programs designed to reduce health disparities
CDC
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
http://www.cdc.gov/minorityhealth/strategies2016/
CS262907