Developing A Manual of Operations for Regional Stroke Care Improvement
Disclosures

- No direct personal disclosures
- IMPROVE Stroke Project funding
  - The Medtronic Foundation
  - Daiichi-Sankyo
  - Chiesi
Objectives

- Review why we need to regionalize stroke care
- Introduce IMPROVE Stroke Care Project
- Discuss measures undertaken to development of the regional Manual of Operations for IMPROVE
Stroke Stats - A local flavor to the story

- Stroke is the fifth leading cause of death in the United States
- The country’s highest death rates from stroke are in the southeast
- **People born and raised in the “stroke belt” are 34% more likely to have a stroke than in other parts of the USA**
- Kills ~140,000 Americans each year; that’s 1 of every 20 death
- Someone in the United States has a stroke every 40 seconds
- Every four minutes, someone dies of stroke
- Every year, about **795,000 people** in the United States have a stroke.
  - About 610,000 of these are first or new strokes; 185,000 are recurrent strokes.
- **Stroke costs the nation $34 billion annually, including the cost of health care services, medications, and lost productivity.**

https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm
The country’s highest death rates from stroke are in the southeastern United States.
Treatment Stats

- The benefits of thrombolysis were demonstrated >20 years ago.
- Acute ischemic stroke patients treated with tPA remains at 3-10% nationwide.
- At highly developed programs, this proportion approaches >20%.
- Mechanical thrombectomy has revolutionized treatment of large vessel occlusive stroke, showing a 20% or more absolute improvement in good neurologic recovery.
- Time window now opened up to 24 hours for some patients.
A Treatment Is Revolutionizing Stroke Care But Not Everyone Receives It

The ‘thrombectomy’ is transforming stroke care, pre-empting brain damage in many patients, but the medical establishment is far from making it standard practice

Feb. 6, 2018 11:07 a.m. ET

By Thomas M. Burton
## Treatment Rate

Stroke experts estimate thrombectomies should go to 20% or more of patients with clot-caused strokes. Thrombectomy rates among the 50 biggest U.S. metro areas:

<table>
<thead>
<tr>
<th>Metro regions with the highest rate</th>
<th>Metro regions with the lowest rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denver-Aurora-Lakewood, Colo.</td>
<td>Boston-Cambridge-Newton, Mass.-N.H.</td>
</tr>
<tr>
<td>Buffalo-Cheektowaga-Niagara Falls, N.Y.</td>
<td>Cincinnati, Ohio-Ky-Ind.</td>
</tr>
<tr>
<td>San Diego-Carlsbad, Calif.</td>
<td>Oklahoma City, Okla.</td>
</tr>
<tr>
<td>Minneapolis-St. Paul-Bloomington, Minn.-Wis.</td>
<td>Charlotte-Concord-Gastonia, N.C.-S.C.</td>
</tr>
<tr>
<td>Portland-Vancouver-Hillsboro, Ore.-Wash.</td>
<td>Raleigh, N.C.</td>
</tr>
<tr>
<td>Salt Lake City, Utah</td>
<td>Riverside-San Bernardino-Ontario, Calif.</td>
</tr>
<tr>
<td>Miami-Fort Lauderdale-West Palm Beach, Fla.</td>
<td>San Antonio-New Braunfels, Texas</td>
</tr>
</tbody>
</table>

*Medicare cases only, 12 months ended June 30, 2017
Source: Definitive HealthCare; Paul Overberg
“Humanity’s greatest advances are not in its discoveries - but in how those discoveries are applied …”

Bill Gates, June 7, 2007
Harvard Commencement Address
Regional systems of stroke care should be developed. These should consist of the following: a) Health Care facilities that provide initial emergency care, including administration of IV alteplase, and b) Centers capable of performing endovascular stroke treatment with comprehensive periprocedural care to which rapid transport can be arranged when appropriate” - Level 1A recommendation

Good Idea - But how do we do this?
IMPlementation of best PRactices fOr acute stroke care - developing and optimizing regional systems of Stroke Care

IMPROVE Stroke Care
What is the IMPROVE Stroke Project

- **Systems of care quality improvement program** utilizing an implementation science approach to optimize health care delivery
- Focus is on improving the system of care delivery rather than the therapeutic intervention (BASF model)
- A collaborative effort among leading stroke care providers in the South Eastern United States to jointly develop and implement best practices of acute stroke care
- An integrated and novel data collection system
- Feed-back in “real-time” to optimize systems
- Disseminate Knowledge: The Consortium -> Other Regions -> The World
IMPROVE Stroke Care Consortium
IMPROVE Stroke Care 3-Way Approach

Community Knowledge ➔ Access to Health Care ➔ Good Outcomes ➔ Best Clinical Practices
**Manual of Operations**

**OBJECTIVE:**

- Disseminate evidence-based best-practice guidelines for implementation of advanced regional stroke care with built-in measurement and feedback measures

- Living document and will be updated as new evidence emerges
Manual of Operations

- Modeled on prior work in other time-sensitive vascular emergencies
- STEMI
- Cardiac Arrest

Optimal Cardiac Arrest System Specification
By Point Of Care Operations Manual
Deciphering “Best Clinical Practices”
High-Level Practice Guidelines Already Exist

AHA/ASA Guideline

2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke

A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

Reviewed for evidence-based integrity and endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons

Endorsed by the Society for Academic Emergency Medicine

William J. Powers, MD, FAHA, Chair; Alejandro A. Rabinstein, MD, FAHA, Vice Chair;
Teri Ackerson, BSN, RN; Opeolu M. Adeoye, MD, MS, FAHA;
Nicholas C. Bambakidis, MD, FAHA; Kyra Becker, MD, FAHA; José Biller, MD, FAHA;
Michael Brown, MD, MSc; Bart M. Demaerschalk, MD, MSc, FAHA; Brian Hoh, MD, FAHA;
Edward C. Jauch, MD, MS, FAHA; Chelsea S. Kidwell, MD, FAHA;
Thabele M. Leslie-Mazwi, MD; Bruce Ovbiagele, MD, MSc, MAS, MBA, FAHA;
Phillip A. Scott, MD, MBA, FAHA; Kevin N. Sheth, MD, FAHA;
Andrew M. Southerland, MD, MSc; Deborah V. Summers, MSN, RN, FAHA;
David L. Tirschwell, MD, MSc, FAHA; on behalf of the American Heart Association Stroke Council
2018 Guidelines and IMPROVE Alignment
### 2018 Guidelines and IMPROVE Alignment

#### 1.1 Prehospital Systems

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public health leaders, medical professionals, and others should design and implement public education programs focused on stroke systems and the need to seek emergency care by calling 9-1-1 rapidly. These systems should be sustained over time and reach racial/ethnically, age, and gender diverse populations.</td>
<td>I</td>
<td>B-R</td>
</tr>
<tr>
<td>Activation of 9-1-1 by patients or others is strongly recommended. 9-1-1 dispatchers should make stroke a priority dispatch; transport times should be minimized.</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>To increase stroke treatment and quality of care, educational stroke programs for physicians, hospital personnel, and EMS are recommended.</td>
<td>I</td>
<td>B-NR</td>
</tr>
</tbody>
</table>
### 2018 Guidelines and IMPROVE Alignment

#### 1.3 EMS Systems

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>EMS leaders, in coordination with local, regional, and state agencies, and with medical authorities and local experts should develop triage paradigms and protocols to ensure that patients with a known or suspected stroke are rapidly identified and assessed by use of a validated and standardized instrument for stroke screening, such as the FAST scale, Los Angeles Prehospital Stroke Screen, or Cincinnati Prehospital Stroke Scale</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>Regional systems of care should be developed, consisting of:</td>
<td></td>
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</tr>
<tr>
<td>a) Healthcare facilities that provide initial emergency care including IV alteplase.</td>
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<td>A</td>
</tr>
<tr>
<td>b) Centers capable of performing endovascular treatment and periprocedural care to which rapid transport can be arranged</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>Patients with a positive stroke screen and/or strong suspicion of stroke should be transported rapidly to the closest facility that can capably administer IV alteplase.</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>When several IV alteplase-capable hospitals exist within a defined region, the benefit of bypassing the closest to bring the patient to one that offers a higher level of care including thrombectomy, is uncertain. Further research is needed.</td>
<td>IIb</td>
<td>B-NR</td>
</tr>
</tbody>
</table>
### 2018 Guidelines and IMPROVE Alignment

#### 1.5 Hospital Stroke Teams

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>An organized protocol for the emergency evaluation of patients with suspected stroke is recommended.</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>It is recommended that DTN time goals be established, with a primary goal of achieving DTN times within 60 minutes in ≥ 50% of AIS patients treated with IV alteplase.</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>It may be reasonable to establish a secondary DTN time goal within 45 minutes in ≥ 50% of AIS patients treated with IV alteplase.</td>
<td>IIb</td>
<td>C-EO</td>
</tr>
<tr>
<td>Designation of acute stroke teams that include physicians, nurses, and laboratory/radiology personnel is recommended. Patients with stroke should have a careful assessment, including neurologic examination.</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>Multicomponent quality improvement initiatives, which include ED education and multidisciplinary teams with access to neurological expertise, are recommended to safely increase IV alteplase treatment.</td>
<td>I</td>
<td>A</td>
</tr>
</tbody>
</table>
# 2018 Guidelines and IMPROVE Alignment

## 1.6 Telemedicine

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>For sites without in-house imaging interpretation expertise, FDA approved teleradiology are recommended for timely imaging review.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Within a telesstroke network, FDA approved teleradiology systems are useful for rapid imaging interpretation for IV alteplase decisions.</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Because of the limited distribution and availability of neurological, neurosurgical, and radiological expertise, the use of telemedicine resources and systems can be beneficial and should be supported by healthcare institutions, governments, payers, and vendors of a method to ensure adequate 24/7 coverage and care for AIS.</td>
<td>IIa</td>
<td>C-EO</td>
</tr>
<tr>
<td>Telesstroke/teleradiology evaluations of AIS patients can be effective for correct IV alteplase eligibility decision making.</td>
<td>IIa</td>
<td>B-R</td>
</tr>
<tr>
<td>Administration of IV alteplase guided by telesstroke consultations may be as safe and as beneficial as that of stroke centers.</td>
<td>IIb</td>
<td>B-NR</td>
</tr>
<tr>
<td>Providing alteplase decision-making support via telephone consultation to community physicians is feasible and safe and may be considered when a hospital has neither access to an in-person stroke team, nor a telesstroke system.</td>
<td>IIb</td>
<td>C-LD</td>
</tr>
<tr>
<td>Telesstroke networks may be reasonable for triaging patients with AIS who may be eligible for inter-facility transfer in order to be considered for mechanical thrombectomy.</td>
<td>IIb</td>
<td>B-NR</td>
</tr>
</tbody>
</table>
### 2018 Guidelines and IMPROVE Alignment

#### 1.7 Organization and Integration of System Components

<table>
<thead>
<tr>
<th>Recommendations</th>
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</tr>
</thead>
<tbody>
<tr>
<td>It may be useful for primary stroke centers and other healthcare facilities that provide initial emergency care, including administration of IV alteplase, to develop the capability of performing emergency noninvasive intracranial vascular imaging to most appropriately select patients for transfer for endovascular intervention and to reduce the time to EVT.</td>
<td>IIb</td>
<td>C-LD</td>
</tr>
<tr>
<td>Mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and comprehensive periprocedural care. Systems should emphasize expeditious assessment and treatment. Outcomes for all patients should be tracked. Facilities are encouraged to define criteria that can be used to credential individuals who can perform safe and timely intra-arterial revascularization procedures.</td>
<td>I</td>
<td>C-EO</td>
</tr>
<tr>
<td>All hospitals caring for stroke patients within a stroke system of care should develop, adopt, and adhere to care protocols that reflect current care guidelines as established by national and international professional organizations, state and federal agencies, and laws.</td>
<td>I</td>
<td>C-EO</td>
</tr>
</tbody>
</table>
### 2018 Guidelines and IMPROVE Alignment

**1.8-9 Data Repositories and Systems QI**

#### Recommendations

<table>
<thead>
<tr>
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<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in a stroke data repository is recommended to promote consistent adherence to current treatment guidelines, to allow continuous quality improvement, and to improve patient outcomes.</td>
<td>I</td>
<td>B-NR</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Healthcare institutions should organize a multidisciplinary quality improvement committee to review and monitor stroke care quality benchmarks, indicators, evidence-based practices, and outcomes. The formation of a clinical process improvement team and the establishment of a stroke care data bank are helpful for such quality of care assurances. The data repository can be used to identify gaps/disparities in care; once identified, specific interventions can be initiated to address these gaps/disparities.</td>
<td>I</td>
<td>B-NR</td>
</tr>
<tr>
<td>Continuous quality improvement processes, implemented by each major element of a stroke system of care and the system as a whole, can be useful in improving patient care or outcome.</td>
<td>IIa</td>
<td>B-NR</td>
</tr>
<tr>
<td>Stroke outcome measures should include adjustments for baseline severity.</td>
<td>I</td>
<td>B-NR</td>
</tr>
</tbody>
</table>
Use of Strategies to Improve Door-to-Needle Times With Tissue-Type Plasminogen Activator in Acute Ischemic Stroke in Clinical Practice

Findings from Target: Stroke

Ying Xian, MD, PhD; Haolin Xu, MS; Barbara Lytle, MS; Jason Blevins, MPH; Eric D. Peterson, MD, MPH; Adrian F. Hernandez, MD, MHS; Eric E. Smith, MD, MPH; Jeffrey L. Saver, MD; Steven R. Messé, MD; Mary Paulsen, RN, MSN, CPHQ; Robert E. Suter, DO; Mathew J. Reeves, BVSc, PhD; Edward C. Jauch, MD, MS; Lee H. Schwamm, MD; Gregg C. Fonarow, MD
Big Data Best Practices Already Exist

- AHA/ASA Target:Stroke program (2010/2014) aimed to improve DTN w Best-Practice strategies
  - Utilize already available resources
  - Coordinate and deliver streamlined care, efficiently

**Target: Stroke 10 Key Best Practice Strategies**

1. Hospital pre-notification by Emergency Medical Services
2. Rapid triage protocol and stroke team notification
3. Single call/paging activation system for entire stroke team
4. Use of a stroke toolkit containing clinical decision support, stroke-specific order sets, guidelines, hospital-specific algorithms, critical pathways, NIH Stroke Scale and other stroke tools
5. Rapid acquisition and interpretation of brain imaging
6. Rapid Laboratory Testing (including point-of-care testing) if indicated
7. Pre-mixing tPA medication ahead of time for high likelihood candidates
8. Rapid access to intravenous tPA in the ED/brain imaging area
9. Team-based approach
10. Rapid data feedback to stroke team on each patient's DTN time and other performance data

Big Data Best Practices Already Exist

- Recent review of GWTG participating hospital data showed significant improvement in DTN w organizational changes to promote best practices

Are Best Practices Being Used?

- Data also showed only a fraction of participating hospitals are utilizing each strategy
Expert Consensus Best-Practices: Do these exist?

- “Lower” Level of Evidence
  - Often new or emerging practices and science starts here
  - Observational, registry or consensus level data
  - Just has not been studied on a large scale...yet
  - Harder to find and summarize
- Should NOT be ignored

But...
Objectives:

- To Understand the processes utilized by high-performing stroke systems to improve patient outcomes
- Seek expert consensus opinion on current controversial topics in acute stroke care
- To evaluate the current state of advanced systems worldwide in order to inform the development of the IMPROVE Stroke Care Manual of Operations

International Progressive Stroke System Survey
Progressive Stroke System Survey

Methods:

- Online-based Survey tool (RedCap\textsuperscript{1})
- 22 progressive and advanced stroke centers in the US, Canada and Europe invited to participate

\textsuperscript{1} REDCap Software - Version 6.10.17 - © 2017 Vanderbilt University
Progressive Stroke System Survey

Methods:
- 81 Questions encompassing many aspects acute care systems
  - Center demographics
  - Staffing
  - Stroke code processes/acute in-hospital management
  - Thrombolytic usage and delivery
  - EVT processes
  - EMS systems and destination selection
  - Stroke IT
  - Telestroke utilization
  - Patient transfers
  - Post-acute management
  - System feedback
  - Transitions of care and post-discharge follow up
Progressive Stroke System Survey

IMPROVE Stroke Progressive Regional Stroke Survey

OBJECTIVE
To understand the elements of progressive regional stroke systems that program leaders utilize to impact stroke patients’ outcomes. These best practices will be aggregated and used as a standardized approach to treating stroke in the new era of preferred reperfusion in eligible patients.

Please answer the following questions to the best of your ability.

CENTER SPECIFIC DEMOGRAPHICS

Name of respondent completing this survey:
* must provide value

Please identify your Region name, City, State, and Country:
* must provide value

Hospital or academic center that you represent (please include address):
* must provide value
Results:

- Of the 22 invited centers, 9 (41%; 2 European, 1 Canadian, 6 US) completed the questionnaire
  - 7 were certified CSCs, all were EVT capable
- Yearly average of 887 ischemic strokes (range 350-1444), and 202 (100-501) primary hemorrhagic strokes.
- Average annual IV tPA volume was 168 (60-440) and EVT volume was 68 (12-130).
Progressive Stroke System Survey

Results:

- At all 9 systems, EMS agencies were trained in identifying potential strokes and reported utilizing an established prehospital stroke scale.

- 6 systems (66.7%) reported a destination protocol based on stroke severity involving bypass to an EVT-capable center.

- All 9 centers have processes for expedited transfer of stroke patients in need of neurointervention from their non-EVT-capable referral hospital network.

- For patients with confirmed LVO being transferred to the hub hospital, 5 (55.6%) centers reported these patients bypass the ED to go directly to the neurointervention suite.
Other interesting findings:

- At 33% of centers, neurointerventionalist responds to all stroke codes to assess EVT eligibility
- 89% report keeping a ‘backup’ interventionalist on call in event of 2 simultaneous EVT cases arriving
  - 66% have a second EVT-capable center in their system to refer to if their suite is unavailable
- 2 systems responding utilize ‘mobile stroke units’
- None of the responding systems’ EMS services use commercial technologies (mobile stroke apps) to record data/track timing and processes
Other interesting findings:

- The majority give feedback on treatment/reperfusion times to EMS providers in <7 days
- 44% report patients with ‘positive’ EMS stroke screening go directly to imaging, bypassing ED*
- Only 57% of stroke patients arrive via EMS
- The majority allow direct stroke code activation by nursing staff
Progressive Stroke System Survey

- Other interesting findings:
  - Average DTN of 44 minutes
    - (GWTG median DTN 56 min; 30.4% within 45 min)
  - Average door-to-groin puncture 111 min
Other interesting findings:

- Most centers will transfer patients to the hub for potential thrombectomy based on clinical suspicion of LVO alone (i.e. proof with vascular imaging not needed)
- Half will transfer a patient with confirmed LVO directly into the interventional suite from EMS/transport
- 78% report using either GA or conscious sedation for EVT procedures at the discretion of treating interventionalist
In conclusion, this international survey of progressive stroke systems revealed useful practice patterns and processes that can be adopted by other stroke systems to improve patient care.
OBJECTIVE:

- Disseminate evidence-based best-practice guidelines for implementation of advanced regional stroke care with built-in measurement and feedback measures
Manual of Operations

- Present guidelines and recommendations in a tiered easy to understand format
- Cover the evidence, and level of that evidence, for all steps in the Stroke Chain of Survival
- Generalizable to other regions, allowing the MoO to act as a playbook for advanced regional stroke care everywhere
- ‘Living document’, which will be updated as new evidence emerges
Manual of Operations

- Designed to provide a standardized and structured guideline for care of the stroke patient throughout the ‘Stroke Chain of Survival’, from symptom detection to post-care disposition and follow-up management.

**Table 3. Stroke Chain of Survival**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection</td>
<td>Patient or bystander recognition of stroke signs and symptoms</td>
</tr>
<tr>
<td>Dispatch</td>
<td>Immediate activation of 9-1-1 and priority EMS dispatch</td>
</tr>
<tr>
<td>Delivery</td>
<td>Prompt triage and prehospital notification ‘allowed by transport to most appropriate stroke hospital</td>
</tr>
<tr>
<td>Door</td>
<td>Immediate ED triage to high-acuity area or CT scanner if patient is stable</td>
</tr>
<tr>
<td>Data</td>
<td>Prompt ED evaluation, stroke team activation, laboratory studies, and brain imaging if not already done</td>
</tr>
<tr>
<td>Decision</td>
<td>Diagnosis and determination of most appropriate therapy: discussion with patient and family</td>
</tr>
<tr>
<td>Drug/Device</td>
<td>Administration of appropriate drugs or other interventions</td>
</tr>
<tr>
<td>Disposition</td>
<td>Timely disposition to stroke unit, intensive care unit or hospital transfer</td>
</tr>
</tbody>
</table>
Practice recommendations are divided into three major evidence categories ranging from established guidelines as the highest level recommendations, to expert/consensus-based best practices.

**Figure 5. Categorical Levels of Recommendations in the Manual of Operations**

- **Category A Recommendations:**
  - The Basics
  - AHA/ASA established guidelines
    - (Level of Evidence A or B, Class I, Ila or IIb)

- **Category B Recommendations:**
  - Prospective cohort data from Get With The Guidelines and Target: Stroke (data-driven best practices)
  - These items were associated with faster DTN times in participating GW TG centers

- **Category C Recommendations:**
  - Advanced System Procedures
  - Best practices from effective, progressive stroke centers
    - (IMPROVE Stroke Progressive Regional System Survey and Expert Consensus)
Within the Manual, Recommendations presented as:

- Basic Recommendations
- Advanced Recommendations
- Other, specific to Manual section

Outcome/Process Measures to be Monitored listed in each section
The manual is intended to be a “living document,” with recommendations being modified as new data becomes available during the process of program implementation.

**Figure 6. Mechanism for Modification of Stroke Care Recommendations**

- **Category A Recommendations:**
  - The Basics
  - AHA/ASA established guidelines
  - (Level of Evidence A or B, Class I, IIA or IIb)

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- **Category C Recommendations:**
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Thank you

Carmelo Graffagnino, MD FNCS FAHA, Co-Primary Investigator
Brad J. Kolls, MD, PhD, MMCi, Co-Primary Investigator
Matthew Ehrlich, MD, MPH, Co-Investigator
Shreyansh Shah, MBBS, Co-Investigator
Erik Hauk, MD, Neurovascular Surgeon, DUMC
Fernando Gonzalez, MD, Neurovascular Surgeon, DUMC
Ying Xian, MD, PhD, Assistant Professor, Neurology
Lisa Monk, RN, MSN- IMPROVE Stroke Operational Director
Mayme Lou Roettig, RN, MSN- Group Director, Systems and Implementation
James G. Jollis, MD- Faculty, Systems and Implementation
Christopher Granger, MD Faculty Director, Systems and Implementation