



GEORGIA STATE SENATE

SENATE RESEARCH OFFICE

204 Coverdell Legislative Office Building | 404.656.0015
18 Capitol Square SW
Atlanta, GA 30334

ELIZABETH HOLCOMB
DIRECTOR

ALEX AZARIAN
DEPUTY DIRECTOR

FINAL REPORT OF THE STROKE TRAUMA SENATE STUDY COMMITTEE (SR 412)

Committee Members

Senator John Kennedy, Chair
District 18

Senator Dean Burke
District 11

Senator Renee Unterman
District 45

Senator Ben Watson
District 1

Christopher Hendry, MD
Navicent Chief Medical Officer

David Hess, MD
Dean of the Medical College of Georgia and Executive Vice President for Medical Affairs and
Integration at Augusta University

Joe Sam Robinson, Jr. MD
Neurosurgeon, Navicent Medical Center

Kiva Schindler, RN CRCC
Research Nurse Coordinator at Emory University, Department of Neurology

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STUDY COMMITTEE FOCUS, CREATION, & DUTIES

The Stroke Trauma Senate Study Committee (Committee) was created with the adoption of Senate Resolution 412 during the 2017 Legislative Session. The following individuals were appointed by the President of Senate to serve as members of this Committee:

- Senator John Kennedy of the 18th – Chair
- Senator Dean Burke of the 11th
- Senator Renee Unterman of the 45th
- Senator Ben Watson of the 1st
- Christopher Hendry, MD, Navicent Chief Medical Officer
- David Hess, MD, Dean of the Medical College of Georgia at Augusta University
- Joe Sam Robinson, MD, Neurosurgeon, Navicent Medical Center
- Kiva Schindler, RN, CRCC, Research Nurse Coordinator at Emory University, Department of Neurology

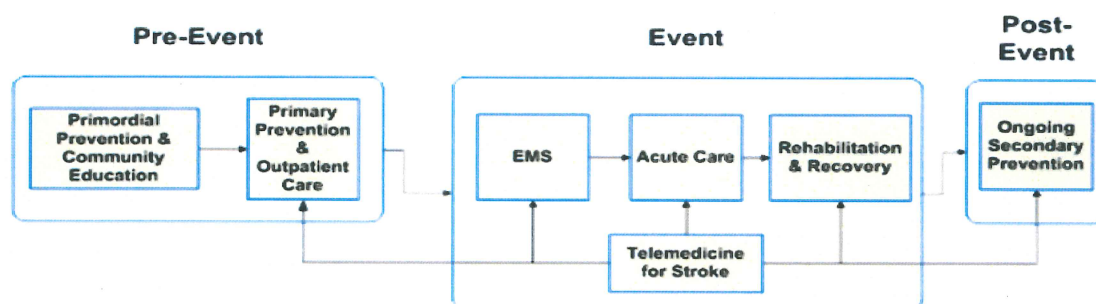
The Committee was tasked with undertaking a study of stroke trauma in Georgia.

The following legislative staff members were assigned to this Committee: Ines Owens of the Senate Press Office; Donavan Eason, and Elizabeth Holcomb of the Senate Research Office; and Macy McFall, Legislative Assistant to Senator Kennedy.

BACKGROUND

In 2000, members of the Brain Attack Coalition¹ published recommendations for the establishment of primary stroke centers, and in 2005 they published recommendations for the establishment of comprehensive stroke centers.² During that same time, several states developed their own certification programs with the goal of improving stroke care and drawing stroke patients to capable centers. Legislation also provided for emergency medical services (EMS) to route ambulances directly to certified stroke centers so that standard acute stroke therapies could be delivered more reliably and rapidly. These efforts have increased the number of stroke centers across the country, and, consequently, enhanced access to acute stroke care.³

The Components of Stroke System of Care



Georgia's Stroke Center Network and Classifications

Recognizing the benefits of stroke center certification, the Georgia General Assembly developed its own program in 2008 to identify certified stroke centers throughout the state, setting specific patient care and support service criteria that prospective stroke centers must meet in order to ensure stroke patients received safe and effective care.⁴ To attract participation, the state also pledged financial support (subject to appropriation) to acute care hospitals that obtained certification.⁵

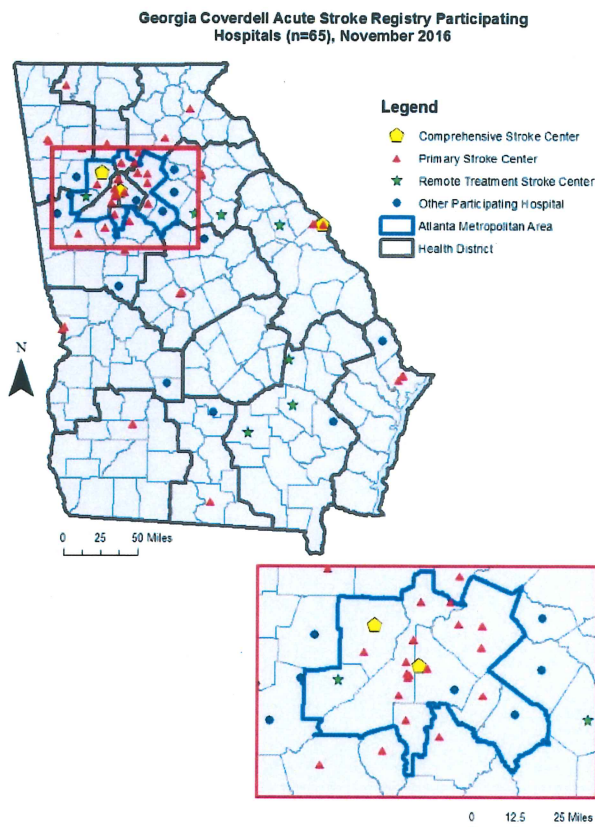
¹ "The Brain Attack Coalition is a group of professional, voluntary, and governmental organizations dedicated to setting direction, advancing knowledge, and communicating the best practices to prevent and treat stroke." The group is convened by the National Institutes of Health, National Institute of Neurological Disorders and Stroke, and Co-Chaired by Michael D. Walker, M.D., and Mark Alberts, M.D. *About Us*, BRAIN ATTACK COALITION, <https://www.brainattackcoalition.org/about.html>.

² Linda J. Schieb et al., *Mapping Primary and Comprehensive Stroke Centers by Certification Organization*, CIRCULATION: CARDIOVASCULAR QUALITY AND OUTCOMES, (Oct. 29, 2015) http://circoutcomes.ahajournals.org/content/8/6_suppl_3/S193.

³ Ken Uchino et al., *Stroke Legislation Impacts Distribution of Certified Stroke Centers in the United States*, STROKE, (Jun. 18, 2015) <http://stroke.ahajournals.org/content/strokeaha/early/2015/06/18/STROKEAHA.114.008007.full.pdf>.

⁴ Coverdell-Murphy Act, S.B. 549, § 2 (2008) (codified at O.C.G.A. §§ 31-11-110 et seq.), <http://www.legis.ga.gov/Legislation/en-US/display/20072008/SB/549>.

⁵ Coverdell-Murphy Act, S.B. 549, § 2 (2008) (codified at O.C.G.A. § 31-11-114), <http://www.legis.ga.gov/Legislation/en-US/display/20072008/SB/549>.



Hospitals seeking stroke center certification must apply to the Department of Public Health (DPH). Three stroke center classifications exist:

- 1) Comprehensive (CSC)⁶
- 2) Primary (PSC)
- 3) Remote (RSC)

Prior to obtaining any certification as a CSC or PSC, hospitals must provide adequate documentation of the hospital's valid certification as a CSC or PSC by a national healthcare accreditation body recognized by DPH.⁷

RSCs must be certified as an acute stroke-ready hospital by a national health accreditation body recognized by DPH or through an application process determined by the DPH.⁸

CSCs and PSCs are also encouraged to coordinate appropriate access to care for acute stroke patients, through agreement, with RSCs.⁹ The coordinating stroke care agreement must be in writing and

include at a minimum:

- 1) transfer agreements for the transport and acceptance of all stroke patients seen by the RSC for stroke treatment therapies which the RSC is not capable of providing; and
- 2) Communication criteria and protocols with the RSC.¹⁰

Data Gathering by the Georgia Coverdell Acute Stroke Registry

Hospitals certified as a stroke center by DPH are required to submit data to the Georgia Coverdell Acute Stroke Registry (GCASR).¹¹ GCASR currently has 65 participating acute care hospitals, of which 44 are

⁶ The classification for comprehensive stroke centers was added in 2016 with the passage of H.B. 853, <http://www.legis.ga.gov/Legislation/en-US/display/20152016/hb/853>. Yet, the classification for comprehensive stroke centers has existed for some time. In 2007, Sen. Don Thomas and Rep. Don Parsons co-chaired the Joint Study Committee on State Stroke System of Care. The American Heart Association presented model legislation designating three levels of stroke care: "(1) primary stroke centers, which would require a hospital to be certified by the Joint Commission on Accreditation of Health Care Organizations as a primary stroke center or at least meet certain criteria such as constantly maintaining an acute stroke team; (2) comprehensive stroke centers, which would be awarded to hospitals that exceed the requirements of a primary stroke center . . . ; and (3) support stroke centers, a designation that would be bestowed upon rural facilities that offer timely access to a limited number of stroke care services and that coordinate with comprehensive and primary stroke centers." The Study Committee Report is found on the Senate's website: <http://www.senate.ga.gov/sro/Documents/StudyCommRpts/07JtStrokeRpt.pdf>.

⁷ O.C.G.A. § 31-11-113(a).

⁸ *Id.* § 113(b).

⁹ *Id.* § 113(d).

¹⁰ *Id.*

¹¹ *Id.* § 116(a). GCASR is named in honor of the late Senator Paul Coverdell of Georgia who died of a massive stroke in 2000. It is funded by the Centers for Disease Control and Prevention (CDC) as part of its national counterpart—the Paul Coverdell National Acute Stroke Registry, https://www.cdc.gov/dhbsp/programs/stroke_registry.htm. GCASR is a partnership between DPH Epidemiology, DPH Office of EMS, Emory University, the American Heart Association, the American Stroke Association, the

comprehensive or primary stroke centers, and seven are remote stroke treatment centers. Georgia EMS provides data on the number of subjects evaluated and transported to acute care facilities with a presumptive diagnosis of acute stroke.¹²

Data collected by GCASR provides DPH with assurances that patients are receiving the appropriate level of care and treatment at each level of stroke center in the state—both in the pre-hospital and in-hospital delivery setting.¹³ The required data includes, but is not limited to, the following:

- (a) Date of admission and discharge
- (b) Patient disposition at discharge
- (c) Patient identifier, currently known as “Georgia LONGID,” that consists of elements defined by DPH
- (d) Patient age, gender, and race
- (e) Location where the stroke occurred
- (f) Patient arrival mode
- (g) Patient’s past medical and medication history
- (h) Clinical diagnosis of type of stroke or transient ischemic attack
- (i) The National Institutes of Health stroke scale score
- (j) Serum low density lipoprotein level
- (k) Whether stroke symptoms were resolved at time of presentation
- (l) Earliest time patient placed on comfort measure only
- (m) Whether patient was admitted for elective carotid intervention
- (n) Whether patient was participating in a stroke related clinical trial
- (o) Whether in-hospital treatment with intravenous or intra-arterial thrombotic or mechanical clot removal, antithrombotic, or venous thromboembolism prophylaxis was provided, or reason for not providing each treatment
- (p) Date and time of last known well visit, hospital arrival, imaging, and treatment administration
- (q) Whether dysphagia screen had been completed
- (r) Whether treatment at discharge with antithrombotic, anticoagulant, or statin (lipid-lowering medication) was provided, or reason for not providing each treatment
- (s) Whether smoking cessation advice or counseling was provided
- (t) Whether stroke education was provided
- (u) Whether rehabilitation services was provided
- (v) Modified Rankin Scale score at discharge¹⁴

Georgia Medical Care Foundation, the Georgia Hospital Association, CDC, and the participating hospitals, rehabilitation centers, and EMS agencies in Georgia.

¹² Information regarding scope of practice for EMS personnel and a stroke thrombolytic checklist can be found the DPH website. *EMS Rules and Protocols*, GEORGIA DEPARTMENT OF PUBLIC HEALTH, <https://dph.georgia.gov/ems-rules-and-protocols>.

¹³ GA. COMP. R. & REGS. 511-9-2-.04(d).

¹⁴ *Id.*

MEETING TESTIMONY

This section provides a brief summary of topics covered at each meeting, including the names and affiliations of individuals who were asked to provide testimony to the Committee. Although testimony has been condensed to ensure the report could be timely submitted, copies of all presentations and materials submitted to the Committee are kept on file in the Senate Research Office.

Meeting 1 – September 6, 2017

The first meeting was held at the Navicent Medical Center in Macon, Georgia on September 6, 2017. Senator Kennedy provided opening remarks and introductions. Dr. Christopher Hendry, Navicent Chief Medical Officer and member of the Committee, provided a brief welcome and shared that Navicent is on a path to become a comprehensive stroke center with the help of Dr. Arthur Grigorian. Dr. Jean Sumner, Dean of Mercer School of Medicine, also welcomed the Committee and noted that patient care was once very much driven by the where the patient ended up in terms of care location and facility.

Before hearing testimony, the Committee received an overview of Certified Stroke Centers in Georgia from Donovan Eason of the Senate Research Office.¹⁵

Testimony was provided by the following individuals and agencies:

- Georgia Department of Public Health
 - Review of 2016 Stroke Data
 - **R. Keith Wages**, Director, Georgia Office of EMS and Trauma
 - **Ernie Doss**, Deputy Director, Georgia Office of EMS and Trauma
- **Dr. Arthur Grigorian**
- **Dr. Dennis Ashley**, Trauma Director at MCG; Chair of the Georgia Trauma Commission

The Committee requested that DPH return to provide testimony at Meeting 2 on the recent implementation of a statewide system of Emergency Cardiac Care Centers, created by the passage of Senate Bill 102 in 2017.

Meeting 2 – November 15, 2017

Meeting 2 was held on November 15, 2017 at the Capitol in Atlanta, Georgia. Continuing the discussion from Meeting 1, the Committee heard testimony from the following individuals:

- “Stroke Care in Georgia: Grady’s Marcus Stroke and Neuroscience Center, the Marcus Stroke Network and the Coverdell Murphy Act and Acute Stroke Registry At Work”
 - **Michael Frankel, MD- Grady Memorial Hospital**, Professor and Director of Vascular Neurology, Dept. of Neurology; Director, Georgia StrokeNet
 - **Karen B. Seagraves, MS, MPH, RN, ANP-BC, ACNS-BC, FAHA**, Executive Director, Marcus Stroke and Neuroscience Center, Grady Health System
- Cardiac Care Presentation (Implementation of SB 102)
 - **David Newton, DrPH(c), MPH, NRP**, Cardiac Care Registrar, Georgia Office of EMS and Trauma, Department of Public Health

¹⁵ See Background information, *supra* at Page 4.

Meeting 3 – December 21, 2017

The Committee met for a final time, at the Capitol in Atlanta, Georgia, to discuss findings, recommendations, and adopt a final report. Senators Kennedy and Unterman were present in Room 450 of the Capitol; Senator Burke, Dr. Robinson, Dr. Hendry, and Ms. Schindler attended the meeting via teleconference. The vote to adopt the final report was unanimous.

COMMITTEE FINDINGS

DAWN Trial

The findings of the DAWN trial were published in the New England Journal of Medicine (NEJM) in November 2017. The clinical trial shows a major breakthrough in stroke care, extending a 6-hour treatment window to 24 hours.¹⁶

The DAWN trial (DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo), results of which are now reported in the Journal, investigated the efficacy and safety of endovascular thrombectomy that is performed 6 to 24 hours after the onset of stroke. The trial was halted on the basis of results of a prespecified interim analysis, which suggested a high probability of success. The trial included patients with occlusion of a large cerebral vessel who presented between 6 and 24 hours after the onset of stroke. Patients underwent successful thrombectomy, even though the usually accepted window for stroke treatment is within 6 hours after the first observation of symptoms. Furthermore, approximately 60% of the patients had had their first stroke symptoms when they woke up, which meant that the time of stroke onset was not known; this circumstance is currently a contraindication to endovascular or thrombolytic treatment. However, patients in the DAWN trial were selected specifically because they had a region of brain that was poorly perfused but not yet infarcted. In essence, the usual 6-hour time window for stroke treatment was replaced with a “tissue window.”¹⁷

Georgia Stroke Centers

At the first meeting, DPH provided Figure 1 (below, Page 11), explaining that there are 42 designated primary stroke centers in Georgia. In addition, 67 hospitals participate in the Coverdell Acute Stroke Registry, with some of these hospitals not being certified as stroke centers. For remote stroke, engaging the rural hospitals in areas where coverage is not as available is a significant component to bridging the care gap.

Testimony from DPH highlighted a pilot program that identified key ambulance services around the state, paired those with primary stroke centers, and attempted to integrate the care. EMS was asked to assess five things:

1. Assess the patient right;
2. Pick the right hospital;
3. Call the hospital in advance to inform the facility you are en route;
4. Provide the hospital good information upon arrival; and
5. Document the call and submit the data.

Hospitals were asked to provide feedback to the EMS community as to whether the assessment was correct and let them know how the patient responded to treatment. Reports of positive feedback that commended EMS for making good choices resulted in an increase of good choices in the future. This

¹⁶ See <http://www.nejm.org/doi/full/10.1056/NEJMoa1706442#t=article>, Nogueira RG, Jadhav A, Haussen DC, Bonafe A, Budzik RF, ... Jovin TG et al. Thrombectomy 6 to 24 hours after Stroke with Mismatch between Deficit and Infarct. NEJM November 11, 2017.

¹⁷ *Id.*

example was provided to stress how to approach and implement a system, and how strengthening one system in turn strengthens systems across the board. Improvements in treatment window time equate to better outcomes. For stroke, time is brain; for cardiovascular and heart episodes, time is muscle; and for trauma patients, time is salvation.

The Georgia Stroke Professionals Alliance (GSPA) has embraced collaboration and Georgia's stroke system journey was described to the Committee and personifying the concept of teamwork. Dr. Grigorian emphasized that there is an enormous difference between comprehensive and primary stroke centers, adding that comprehensive stroke centers are the only centers capable of doing interventional treatment. This position aligns with that of the DAWN study.

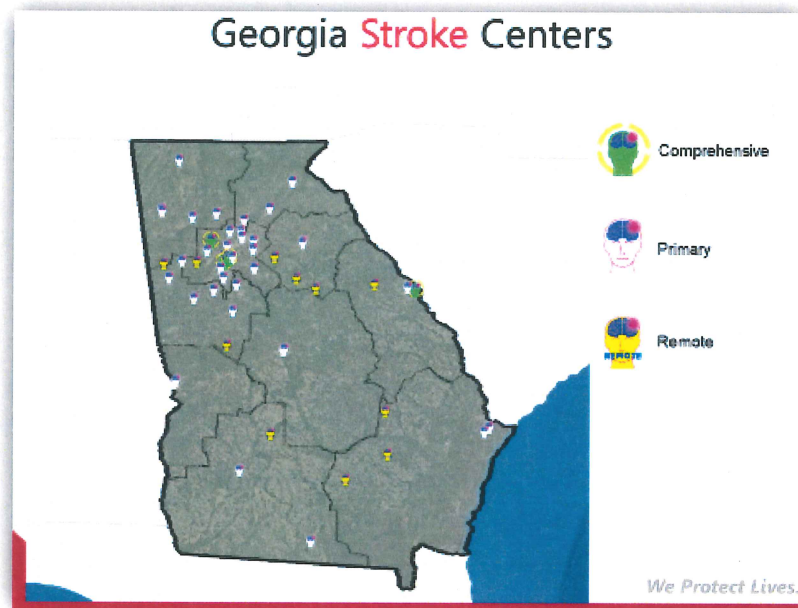


Figure 1: Slide from DPH's Presentation at Meeting 1

Data Reporting Standards

Mr. Doss of DPH provided testimony on GEMSIS, Georgia's statewide EMS data system. GEMSIS is a web-based, central data repository that provides a statewide data standard that is applicable to all service licensees. If needed, GEMSIS allows service providers to create data using its analytical and reporting features. DPH is currently migrating from the original GEMSIS to a newer data standard called GEMSIS Elite. They have developed five stroke measures that will be based on the new EMS reporting. As EMS transports stroke patients, they are able to view performance measures such as whether blood glucose was documented with a provider's primary impression of the patient presenting with TIA. Documentation like this is not available in the older GEMSIS system. Other solutions that are being worked on include connecting the GEMSIS data set with the trauma registry as well as the stroke registry, aiming for linkage to run reports from a statewide perspective without having to conduct manual imports. After discussion at Meeting 1, the Committee agreed that algorithms help the patient reach the right treatment means center. Although Emory uses a stroke algorithm called FAST-ED, there is no state-mandated algorithm.

Overview Statewide System of Emergency Cardiac Care Centers (SB 102)

Sponsored by Senator Miller of the 49th during the 2017, Senate Bill 102 establishes the Office of Cardiac Care (office) within the Department of Public Health (DPH). This office will designate hospitals that meet

the criteria to become emergency cardiac care centers. These centers will receive a designation of Level I, II, or III, based on the following criteria.

Level I – must have all of the following:

- Cardiac catheterization and angioplasty facilities available at all times;
- On-site cardiothoracic surgery capability available at all times;
- Protocols established for therapeutic hypothermia for out-of-hospital cardiac arrest patients;
- Ability to implant percutaneous left ventricular assist devices for support of hemodynamically unstable; patients experiencing out-of-hospital cardiac arrest or heart attacks;
- Neurologic protocols to measure functional status at discharge; and
- Ability to implant automatic implantable cardioverter defibrillators.

Level II – must have all of the following:

- Cardiac catheterization and angioplasty facilities available at all times;
- Protocols established for therapeutic hypothermia for out-of-hospital cardiac arrest patients;
- Neurologic protocols to measure functional status at discharge; and
- Transfer plan to a Level I facility for those who need left ventricular assist devices or cardiothoracic surgery.

Level III – must have all of the following:

- Protocols established for therapeutic hypothermia for out-of-hospital cardiac arrest patients; and
- Transfer plan to a Level I or Level II facility.

DPH has the authority to establish additional levels as necessary. The office must establish a data reporting system on out-of-hospital cardiac arrest patients and all heart attack patients; establish protocols on triage, assessment, treatment, and transport of cardiac patients for emergency medical services providers; and provide a list of emergency cardiac care centers to each licensed emergency medical services provider in the state, maintain a copy at the office, and publish this list on their website by June 1, 2018.

With the enactment and implementation of SB 102, Georgia is one of three states with a statewide system of designated cardiac care centers, joining Washington State and Arizona.

At Meeting 2, the Committee discussed the 2007 Joint Study Committee on State Stroke System of Care, co-chaired by Sen. Don Thomas and Rep. Don Parsons.¹⁸

¹⁸ See FN 6 at Page 6.

COMMITTEE RECOMMENDATIONS

- The Committee agrees that the economic issues of stroke care deserve careful consideration and should continue to be examined. An understanding of the costs and efficiencies stemming from investments in prevention as well as after-care is key. Emergency transport through helicopters and ambulances should be explored in addition to other funding mechanisms such as grant programs on the state and federal levels that could improve outcomes and the delivery of stroke trauma care in Georgia.
- Georgia should embrace the findings of the DAWN Trial and strive to create a health care delivery system where patients should be taken to the closest available institution for a CT and TPA within 6 hours of the acute event. If this is not possible, those patients with a stroke onset between 6 to 24 hours should go to a comprehensive stroke center. Regardless of treatment location, statistics should be collected on all acute stroke patients up to a 24-hour period.
- The Committee encourages the Joint Commission's standing committees, advisory groups, accredited organizations, and professional associations specializing in acute care to conference together to examine efficiencies of scale as it relates to the standards development process.
- The Committee supports the establishment of a Georgia Stroke Commission, which would work in concert with the Georgia Coverdell Acute Registry. The resources in place at Grady Health System and the Medical College of Georgia are significant and may also be utilized by such Commission.
- A joint hearing of the Senate and House Health and Human Services Committee should be held in January 2018 to discuss the findings of this Committee and to streamline discussion amongst the institutions in Georgia that monitor acute care problems, including the Trauma Commission, the Cardiovascular Commission, and the Stroke Commission, as well as possibly the Poison Control apparatus, to expedite improved acute care in the state. In the future, great efficiencies of scale may be possible with such a consortium.
- The Georgia Stroke Commission should center around the following objectives and goals, which should be discussed in more detail at the joint hearing:
 - Prevention. Recognized, preventable comorbidities (morbid obesity, hypertension, diabetes, cardiovascular disease, and peripheral artery disease) exist particularly in the underserved areas of the state which predispose an at-risk population to cerebrovascular insult. With appropriate treatment of these comorbidities, stroke risk in Georgia could be substantially reduced.
 - Identify the at-risk population. Make aware on an individual and family basis the clinical picture of a cerebrovascular insult and ensure the stroke victim and his family are informed as to the quickest way to obtain emergency care (An emergency care plan, for instance, could be placed on the refrigerator of a patient at risk).
 - Endeavor to include all appropriate Georgia healthcare institutions in the state stroke system.
 - Expand and make use of telemedicine, particularly in those areas where healthcare is limited.
 - Establish a state-wide 911 emergency hotline for stroke. (and possibly all acute healthcare issues.) Such a center would have knowledge of all stroke therapeutic resources on a 24-hour basis and could direct a stroke victim to the appropriate location for treatment and forewarn the receiving institution of the stroke victim's impending arrival.
 - Make use of the Smart-Form platform for field triage of patients with stroke.
 - Design, validate, and use a pre-hospital stroke scale for large vessel occlusion.
 - In metropolitan Atlanta, expand the use of stroke-mobiles.
 - When possible, direct patients to a comprehensive stroke center as the first therapeutic choice.
 - The Impact of the DAWN Trial. If possible, all patients should be taken to the closest available institution for a CT and TPA within 6 hours of the acute event. If this is not possible, those patients with a stroke onset between 6 to 24 hours should go to a comprehensive stroke center—

moreover, logically statistics should be collected on all acute stroke patients up to a 24-hour period.

- Understand and expand the efficiencies and benefits of after-stroke care.
- Understand the economic issues of stroke care, its cost and efficiency of investment in prevention, as well as after-care. The stroke commission should also explore the economic utility of the use of helicopter and ambulance transport.
- Finally, the Committee supports and appreciates the ongoing efforts of DPH in establishing statewide systems of care in Georgia, including the updates to the Coverdell-Murphy Act in 2015. Specifically, the Committee applauds DPH's role in establishing the State Office of Cardiac Care and implementing SB 102 from 2017, allowing Georgia to become the third state in the nation to create such a system (following Washington State and Arizona).

Respectfully Submitted,

FINAL REPORT OF THE STROKE TRAUMA SENATE STUDY COMMITTEE

A handwritten signature in black ink, appearing to read "John Kennedy", is written over a horizontal line.

Honorable John Kennedy, Chair
Senator, District 18