The Lone Star Stroke Consortium

CHARTER

INTRODUCTION

The Lone Star Stroke (LSS) Consortium, an affiliate of the Texas Council on Cardiovascular Disease and Stroke, is a collaboration among leading medical research institutions in Texas to improve the health of Texans affected by stroke and cerebrovascular disease through patient-centered stroke research.

PURPOSE and GOALS

The first and primary objective of the consortium is to establish a state-wide network for stroke patient-centered research and therapeutic trials in the adults and children of Texas, linking academic health institutions with proven expertise in stroke research to community stroke centers. The network will initially employ dedicated research personnel at up to 20 regional centers throughout the state, linked by telemedicine to five “hub” academic comprehensive stroke centers which are actively conducting stroke clinical research (total of 25 research sites). This will create a platform for quickly disseminating important advances in clinical stroke care throughout the state, with improvements in cerebrovascular health for Texans. It will also create the infrastructure for performing clinical stroke trials and epidemiologic studies with economies of scale. We anticipate that this coordinated approach will attract new industry-sponsored clinical stroke research to Texas, in addition to allowing for competitive applications for government and foundation funding. Finally, this program will support existing Texas technology, promote new technology development, and create jobs in community hospitals throughout the state.

Consortium goals include:

1. Conduct patient-centered clinical stroke research via a state-wide network in Texas aimed at improving the health of Texans.
2. Identify and invite organizations that have capability for carrying out clinical stroke research and/or which have general experience with clinical research to join and build the LSS consortium.

3. Promote innovation and technology development which leads to faster diagnosis and more effective treatments for patients with stroke. A specific focus will be on promoting Texas-based industries.
4. Support development of new systems of stroke management which improve state-wide access and reduce disparities in care.
5. Develop and disseminate evidence-based guidelines for safe, high-quality, and cost-effective stroke care in Texas.
6. Increase the workforce of physicians and health professionals available to provide stroke care in Texas, through recruitment and training.
7. Leverage the network to solicit extramural funding for clinical research, i.e., funding outside of funding provided by the Texas Legislature.

ADMINISTRATIVE STRUCTURE

1. **Member Organizations.** The LSS consortium is composed of member organizations and their research partners. Founding leadership organizations include University of Texas Southwestern Medical Center, University of Texas Health Sciences Center San Antonio, University of Texas Health Sciences Center Houston, Baylor College of Medicine, Seton Healthcare Family and University of Texas System. Additional member organizations will include Texas Tech Health Sciences Center, and the Texas Council on Cardiovascular Disease and Stroke. New member organizations from across Texas will be sought and may be added by a two-thirds majority vote of the Executive Committee.

2. **Executive Committee**. The executive committee (EC) is comprised of a representative from each of the member organizations and additional members with expertise in stroke research. New EC members are added by a two-thirds majority vote of existing EC. The EC meets no less frequently than quarterly by teleconference or in person. The EC is led by a chair and a co-chair. The term of the founding chair will be from July 8, 2013 and August 31, 2015. Subsequent chairs will serve 2 year terms, coordinated with the state FY (September 1 – August 31). The EC will appoint an external advisory committee, approve additional hub and spoke sites, and select network projects and studies.

3. **Stroke Research Network.** A hub and spoke structure will be used to implement the primary goal of LSS, which is to implement and resource a state-wide clinical trials network that spans urban and rural Texas. This structure initially includes five hubs, chosen for current expertise and infrastructure assets that will allow rapid deployment of LSS. These initial hubs include the hospital-based member organizations: University of Texas Southwestern Medical Center,

University of Texas Health Sciences Center San Antonio, University of Texas Health Sciences Center Houston, Baylor College of Medicine, and the Seton Healthcare Family.

Each hub will have responsibility for selecting and guiding implementation of clinical trials at four spoke institutions. To assure readiness to participate in the stroke network a spoke shall be a Texas hospital that has been designated as a primary or comprehensive stroke center by DSHS or has achieved or is actively seeking certification as a primary stroke center by The Joint Commission (TJC), Healthcare Facilities Accreditation Program (HFAP), Det Norske Veritas (DNV) or other organization authorized by the Centers for Medicare and Medicaid Services (CMS) as an organization for stroke center accreditation. Other selection factors for the spoke hospital include willingness to permit clinical trial enrollment via telemedicine, a commitment to screening for all eligible patients for study, the ability to enter a collaborative agreement with the hub facility and initiate research protocols in a timely fashion, prior experience of the hospital and its personnel in clinical trial participation. Nominations of spoke centers will be brought to the EC discussion for discussion and approval.

Spoke performance will be monitored by its hub on an ongoing basis, and an annual evaluation Each research protocol will provide an estimate of expected target number of patients screened and enrolled in studies. Spoke centers may be replaced for failure to meet screening and recruitment targets, protocol violations, inadequate record keeping, or administrative considerations including the best interests of patient protections, data quality, research integrity, availability of funds to support the spoke research activities, or changes in hospital operations that render the spoke a non-productive research site. Replacement of a spoke hospital will be brought to the EC discussion for discussion and approval.

4. **Annual Meeting and Report.** The consortium will meet annually in a public, open access meeting in Austin, Texas. An annual progress report will be prepared and reported to the Texas Department of State Health Services.

OPERATIONS

1. Telemedicine network for stroke clinical trial enrollment.

Each hub and its respective spoke hospitals will use telemedicine to permit remote evaluation and enrollment of patients. The creation of a stroke network

linked by telemedicine (TM) provides both a platform for remote "spoke" site to consult with stroke experts at the hub center regarding stroke care as well as an opportunity to screen, enroll and collect data for clinical research studies. During the process of evaluating a patient at the spoke site, either the spoke physician or the hub TM physician identifies the patient as a possible study candidate and sends out a page to the hub research team notifying them of a possible study patient at the spoke TM site. After doing so, the hub TM physician and the spoke ED team carry out standard management, including IV-tPA if indicated. A member of the hub research team and the local spoke stroke coordinator obtain informed consent via TM from the patient or the patient's legally authorized representative. The informed consent is signed with the ER nurse, spoke stroke coordinator, or ER physician as the witness. Then the spoke stroke coordinator or ER physician proceeds with study specific preparatory steps while the hub research team determines and communicates the treatment assignment (if randomized allocation is applicable).

The patient then receives the study specific intervention (or control) per protocol at the spoke, and the hub TM physician performs the follow up NIHSS and other required examinations per protocol over TM. If the patient is subsequently transferred to the hub, the spoke nurses make copies of all the paperwork to be transferred with the patient.

2. Selection of Network Procedure for Choosing Research Protocols

The Lone Star Stroke Consortium (LSS) is dedicated to conducting and participating in high quality patient-oriented research studies of the epidemiology and treatment of stroke. The consortium will consider participating in high quality studies from a variety of sources: peer-reviewed studies funded by governmental agencies such as NIH and non-for-profit agencies such as the American Heart Association and other foundations; studies funded by Industry; and investigator-initiated studies proposed by LSS members. The selection process of studies conducted by the consortium will include consideration of the following principles:

- Quality, feasibility, and impact of the study in the field of stroke
- Feasibility of conducting the study when taking into consideration other studies the LSS is conducting or to which the LSS has already made a commitment
- Whether the study under consideration competes with other studies the LSS is already conducting or to which the LSS has already made a commitment
- Whether the study under consideration might jeopardize the ability to complete other ongoing studies due to complexity of design or anticipated time

commitment/required resources for the study exceeds the capacity of the LSS collaborators

The LSS Executive Committee members will carefully review all studies brought to them for potential participation, and seek outside advice where needed. The possibility of LSS participation in a particular study will be brought to the attention of the LSS Executive Committee by individual LSS Executive Committee members, or from outside individuals or agencies. The LSS Executive Committee will discuss potential participation in each study on their conference calls as opportunities arise. The decision about whether or not to participate will be based on consensus among members using the principles listed above.

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