

BMJ Open Rationale and design of a statewide telestroke registry: Lone Star Stroke Consortium Telestroke Registry (LeSteR)

Cesar Astudillo,¹ Christy Ankrom,¹ Alyssa Trevino,¹ Rene M Malazarte,¹ Arvind B Bambhroliya,¹ Sean Savitz,¹ Christopher H Topel,² Truman J Milling,³ Tzu-Ching Wu¹

To cite: Astudillo C, Ankrom C, Trevino A, *et al.* Rationale and design of a statewide telestroke registry: Lone Star Stroke Consortium Telestroke Registry (LeSteR). *BMJ Open* 2019;**9**:e026496. doi:10.1136/bmjopen-2018-026496

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-026496>).

Received 11 September 2018

Revised 6 May 2019

Accepted 18 June 2019



© Author(s) (or their employer(s)) 2019. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹Department of Neurology, Institute for Stroke and Cerebrovascular Disease, McGovern Medical School, The University of Texas Health Science Center at Houston, Houston, Texas, USA

²Department of Neurology, University of Texas Health Science Center, San Antonio, Texas, USA

³Department of Neurology, Dell Medical School, University of Texas, Austin, Texas, USA

Correspondence to

Christy Ankrom;
christy.ankrom@uth.tmc.edu

ABSTRACT

Introduction The Lone Star Stroke Consortium Telestroke Registry (LeSteR) currently consisting of 3 academic hub centres and 27 partner spokes is a statewide initiative organised by leading academic health centres in the State of Texas to understand practice patterns of acute stroke management via telestroke (TS) in Texas, a state with one of the largest rural populations in the USA.

Methods and analysis All patients who had presumed stroke for whom a TS consultation has been obtained in the network are entered into a web-based, Health Insurance Portability and Accountability Act-compliant database from September 2013 to present. Spokes were enrolled into LeSteR in a staggered approach in two data collection phases: a retrospective phase and a prospective phase. Basic clinical, demographic data and relevant time metrics are collected in the retrospective phase. Starting 1 September 2015, additional outcome data including 90-day modified Rankin score, readmission and 90-day disposition are obtained by a standard phone interview. From the registry initiation to 31 December 2017, there are 8089 patients who had suspected stroke in the registry. Over 60% of patients enrolled after 1 September 2015 have reported outcome data. Enrolment is still active for this registry.

Ethics and dissemination LeSteR is a statewide TS registry organised by academic health centres that will provide significant insight regarding the impact of TS in the State of Texas. Findings from LeSteR will provide data that can be analysed to improve the allocation of healthcare resources using TS to treat stroke in a state with one of the largest rural populations.

BACKGROUND

Although stroke mortality has decreased from the third leading cause of death in the USA to the fifth leading cause of death, there are over 800 000 strokes per year, and stroke is still the leading cause of long-term disability. In addition to the social and psychological costs, stroke poses substantial economic costs for the US healthcare system. It is projected that between 2015 and 2035, the total direct medical stroke-related

Strengths and limitations of this study

- Prospective, patient-level, statewide registry of telestroke.
- The registry provides unique opportunities to study health services and health disparities in rural populations with stroke.
- The registry provides long-term patient-centred outcomes.
- The registry does not provide data from randomised clinical trials.
- There is no control comparator group or non-telestroke comparator group.

costs will likely double from US\$36.7 billion to US\$94.3 billion.¹

Despite the substantiated clinical and cost benefits of intravenous tissue plasminogen activator (tPA), for patients who had ischaemic stroke, only 5.9%–9.5% of patients who had ischaemic stroke receive tPA,² and one-quarter of eligible patients are not receiving treatment.³ Causes for the low treatment rate are numerous; however, one of the major reasons is the lack of access to acute neurological expertise. Patients living in rural, underserved areas must rely on local community or critical access hospitals which may be uncomfortable in taking care of patients who had acute ischaemic stroke or in initiating tPA treatment with confidence. Unlike urban settings in which resources are more abundant and are more likely to attract vascular neurologists, rural and underserved areas often lack the means to entice neurologists into their community leading to a gap in access to acute stroke care. Nonetheless, some urban hospitals also currently struggling with acute stroke coverage as shortages of neurologists continue to worsen and many community neurologists are unable to provide consistent coverage to emergency departments.

A widely adopted solution to increase access to acute neurological expertise is the application of telestroke (TS). Telestroke is the use of telecommunication technologies to provide medical information and services that allows for the delivery of quality healthcare from afar. Telestroke has been shown to be safe and effective in acute stroke care and can also improve the utilisation of intravenous tPA.⁴ Currently in the State of Texas, it is estimated that 75% of the population has access to stand-alone primary stroke centres within 60 min and TS increases the access to acute stroke care by ~8.5% or 2 026 016 additional Texans.⁵ Telestroke can be used to expand access to acute stroke care for rural hospitals and provide additional back-up coverage to local neurologists who practice in the urban setting as well.

Despite its increasing utilisation, there continue to be substantial gaps in knowledge regarding the use of TS and the long-term outcomes of these patients, particularly in large regions with underserved populations and geographical disparities. In the State of Texas, where the stroke is the third leading cause of death, and with one of the largest rural populations, we do not know the full extent or impact of how TS is delivered or how it has changed acute stroke care and outcomes of these patients. We also need to understand how TS services are useful for patients with other conditions such as brain haemorrhage. The Lone Star Stroke Consortium Telestroke Registry (LeSteR) was developed to address these gaps in knowledge in order to build a database of useful data to advance TS care and to use that knowledge to actively monitor quality metrics and improve outcomes.

OBJECTIVES

We aim to understand the patterns, mechanisms and impact of regional stroke care in the context of an expanding TS network in the State of Texas that covers three growing metropolitan areas. We seek to understand how stroke care is delivered and what outcomes are achieved with the use of TS.

METHODS AND DESIGN

Study design and setting

LeSteR is designed to be a patient registry that collects preliminary, clinical, treatment and long-term follow-up outcomes on all patients who had stroke treated by the Lone Star Stroke Consortium Telestroke Network. At the date of institutional review board (IRB) approval or IRB reliance agreements, we began collecting data prospectively by chart reviews of the participating hubs and spokes that are listed in [table 1](#). The first data collection began 1 September 2013 and spokes were enrolled in a staggered approach.

Study population

All patients ≥ 18 years of age with suspected stroke on whom a video TS consultation is obtained on or after 1 September 2013 are included in LeSteR.

Patient and public involvement

Patients and/or the public were not involved in the design of this registry.

Study procedures

Waiver of consent was approved for this study by the IRB, so all patients with a suspected stroke seen by the TS team via video are automatically enrolled in LeSteR.

Each patient evaluated is collected on a Master List by either the hub treating physician or hub coordinator. The Master List is an Excel spreadsheet that serves as a source document to a unique identifier called 'LeSteR ID' in our REDCap Database. This file is stored as a password-protected document at each hub and kept secure as per Health Insurance Portability and Accountability Act of 1996 (HIPAA) guidelines. As part of the standard of care, the physician providing the consult enters a TS consult note in the appropriate electronic medical record (EMR) for the spoke site.

Each month a hub research assistant accesses the Master List to perform data cleaning on the new information.

Table 1 List of participating hubs and spokes

Hub	Spokes
University of Texas Health Science Center San Antonio, San Antonio, Texas	<ul style="list-style-type: none"> ▶ Baptist Medical Center ▶ North Central Baptist Hospital ▶ Northeast Baptist Hospital ▶ St Luke's Baptist Hospital ▶ Mission Trail Baptist Hospital
University of Texas Health Science Center at Houston, Houston, Texas	<ul style="list-style-type: none"> ▶ Memorial Hermann Greater Heights ▶ Memorial Hermann Katy ▶ Memorial Hermann Southwest ▶ Memorial Hermann Memorial City ▶ Memorial Hermann Pearland ▶ Memorial Hermann Sugar Land ▶ Memorial Hermann The Woodlands ▶ Memorial Hermann Cypress ▶ Memorial Hermann Northeast ▶ Baptist Beaumont ▶ Baptist Orange ▶ Brazosport Regional Health System ▶ Citizens Medical Center ▶ DeTar Healthcare System ▶ Huntsville Memorial Hospital ▶ Matagorda Regional Medical Center ▶ Medical Center of Southeast Texas ▶ St. Joseph Medical Center ▶ UT Northeast (Tyler) ▶ Midland Memorial Hospital
Seton Healthcare Family, Austin, Texas	<ul style="list-style-type: none"> ▶ Seton Medical Center Hays ▶ Seton Medical Center Williamson

During this process, it is confirmed that the formulas have worked properly and the data follow the predetermined data validation rules. If any discrepancies are noted, they are corrected at this stage. The ultimate goal of this process is to have a complete, accurate and standardised set of data that will help the research assistant to determine which patients will be assigned a LeSteR ID. The LeSteR ID is only assigned to patients who are ≥ 18 years of age with a presumed stroke and were evaluated by a video TS consultation in an emergency setting.

Only the de-identified data that have a LeSteR ID are uploaded to the REDCap Database. The University of Texas Health Science Center at Houston (UT Health) is licensed to use the web-based, secure database, utilising data server management services at the UT Health School of Bioinformatics. As it is web based, it is accessible to all hub data entry sites using a web browser on a computer terminal with internet connection—without the need to get behind a firewall. The data are saved on HIPAA compliant, zone 100, MS SQL servers at UT Health with restricted administrative rights.

Once the data are uploaded, the hub research assistants begin the process of additional data abstraction from the medical records, such as demographic data not collected at the point of video consult. At the 90th (± 15 days) day from the date of the TS consult, a long-term follow-up phone call is made where the hub research coordinator collects modified Rankin Scale and other outcome information. Every 2 months the hub research coordinator will send an Excel file via encrypted email or through the University's secure share file portal with missing data that we are not able to abstract from the TS consult note to the stroke coordinators at spoke hospitals. When the information is returned, spoke coordinators also send the patient demographic sheets of the patients to complete the record in REDCap.

Data quality check procedures are performed regularly and include source data verification by randomly selecting 10% of registry participant records with a comparison between the source documents and the registry record of that same data. One hundred per cent of the data will be completely checked for those fields for which errors are common.

A schematic representation of the workflow, data elements collected and time durations generated at various stages can be found in [figure 1](#).

IRB approvals and multisite implementation

The hubs and spokes mentioned in [table 1](#) joined the research database once we received IRB approval. The hubs are responsible for providing personnel, equipment and resources needed for data collection at their respective hospital institutions and their spoke sites, timely entry of data elements within 30 days of hospital discharge of the patient, data quality assurance procedures including staff training, and allow for monitoring of data on a periodic basis, respond to queries and correct errors. The

spokes are responsible for responding to requests for data to complete records in a timely manner.

Data management

Data coordination and analysis

The University of Texas Health Science Center at Houston (UTHealth) performs the functions of a Data Coordinating Center (DCC) as well as Data Analysis Center (DAC). The DCC section for LeSteR is staffed by a postdoctoral research fellow, two research assistants, and a research coordinator. The DAC is led by a faculty director, and staffed by a postdoctoral research fellow, a programmer, a research coordinator, and two research assistants.

As the DCC, the data core of the stroke team at the UTHealth develops and manages the database, develops and maintains the codebook and data dictionary, develops training materials and provides training to the hub and spoke data abstractors, coordinates data collection from all network sites in conjunction with the research coordinator, develops and implements ongoing data validation and quality processes, generates quarterly reports of pooled data and reviews data collection processes along with developing definitions for common data elements.

The DAC is responsible for generating and sharing predefined reports, assist in the development of a data analysis plan for any proposed or approved projects, help prepare and clean data for analysis, provide epidemiological and statistical support in study design and data analysis, analyse data for manuscript preparation, generate graphs and tables for manuscripts, and assist in writing methods and results of analyses.

Data sharing policy

Once data have been cleaned and passed quality assurance within 30 days of data entry completion, individual hubs have open access to data collected at their own institutions. Requests for pooled data are processed through a data request form, which are reviewed within 2 weeks by the DCC and Lone Star Stroke Consortium (LSS) Executive Committee.

Data collected for publications and data sharing for analyses completed by other hubs are approved through the DCC and LSS Executive Committee as well.

Proposals for additional projects that would require the capture of data in addition to data elements listed in the protocol require the approval of the LSS Executive Committee and the DCC. The details pertaining to new projects are discussed and decided on a project-by-project basis. However, these would include decisions on elements to be captured, timelines for development/modifications to the database, and data analysis and reporting plan.

Risks and benefits

There are no risks, as LeSteR is an observational data registry capturing clinical information only. There are numerous benefits for patients and clinicians with this registry as there continues to be substantial gaps in

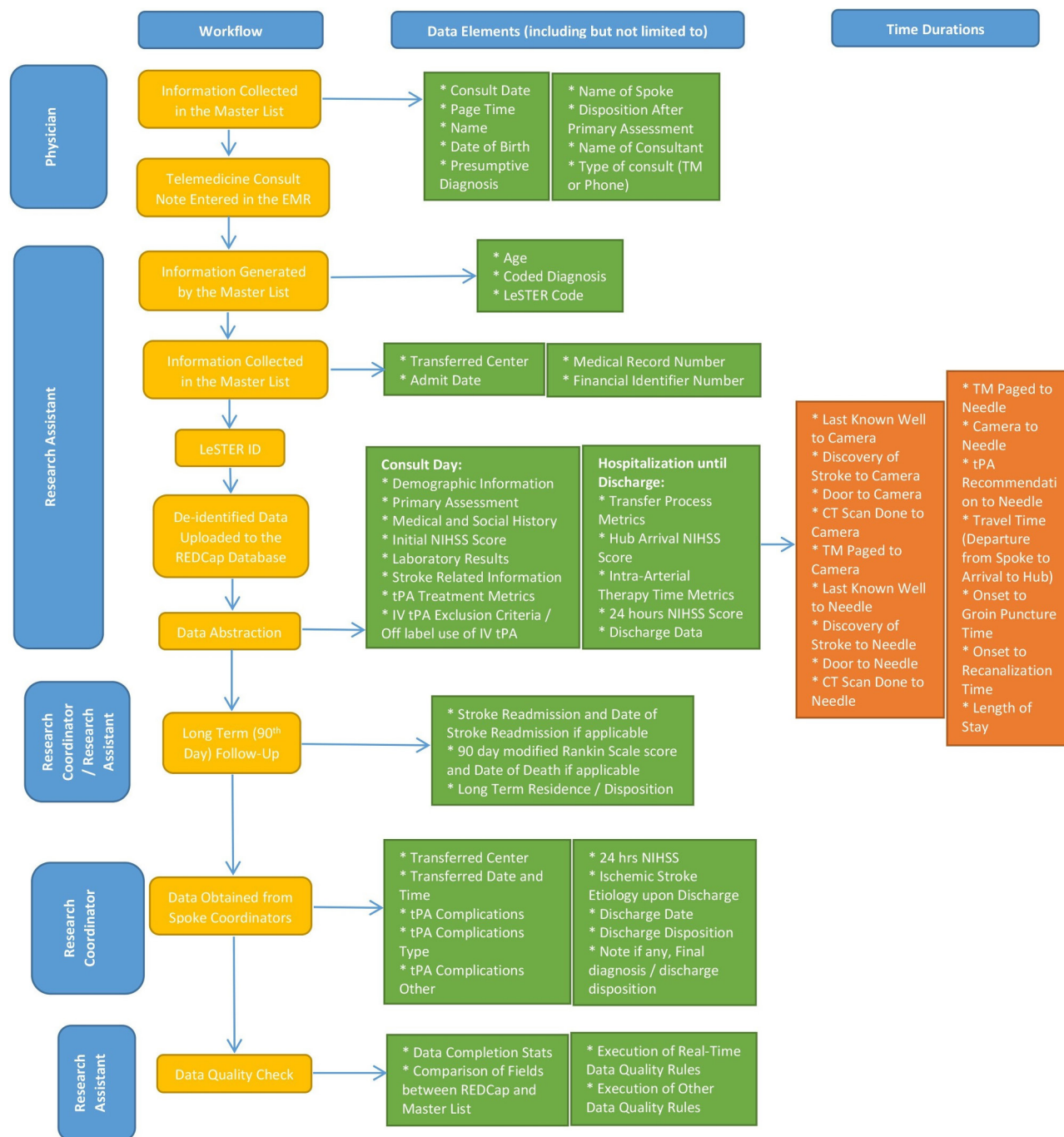


Figure 1 Schematic representation of workflow, data elements captured and time durations generated at each stage. Responsible parties of each stage are indicated vertically. LeSteR, Lone Star Stroke Consortium Telestroke Registry; NIHSS, National Institutes of Health Stroke Scale; TM, telemedicine; tPA, tissue plasminogen activator.

knowledge regarding the use of TS in acute stroke care in the State of Texas. We do not know the full extent or impact of how TS has changed acute stroke care and outcomes of stroke patients in Texas.

DISCUSSION

LeSteR is a statewide TS registry organised by academic health centres seeking to understand how acute stroke care is delivered and how outcomes are achieved with the use of TS in the State of Texas. The range of TS in our network extends to the rural areas of west, southeast, south and

central Texas. Acute ischaemic stroke is a socially and financially costly disease, and data clearly show that patients in rural or underserved communities are much less likely to receive appropriate acute care leading to potentially long-term disabilities.⁶ Telestroke has been shown to improve the disparity gap in rural healthcare;⁴⁻¹¹ however, data regarding long-term outcomes and impact of TS care at the population level are lacking.

LeSteR is a unique registry that not only collects data and metrics focused on the initial TS encounter but also captures data points beyond that time point, most

notably long-term outcomes and complications. The data captured are more robust than large repositories of insurance claims data as LeSteR is solely focused on TS-treated patient and data are at the patient level, with detailed severity of disease and short-term and long-term outcomes. This information can be vital to enlighten private insurance payers and federal/state stakeholders on the value of TS for the State of Texas and potentially nationally. LeSteR also offers hospitals that are not certified stroke centres to participate in data collection as many of those metrics and outcomes of patients who had stroke at smaller non-stroke centres are not routinely captured. In addition, LeSteR offers a unique opportunity to study TS team response times and their impact on achieving national benchmarks for tPA treatment times.

The LeSteR is aimed to address gaps in knowledge in TS care delivery. The registry will provide data regarding the types of patients that are being treated using TS, utilisation and quality metrics regarding intravenous tPA administration, and will identify further needs to improve the care of patients who had stroke in the State of Texas that TS can provide. By understanding practice patterns of acute stroke care management, resource utilisation and outcomes using TS in Texas it potentially could impact policies regarding improved and targeted health-care resource allocation.

Future plans for LeSteR are to expand to other metropolitan areas of the state such as Dallas-Fort Worth, El Paso and other under-represented areas throughout the state. The goal is to obtain full coverage of the state and expand the data points captured to include more transfer time metrics and intra-arterial thrombectomy utilisation data to help optimise the flow of patients from smaller community hospitals to tertiary stroke centres.

Contributors CA, ChA, AT, ABB, and T-CW: provided substantial contributions to the conception or design of the work, the acquisition, and analysis or interpretation of data. All authors: contributed to drafting the work or revising it critically for important intellectual content; gave final approval of the version published and was in agreement to be accountable for all aspects of the work in ensuring

that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding This research is made possible by funding from the State of Texas Legislature to the Lone Star Stroke Clinical Research Consortium.

Disclaimer The contents are solely the responsibility of the authors and do not necessarily represent the official views of the State of Texas.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

REFERENCES

1. Benjamin EJ, Virani SS, Callaway CW, *et al*. Heart Disease and Stroke Statistics—2018 update: a report from the American Heart Association. *Circulation* 2018;137.
2. Man S, Cox M, Patel P, *et al*. Differences in Acute Ischemic Stroke Quality of Care and outcomes by Primary Stroke Center Certification Organization. *Stroke* 2017;48:412–9.
3. Messé SR, Khatri P, Reeves MJ, *et al*. Why are acute ischemic stroke patients not receiving IV tPA? Results from a national registry. *Neurology* 2016;87:1565–74.
4. Mazighi M, Meseguer E, Labreuche J, *et al*. TRUST-tPA trial: telemedicine for remote collaboration with urgentists for stroke-tPA treatment. *J Telemed Telecare* 2017;23:174–80.
5. Wu TC, Lyerly MJ, Albright KC, *et al*. Impact of telemedicine on access to Acute Stroke Care in the State of Texas. *Ann Clin Transl Neurol* 2014;1:27–33.
6. Gebhardt JG, Norris TE. Acute stroke care at rural hospitals in Idaho: challenges in expediting stroke care. *J Rural Health* 2006;22:88–91.
7. Wu TC, Sarraj A, Jacobs A, *et al*. Telemedicine-guided remote enrollment of patients into an acute stroke trial. *Ann Clin Transl Neurol* 2015;2:38–42.
8. Lyerly MJ, Wu TC, Mullen MT, *et al*. The effects of telemedicine on racial and ethnic disparities in access to acute stroke care. *J Telemed Telecare* 2016;22:114–20.
9. Albright KC, Boehme AK, Mullen MT, *et al*. The effect of telemedicine on access to Acute Stroke Care in Texas: the story of age inequalities. *Stroke Res Treat* 2015;2015:1–6.
10. Jagolino AL, Jia J, Gildersleeve K, *et al*. A call for formal telemedicine training during stroke fellowship. *Neurology* 2016;86:1827–33.
11. Wolff C, Boehme AK, Albright KC, *et al*. Sex disparities in access to acute stroke care: can telemedicine mitigate this effect? *J Health Dispar Res Pract* 2016;9.