

Appendix V: Texas Youth Depression and Suicide Research Network (TX-YDSRN)

Texas Youth Depression and Suicide Research Network (TX-YDSRN) Hub and Network: Status Report to the Texas State Legislature

Institution:

UT Southwestern Medical Center

Principal Investigators:

Madhukar H. Trivedi, MD, UT Southwestern Medical Center
Sarah Wakefield, MD, Texas Tech University Health Science Center

Date: November 2020

TX-YDSRN BACKGROUND

Depression and suicide in youth are devastating and critical public health problems, and both are on the rise in the United States. Rates of past year major depressive episodes increased 52% between 2005 and 2017 (from .1% to 13.2%) among adolescents (Twenge et al., 2019). Youth depression is a life altering illness, given that it is burdensome, often chronic, and disabling. Depressed youth experience functional impairments, observed in school difficulties, social impairment, poorer family relationships, and even substance abuse problems (AACAP, 2007). Because adolescence is a critical period for brain development and the development of social skills and peer networks, undetected and untreated depression has far-reaching consequences for educational, social-emotional, and economic outcomes in adulthood. The CDC estimates that mental illnesses among children result in an annual cost of \$247 billion due to their impact not only on children, but on families and communities (Perou et al., 2013).

Suicide is now the second leading cause of death in persons aged 10-24 in the United States. A recent CDC report focused on this age group highlighted that after a stable trend in suicide rates from 2000 to 2007, the rate sharply increased from 2007 (6.8 per 100,000 persons) to 2017 (10.6 per 100,000 persons; Curtin et al., 2019).

The statewide Texas Youth Depression and Suicide Research Network was created to stand up a state wide research network across all 12 Health Related Academic Institutions. The Network also aims to support the development of a Network Participant Registry and characterize systems and interventions to examine statewide population health outcomes. The questions asked in this research will advance care for depression and suicide for children and adolescents in Texas, actively improve the outcome through the use of Measurement Based Case (MBC) and Collaborative Care by training clinical systems across the state. The Network will in turn also identify unique needs across disparate systems and geographical and demographic variations across the state in order to assist the legislature to deploy resources where needed.

OBJECTIVES

- To create the Texas Youth Depression and Suicide Research Network (TX-YDSRN), developing collaborative partnerships between the 12 major medical centers throughout the state (12 “Nodes”) and building the infrastructure to support the high quality research inquiries, regulatory, operations, and research functions (UT Southwestern “Hub”)
- To stand up research trained staff across the state
- To develop the TX-YDSRN Participant Registry
- To collect information to characterize the current systems of care and intervention approaches for depressed and suicidal youth, to examine statewide population health

Numbers of Children and Youth Expected to Participate in the TX-YDSRN Hub

The TX-YDSRN anticipates enrolling up to 1,800 participants statewide before the end of the fiscal year. The Hub team provides leadership and rounds on all 12 Nodes weekly to ensure continued commitment with their recruitment goals and to help problem solve recruitment strategies. Additionally, the Nodes are encouraged to collaborate with each other on communication platforms such as Slack and on various network calls to discuss tips on developing unique strategies for recruitment. For example, a pre-screening script was developed by one of the 12 Nodes as a strategy for recruitment. With the Node’s permission, the Hub disseminated this useful script to the other Nodes. This collaborative effort helped provide talking points to Nodes requesting guidance on how to discuss the study with potential participants effectively.

How the TX-YDSRN Research Addresses Needs in Texas

Depression and suicide impact a significant number of Texas youth. Specifically, among youth aged 13-17 in Texas, the 12-month prevalence rates are estimated to be 160,877 for depression and 186,382 for self-injury or self-harming behaviors. According to the 2017 Youth Risk Behavior Survey Texas data brief, 34.2% of Texas high school youth report feeling so sad or hopeless almost daily for 2 or more weeks that they stopped doing some usual activities in the past year (Texas Department of State Health Services, 2018). Additionally, 17.8% of Texas high school youth reported having serious thoughts about suicide, 14.5% made a plan, 12.3% attempted suicide, and 4.5% reported having made a suicide attempt that required medical attention in the past 12 months. Even more striking, Texas high school students had a 66% higher rate of attempted suicide in the past year than those in the U.S. (12.3% in Texas vs. 7.4% in US overall, based on the 2017 Youth Risk Behavior Survey data). Furthermore, Mental Health America ranks states according to prevalence of mental illness and access to care, and Texas ranks last among U.S. states for access to mental healthcare (Mental Health America, 2020).

The ultimate goal of the TX-YDSRN is to standardize screening and measurement-based care across primary care and all other providers across the state providing Texas youth with early screening and intervention for depression and suicide. Additionally, TX-YDSRN research will provide predictive models to identify regionally-specific and state-wide service delivery gaps in order to inform the next best targets for policy makers and legislators to improve the health care of youth in Texas.

TX-YDSRN ACCOMPLISHMENTS TO DATE

The TX-YDSRN Hub and Nodes have met consistently since April of 2020, collaborating to develop the initial research protocol for the Participant Registry project. The protocol was finalized on July 21, 2020 and the TX-YDSRN Kick-Off Meeting was held on July 29, 2020. Key progress is highlighted below, and additional information is available at:

Public: <https://utsouthwestern.edu/education/medical-school/departments/psychiatry/research/center/txydsrn.html>

Internal: <https://app.smartsheet.com/b/publish?EQBCT=963acb41ec8b486392221fb2f69df6ff>

TX-YDSRN Hub/Node Infrastructure Development

The first step in creating a Network is to establish the infrastructure. The following activities were completed to establish the infrastructure, enhance and enrich communication, and foster collaborative ideas for the development and implementation of the research project:

- Created a Zoom Account on behalf of the Hub to coordinate virtual trainings and meetings in lieu of travel restrictions. All meetings are recorded and uploaded to a UTSW IR secure platform (OneDrive).
 - Monthly Hub and Node Leadership Meeting
 - A total of 9 meetings with roughly 50+ individuals in attendance
 - Weekly Coordinator and Assessor Meeting
 - A total of 14 meetings to date with roughly 30+ individuals in attendance
 - Monthly Assessor Consultation Meeting
 - A total of 4 meetings to date with 30+ roughly individuals in attendance
 - Weekly Office Hours for Electronic Data Capture Assistance
 - A total of 4 sessions to date with 15 individuals in attendance
- Developed email account for general questions: ydsrn@utsouthwestern.edu
- Created shared OneDrive account to upload all pertinent recorded virtual meetings, trainings, agendas, and meeting minutes, and referenced documents
- Created a shared Slack account as a communication platform to problem solve real-time questions collaboratively between Node and Hub
- Created a “Dashboard” to organize study related materials and study related updates for all nodes

TX-YDSRN Dashboard

The TX-YDSRN Dashboard serves as the main landing page for nodes to access study-related information such as important updates, enrollment progress, key study documents, and all external website links. The main page features:

- Enrollment Progress dashboard
- Important Information section featuring upcoming meeting dates, recent news, funding updates and Hub contact information
- Network Structure outlining the Hub Leadership Team, Node Leads and Co-Leads, and Committees

- Node Institutional Websites linking each node's Department of Psychiatry to their institution's logo
- Additional pages linked to the main page provide access to meeting information (e.g. agenda, minutes, and recordings), IRB & regulatory documents, and resources for coordinators and assessors.

The TX-YDSRN utilizes multiple platforms to ensure information sharing is easily accessible and user-friendly. Such platforms, linked to the main page of the Dashboard, include:

- **REDCap** – The Electronic Data Capture (EDC) system used extensively for TX-YDSRN. Study personnel are provided access to 3 main REDCap sites:
 - Training Tracker – Onboarding and training site for all study personnel (Figure 2). The Hub assigns modules based on study role and personnel complete the modules by viewing recordings, reviewing documents, taking quizzes, uploading certificates, and attesting to completion of tasks. Figure 3 shows an example of the tasks Coordinators/Assessors must complete as part of their EDC training.
 - Production – Collects and maintains study data and is accessible only to study personnel who are IRB approved and who have completed all training requirements.
 - Certification – Mock version of the Production site where personnel can use fake data to complete EDC training and familiarize themselves with the EDC system.
- **Slack** – A web-based communication application which allows coordinators and assessors to problem-solve with their peers at other nodes quickly and efficiently, rather than multiple email communications. Figure 4 shows an example of a coordinator sharing a template she developed to assist others in tracking their enrollment numbers.

Participant Registry Project Development

Finalized protocol on July 21, 2020

Within the very early weeks of development, the investigators agreed that a robust protocol was warranted for the Patient Registry. Over the course of the next three months, we conducted thorough research to produce a final protocol. Activities accomplished during protocol development included:

- Identified appropriate recruitment methods, and ensuring TCHAT, CPAN and CPWE are not used as recruitment sources
- Established the parameters of assessment schedules
- Selected measurement tools
- Developed forms, including patient/family forms in English
- Coordinated additions / changes to the protocols
- Evaluated the latest research findings, and updating the study measurement-based care standards as these need to evolve based on the latest research

Established data management and monitoring plans in August, 2020

A critical component in any large research project is to ensure data integrity. This can only be accomplished through developing strategic methods of ensuring adequate training of personnel, quality control checks, and systems for continual monitoring of personnel and data management.

- Finalized the Electronic Data Capture (EDC) system on August 14, 2020
- Developed the statistical analysis plan and the data management plan by utilizing Hub expertise
- Developed Data Monitoring Plan which was approved by the UT Southwestern Hub IRB and included:
 - Trained Sites on regulatory requirements, including working with sites to identify site-specific IRB requirements
 - Developed and implemented systems for ongoing monitoring of study data and recruitment
 - Provided training and coaching to Node Site investigators and coordinators, including assisting Node coordinators in developing site-specific procedures

Institutional Review Board and Regulatory Management

To streamline regulatory activities for the Network, the UT Southwestern IRB was used as the single IRB of record for the study. Because using single IRBs is still early in its use for academic centers, a great deal of work was done across the centers to establish best practice processes for doing this. To accomplish this in a timely fashion, the following activities took place from July to August, 2020.

- Met with each node individually to discuss plan for IRB approval, recruitment of node sub-sites, workflow for recruitment of participants at the Node Sub-Sites, and hiring of node research staff
- Provided guidance on organizing Regulatory Documents and with instilling Regulatory Processes as recommended by Good Clinical Practice.
- Prior to opening any node for enrollment, each node had a 1:1 session with the Hub team providing information on regularity compliance, adverse event reporting, and safety considerations.
- Provided considerations for handling regulatory documents and consenting while conducting visits remotely.
- IRB for HUB Approved on July 27, 2020. To date, 10 out of 12 nodes have received full IRB approval and are open for enrollment.

TX-YDSRN Committees

We have established the following Committees involving various Node Leads and Hub members:

- Measurement-Based Care and Collaborative Care (CC) Committee (Chairs: Drs. Wakefield, Storch and Hughes)
The Measurement-Based Care (MBC) and Collaborative Care (CC) Committee provided trainings for nodes and sub-sites to learn about the benefits of MBC and CC, as well as strategies for implementing MBC and CC into practice.
- Extramural Funding (Chairs: Drs. Trivedi and Liberzon)
The Extramural Funding Committee identified various additional funding opportunities, including foundation and federal funding, that would be a good fit for continuing the work of the TX-YDSRN.
- Recruitment (Drs. Garza, Hughes, and Kennard)
The Recruitment Committee developed various recruitment materials for the network which include: Flyers, Posters, Pamphlets, and PowerPoint Presentation slides.
- Publications Committee (Drs. Trivedi and Minhajuddin)
The Publications Committee is developing a Publications Plan for TX-YDSRN participating Nodes and investigators to submit manuscript proposals and data analysis requests.
- Acculturations Committee (Dr. Escamilla)
The Acculturations Committee aided in the selection of culturally sensitive measures and has assisted in the translation of measures to allow for engagement of youth and families across Texas.

Trainings and Certifications

- Developed and hosted trainings for all Node Leadership and study team members
 - Kick-Off Training: July 29, 2020
 - 2-Part Assessor Training: July 31, 2020 and August 7, 2020
 - Database Training: August 12, 2020
 - MBC/CC Training: October 12, 2020

Developed a platform in REDCap called the “Training Tracker” which serves as a streamlined process for new team members to receive training per their identified role on the study.

Developed processes and checklists for in-depth training on the electronic data capture (EDC) system (REDCap). This training also covered the process for consenting participants virtually. To date, 48+ individuals are EDC certified. As noted above, one of the systems was developed to track mock participant data entry for staff certifications (Figure 5).

Developed processes and checklists for in-depth and thorough certifications for conducting various validated assessments. Mock assessment videos were developed by each assessor and were reviewed by experienced clinical psychologists from the Hub, Dr. Jennifer Hughes and Dr. Joseph Trombello. Follow-up 1:1 sessions were scheduled with each assessor following review for feedback prior to granting assessment certification.

To date, 23 individuals are certified, and the remaining 10 individuals have their feedback sessions scheduled (will be certified by December 3, 2020).

Recruitment

We have developed several informational flyers and pamphlets for education and recruitment. A sample of these materials is seen in (Figure 6).

TX-YDSRN PROJECT IMPACT TO DATE

TX-YDSRN Network Established

Overall, the first objective of this initiative has been met, given the TX-YDSRN has been established, with the UT Southwestern Hub coordinating the infrastructure for the 12 Nodes. Over 30 assessors across the Texas have been trained and certified in conducting standardized research assessments to collect data on psychiatric diagnoses, depression, suicide, and trauma. Approximately 50 individuals have been trained and certified in research methodologies and data collection and management for TX-YDSRN initiatives. Lastly, approximately 50 individuals have been trained in measurement-based care (MBC) strategies for addressing youth depression and suicide, with planned dissemination of this training and the associated MBC manual to TX-YDSRN Node-affiliated clinics throughout the state.

TX-YDSRN Participant Registry Study Recruitment

Additionally, the TX-YDSRN has developed the TX-YDSRN Participant Registry. Ten of 12 Nodes have been approved to begin recruitment of youth with depression or recent suicidal ideation or behavior into this registry, collecting data to examine risk, course of illness, treatments received, and outcomes in Texas youth. As noted above, IRB approval for the overall project was obtained on July 27, 2020, with individual Nodes added over time. To date, n = 35 youth /parents have been consented for participation and all 35 have completed the baseline assessment. The sample is comprised of 35 youth, ranging in age from 10 to 19 (mean = 14.5, SD =2.1). The sample is 77.1% female, which is expected in a study of depressed youth given the increased risk of depression in girls compared to boys, and 62.9% white.

Baseline depression and suicide data on the sample to date are presented in Table 1. At baseline, the depression severity, as measured by the Patient Health Questionnaire – A (PHQ-A) mean score, is 13.9 (SD=6.7, range 0-27), indicating moderate depression. Self-reported suicidality is measured by the Concise Health Risk Tracker- Self Report and presented as two domain scores. The CHRT-SR Suicide Propensity mean score is 17.3 (SD = 8.0, range 2-36) and Suicide Thoughts mean score is 3.3 (SD = 3.4, range 0-12).

Table 1. Depression and Suicide in Current Sample (n=31 with complete baseline)

	N	%
Depression ¹		
Current Depressive Episode	29	93.5%
Past Depressive Episode	22	71%
Suicidal Ideation, Suicidal Behavior, and Non-Suicidal Self-Injury ²		
Lifetime Suicide Attempt	16	51.6%
Lifetime Suicidal Ideation	30	96.8%
Lifetime Non-Suicidal Self-Injurious Behavior	25	80.6%
Recent Suicide Attempt (Past Week)	2	6.5%
Recent Suicidal Ideation (Past Week)	17	54.8%
Recent Non-Suicidal Self-Injurious Behavior (Past Week)	4	12.9%

¹Based on MINI-KID Best Estimate Summary

²Based on Concise Health Risk Tracker – Behavioral Module

Overall Potential Impact/Benefit of the TX-YDSRN Research Efforts to the People of Texas

The TX-YDSRN and associated TX-YDSRN Patient Registry will impact Texas youth and families in several ways.

1. Many Texas communities lack the education, resources, and infrastructure needed for early detection and evidence-based treatment.
 - The clinical sites have been trained and provided methods to implement evidence-based depression care for youth, including universal screening for depression, use of the collaborative care model, and use of measurement-based care (MBC).

These steps will improve patient outcomes, save money, and reduce stigma related to mental health.

2. Many pediatric providers remain reticent to treat mental health concerns, leading to inconsistent identification and treatment of depression (Wissow et al, 2017).
 - The TX-YDSRN Hub team, in collaboration with Node leadership, offers educational and consultation opportunities for partnering clinics. In addition, clinic-level data will be provided in reports and dashboards to partnering clinics.

These trainings and collaborations will lead to enhanced engagement and provide real-time feedback to improve processes.

3. Substantial gaps exist in knowledge related to clinical, functional, behavioral, social, and biological mechanisms of depressive disorders as related to an individual's risk of developing depression, ability to cultivate resilience, and response to treatment.
 - Data from the TX-YDSRN Participant Registry will allow for the identification of risk markers, indicators of onset, long-term (natural) course of disease, and treatment-associated outcomes.

Results from this project will lead to improvements in early and accurate response to depressive symptoms in youth.

4. Large grant opportunities are highly competitive and are often awarded to those with significant past proven research experience, to those with significant pilot data, or to those with access to a large population so that the results might provide more generalized data to be utilized across the nation.
 - The TX-YDSRN Hub includes researchers with significant past proven research experience, in addition to more junior researchers from across the state.

By merging high level research expertise and mentorship for junior researchers, we will be better situated for obtaining future grant funding.

5. While Texas has several large research institutions, many of the Health-Related Institutions across the state are focused primarily on clinical care and do not have significant research infrastructure.
 - Establishing The TX-YDSRN, comprised of the Health-Related Institutions across the state, leverages the infrastructure and expertise of larger Health-Related Institutions to support smaller Health-Related Institutions.
 - Each Node has received significant training, and will continue to receive support and maintenance training, from the TX-YDSRN Hub to ensure high fidelity to research methods.
 - Establishing the TX-YDSRN across a state as varied as Texas will allow for investigation of a more diverse population and provide specific information that can be applied more accurately for each region.

Ultimately, by creating this collaborative Network, many future efforts around our Texas youth will be enriched by leveraging the cultural and economic diversity of our state.

TX-YDSRN FUTURE INITIATIVES

Through the TX-YDSRN, all Node members will have access to pilot data for future grant applications, which will ultimately lead to exponential opportunities for advancement of research across Texas and the possibility of vast and varied populations in Texas who can engage in research with the Network. To date, a Letter of Intent for the Patient-Centered Outcomes Research Institute (PCORI) announcement, “Suicide Prevention: Brief Interventions for Youth – Cycle 3, 2020”, was invited for the full application; if funded, the proposed project would include TX-YDSRN Nodes as sites to test brief interventions for safety planning with suicidal youth.