RTRC Study Protocol

Protocol to Collect Data on a Uniform Set of Data Elements by EB THNP Grantees and SAT TNGP Grantees Using the Behavioral-Telehealth Evidence Collection (B-TEC) Tool

Overview

The high prevalence of behavioral health conditions, shortage of available treatment services, and initial evidence supporting telehealth approaches point to the need for additional, well-designed studies to help build the evidence base to support the further adoption of and reimbursement for telebehavioral health services (both mental health and substance use) to increase access in rural settings. The Rural Telehealth Research Center (RTRC) has been charged by the Federal Office of Rural Health Policy (FORHP) to identify approaches that can be used across the Evidence-Based Telebehavioral Health Network Program (EB THNP) grantees and the Substance Abuse Treatment Telehealth Network Grant Program (SAT TNGP) grantees to enhance the evidence base for telebehavioral health use in rural communities.

Purpose

The purpose of this document is to describe the research design and procedures for a study to routinely collect data on a uniform set of data elements to be submitted by the grantees to RTRC for analysis and dissemination. The ultimate objective of this project is to enhance the evidence base for telehealth in rural settings using a standardized set of data elements related to clinical outcomes, access/utilization, and cost/efficiency measures.

Sample for Data Collection

Three organizations were awarded three-year grants beginning in September 2017 in response to a FORHP notice of funding opportunity (NOFO) for the Substance Abuse Treatment Telehealth Network Grant Program (SAT TNGP) and 14 organizations were awarded three-year grants beginning in September 2018 in response to a FORHP NOFO for the Evidence Based Telebehavioral Health Network Program (EB THNP).

Study Design

Data are to be collected on all patients where telehealth services are used as part of the grant (Telehealth group) and on a 1 to 1 comparison sample of patients who receive comparable services face-to-face (Non-telehealth comparison group). Ideally, grantees will be able to identify clinics or treatment sites that provide face-to-face services that are comparable to those delivered through telehealth, and to patients who are similar to those receiving telehealth services. Collecting data on Non-telehealth comparison groups is an important component of the research design and will enable us to answer

important research questions using a more rigorous research approach. We recognize that collecting these data elements on Non-telehealth comparison sites will present challenges for grantees. Ideally across grantees, we will end up with roughly equal numbers of patients in the Non-telehealth comparison group and the Telehealth group and the patient characteristics (e.g. age, sex, race, ethnicity, insurance coverage, principle diagnosis) will be similar for the two groups.

Data Elements to be Included in Data Collection

In a FORHP-funded project, RTRC identified a set of evidence-based behavioral health data elements appropriate for use in telehealth studies. A list of the 28 data elements is shown in Tables 1-3. These data elements are grouped into five domains: (1) Identification; (2) Demographics; (3) Access; (4) Clinical Outcomes; and (5) Cost Savings/Cost Effectiveness.

Table 1. Data Elements to be Collected Once at Baseline for Each Patient

Domain	Data Element	Description of Data Element
Access	1. Treatment group	Indicates whether the patient is in the telehealth group or the non-telehealth comparison group
ID	2. Treatment Site ID	An ID assigned to each treatment site
ID	3. Patient ID	An ID assigned to each patient that is converted to a non-linkable ID when data are submitted to RTRC
Demographics	4. Age	The patient's age (years) at intake
Demographics	5. Sex	The patient's sex
Demographics	6. Race	The patient's racial group
Demographics	7. Ethnicity	The patient's ethnic group
Cost Savings/ Effectiveness	8. Patient's insurance status	The type of insurance that the patient has at intake
Cost Savings/ Effectiveness	9. Patient travel miles to the initial planned place of behavioral health services	Miles from the patient's location to where the patient plans to receive behavioral health services
Cost Savings/ Effectiveness	10. Patient travel time to the initial planned place of behavioral health services	Travel time from the patient's location to where the patient plans to receive behavioral health services
Cost Savings/ Effectiveness	11. Patient travel miles to next likely source of behavioral health services	Miles from the patient's location to the next likely source of behavioral health services if the planned place of services was not available
Cost Savings/ Effectiveness	12. Patient travel time to next likely source of behavioral health services	Travel time from the patient's location to the next likely source of behavioral health services if the planned place of services was not available

Cost Savings/ Effectiveness	13. Patient likelihood of using next source of behavioral health services	The patient's likelihood of using next source of care for type of service delivered

Table 2. Data Elements to be Collected at Baseline and Monthly for Each Patient (for the first three months)

Domain	Data Element	Description of Data Element
Clinical Outcomes	14. Survey instrument administration timing	The number of weeks from initiation of treatment to when the survey instrument(s) were re-administered
Clinical Outcomes	15. PROMIS Global Health – Mental Health score (component)	Use the PROMIS to track patient functioning scores (mental health component)
Clinical Outcomes	16. PROMIS Global Health – Physical Health score (component)	Use the PROMIS to track patient functioning scores (physical health component)
Clinical Outcomes	17. PROMIS Global Health score (total)	Use the PROMIS to track patient functioning scores (total global health score)
Clinical Outcomes	18. PHQ-9 depression symptoms score	Use the PHQ-9 to assess depression symptoms
Clinical Outcomes	19. GAD-7 generalized anxiety symptoms score	Use the GAD-7 to assess anxiety symptoms
Clinical Outcomes	20. DUDIT-C substance use severity score	Use the DUDIT-C to assess substance use severity

Table 3. Data Elements to be Collected for Each Encounter for Each Patient (for the first three months)

Domain	Data Element	Description of Data Element
Access	21. Treatment type	Whether encounter was planned for telehealth or non-telehealth services
Access	22. Timing of encounter	Number of days since first treatment encounter
Access	23. Therapy scheduling success	Whether or not scheduled session was completed
Access	24. Provider type	Type of provider/clinician seen for behavioral health services during this encounter
Clinical Outcomes	25. Patient's behavioral health diagnosis	The ICD-10 code(s) associated with the diagnosis chiefly responsible for the behavioral health services
Access & Cost Savings/ Effectiveness	26. Treatment service type	CPT code for each encounter
Clinical Outcomes	27. Disposition recommendation	Indicates the provider's recommended disposition for the patient at the end of the encounter
Cost Savings/ Effectiveness	28. Treatment billing	Indicates whether or not the behavioral health services encounter was billed to insurance

Data elements were identified that met multiple priorities: 1) manageable data set that addresses access, clinical outcomes, or cost/efficiency; 2) derived from the published literature on tele-behavioral health and prioritized for usefulness in building the evidence-base; 3) alignment with commonly used clinical outcome assessment instruments to permit benchmarking against published norms; 4) demographics needed for describing the study sample; and 5) HIPAA compliant (no personal health information) to decrease barriers to data collection.

Data Collection Procedure

Data use agreements will be established between RTRC and each of the EB THNP and SAT TNGP grantees. Likewise, the University of Iowa IRB has approved the protocol for collection of data on these measures in conjunction with the grantees. Moreover, FORHP has submitted the data elements and data dictionary to OMB for clearance.

In addition to extensive work to review the related published literature to identify and define the data elements, work is underway on developing a Behavioral-Telehealth Evidence Collection (B-TEC) Tool for data collection and a user manual. Using the B-TEC Tool and B-TEC User Manual, grantees will be responsible for capturing data relevant to this set of data elements, either through working with coders at their participating clinics or centrally reviewing and coding patient records. Grantees are expected to use the B-TEC Tool to input the data, and to export and submit, on a periodic basis, a de-identified patient-level data file to RTRC for analysis. Secure data transmission processes will be employed.

Data Transmission Schedule

RTRC will establish a schedule of data transmission with grantees. The B-TEC Tool will be designed so that data for each patient will be entered only once, at the conclusion of their 3-month follow-up period. Thus, at the conclusion of the three-month follow-up period for a given patient, all of their data will be entered into the B-TEC Tool and submitted to RTRC at the next scheduled data transmission period. This process will simplify data entry for grantees. As shown in Table 1, a set of data elements including demographic data are to be collected when the patient goes through intake or baseline at the beginning of entering into treatment. As shown in Table 2, a set of data elements involving the clinical outcome assessment instruments are to be administered to patients at intake/baseline and then ideally repeated at 1 month, 2 months, and 3 months after the initiation of treatment. This is an ideal schedule and we realize that it may not be attainable for all grantees. The clinical outcome assessment instruments are some of the most important data elements and we ask grantees to make sure that there are at least two repeated administrations within the first 3 months of treatment (e.g., we understand that some grantees are planning for repeated administrations every 6 weeks). As shown in Table 3, a set of data elements involving treatment processes are to be gathered for each encounter during the first 3 months of treatment. We understand that there will be patients who are lost to follow-up during the first 3 months of treatment, in which case the planned number of encounters will not be

realized. The research design follows “intent to treat” principles and thus it is important that data are transmitted for every patient who enters treatment, even if they are lost to follow-up.

Data Management Procedure

Data monitoring and management activities will include: 1) overseeing the progress of the data collection process; 2) quality control measures to identify trends and areas for improvement; 3) identifying root cause of problem; and 4) taking steps to correct processes and reduce or eliminate problems. The aim of the data monitoring and management function is to verify data validity (e.g. responses are within valid value ranges), accuracy (e.g. responses are clinically meaningful), completeness (e.g. low percent of missing data), consistency (e.g. data extraction practices are consistent within and across organizations), and timeliness (e.g. data are transferred to RTRC in a timely fashion). Thus, after each data submission period, RTRC will process the submitted data from each grantee and will create “issue reports” for grantees to review and address.

Analysis and Dissemination

The purpose of this data collection effort is not to evaluate any individual grantee’s efforts, but rather to pool data across grantees to provide sufficient data for statistical analysis aimed at addressing important research questions. The goal will be to contribute to the evidence base by publishing multiple peer-reviewed journal articles. Individual grantee data will be kept confidential and will not be identified in manuscripts.