RTRC Study Protocol

Protocol for Collecting Data on a Uniform Set of Data Elements by EB TNP Grantees for a Data Pooling Study

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 EB TNP grantees to RTRC for pooling, analysis, and dissemination. This document includes the following major sections:

Contents

Overview, Purpose, Study Design, and Research Questions

Overview

Rural areas in the U.S. suffer from a shortage of available healthcare services. Telehealth services have helped to address local health care provider shortages. While initial evidence supports the use of telehealth, additional well-designed studies are needed to elucidate the best applications of telehealth services to increase access in rural settings. The Office for the Advancement of Telehealth (OAT) funded the Evidence Based Telehealth Network Program (EB TNP) grantees and charged the Rural Telehealth Research Center (RTRC) with identifying approaches that can be used across the grantees to contribute to the evidence base for direct-to-consumer telehealth use in rural communities.

Background and Rationale

The shortage of available treatment services in rural areas and initial evidence supporting telehealth approaches point to the need for additional, well-designed studies to build the evidence base to support further adoption of and reimbursement for telehealth services to increase access in rural settings. To address the shortage of available treatment services, OAT has been offering grant funding to existing telehealth networks to further expand their services to rural and underserved areas. Specific to this project, OAT released a Notice of Funding

Opportunity (NOFO) (HRSA 21-082) for the EB TNP focused on direct-to-consumer telehealth. In September 2021, OAT identified 11 grantees to receive 5 years of funding. The NOFO specified that the grantees would submit data to RTRC on patients who receive direct-to-consumer telehealth and a comparable group of patients who receive in-person services. The NOFO specified that RTRC would identify data collection protocols and would serve as the data coordinating center for this grant program.

A priority area for OAT is the clinical effectiveness of telehealth. This proposed project is specifically designed to conduct comparative effectiveness analysis of direct-to-consumer care using telehealth versus in-person services. Further, it will do so across 11 healthcare networks, connecting to multiple rural settings, which will greatly increase the generalizability and applicability of policy-relevant findings.

Direct-to-consumer telehealth was the fastest growing telehealth application prior to the pandemic and was largely provided by a few commercial firms. Research on this delivery model by these commercial firms has been particularly limited. To help mitigate concern about the spread of COVID-19, a different model of direct-to-consumer telehealth became widespread during the public health emergency. This newer model provides direct-to-consumer telehealth through the patients' medical home in established healthcare delivery systems. Given the novelty of this expansion, research on its' use and outcomes in large-scale prospective studies is limited, and to date, few comparative effectiveness studies have been published. Thus, this project is positioned to contribute substantially to the evidence base around telehealth by pooling data across multiple health networks and comparing direct-to-consumer telehealth with in-person care within those established systems.

As research on telehealth grows, efforts to examine the evidence base for telehealth applications, such as conducting systematic reviews of this evidence, are hampered by the disparate structures, processes, and outcome measures used in telehealth research. Policies to reduce the barriers to telehealth and further its useful expansion will rely on sound evidence of its effectiveness. It will be especially meaningful when multiple studies replicate positive findings on a common set of measures. This data pooling project will help advance the field by using a comparative effectiveness research design and pooling data across multiple grantees on a defined set of measures to enhance external validity and generalizability.

Purpose

The ultimate objective of this project is to contribute to the evidence base for telehealth in rural settings by pooling data collected across EB TNP grantees on the services they offer through telehealth and in-person care related to primary care, urgent care, behavioral health, maternal care, substance use disorder, and/or chronic care management services. Pooling data will be possible by using a standardized set of data elements related to access/utilization, cost/efficiency, and clinical outcomes. Enhancing the evidence base will be possible by collecting an adequate amount of patient-specific data, statistically analyzing that data to

compare the telehealth treatment group with the in-person treatment group, and publishing peer-reviewed journal articles of the findings.

Patients in Data Collection Activities

Eleven organizations were awarded five-year grants beginning in September 2021 in response to an OAT NOFO for the EB TNP. Each organization is responsible for recruiting and enrolling patients for both telehealth and in-person data collection.

Study Design and Research Questions

Data are to be collected on all patients where direct-to-consumer telehealth services are used as part of the EB TNP telehealth group and on a comparison group of patients who receive comparable services in-person. Thus, the study design is a prospective, observational, comparative effectiveness study of two active interventions.

The primary research questions that can be investigated focus on the comparative effectiveness of patients who receive direct-to-consumer telehealth services versus a group of similar patients who receive comparable in-person care. Some of these include:

1. How do patient characteristics (e.g., age, gender, race, ethnicity, health insurance type, rurality) compare in direct-to-consumer telehealth services versus in-person care?
2. How do care processes (e.g., indicated by CPT/HCPCS codes, clinician providing care, medication changes) compare in direct-to-consumer telehealth care versus in-person care?
3. How do clinical outcomes (e.g., measured by PHQ-9, GAD-7, SBP/DBP, HbA1c, smoking status, weight) compare in direct-to-consumer telehealth care versus in-person care for patients receiving relevant services?
4. What is the natural course of direct-to-consumer telehealth care compared to in-person care (e.g., how does the frequency and timing of telehealth encounters compare to in-person encounters)?
5. How do maternal care and chronic care management differ when remote patient monitoring is or is not incorporated into these services (e.g., how does the duration of services and clinical outcomes compare)?
6. What is the frequency and pattern of crossovers from one treatment modality to another?
7. How do patient characteristics, care processes, outcomes, natural course of care, and frequency and pattern vary by treatment site type?

In-person (Non-telehealth Comparison) Group Guidelines

This section is meant to clarify the purpose of the in-person (Non-telehealth comparison) treatment group[1] and offer guidelines for identifying a Non-telehealth comparison group. We

[1] Throughout this document we refer to this group as the "in-person treatment group" except in this section when quoting directly from the NOFO which used the term "non-telehealth comparison group".

begin with presenting the wording in the EB TNP NOFO (upon award, grantees are bound to the guidelines presented in the NOFO), then provide guidelines to further clarify criteria for identifying the Non-telehealth comparison group. The EB TNP NOFO definitions for identifying a Telehealth group and a Non-telehealth comparison group are shown below:

Evidence Based Telehealth Network Program
Notice of Funding Opportunity: HRSA-21-082
Appendix: Common Definitions – Page 41

> **"DIRECT -TO -CONSUMER TELEHEALTH:** Direct-to-Consumer (DTC) care is defined as patient initiated telehealth care, typically from their home. In DTC telemedicine, no clinician is physically present with the patient as he or she interacts with the distant telemedicine clinician."
>
> **"COMPARISON GROUP:** Data are to be collected on all patients where telehealth services are used as part of the award (Telehealth group) and on a 1-to-1 comparison sample of patients who receive comparable services in-person (Non-telehealth comparison group). Collecting data on Non-telehealth comparison groups is an important component of the research design and will enable important research questions to be answered using a more rigorous research approach. Ideally, award recipients will be able to identify treatment sites that provide in-person services that are comparable to those delivered through telehealth, and to patients who are similar to those receiving telehealth services. The type of services should be roughly comparable in terms of delivering similar diagnostic and treatment services to patients with similar acuity (for example, an urgent care clinic). Likewise, the patient characteristics (e.g., rural location, age, gender, race, ethnicity, insurance coverage, principal diagnosis, and presenting complaint) should be similar for the two groups – Telehealth group and Non-telehealth comparison group. The most important matching variables are comparable services and presenting complaint and/or principal diagnosis. Following those, the patients should be matched, as a group, on the remaining patient characteristics."

Specific Operational Clarification for Groups

As a first point of clarification, our aim is to identify a group of patients who receive in-person (Non-telehealth comparison group) services that are comparable to the group of patients who receive direct-to-consumer telehealth (Telehealth group) services. We want to be able to compare average characteristics of the two groups and find them similar.

- For example, when we average the ages of the Telehealth group patients and the In-person comparison group patients, the group averages should be similar. It does NOT mean if a grantee has a 60-year-old male in the Telehealth group, that they need to treat a 60-year-old male in the In-person comparison group. Instead, grantees' aim is to identify two groups whose average characteristics are roughly the same.

Specific Operational Clarification for the Most Important Matching Variables

The definition above states, "The most important matching variables are comparable services and presenting complaint and/or principal diagnosis …. The type of services should be roughly comparable in terms of delivering similar diagnostic and treatment services to patients with similar acuity."

Data elements for both the Telehealth group and In-person comparison group will include the type of service delivered as indicated by Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes for each encounter. Summing across patients and encounters, CPT/HCPCS codes for both groups should match reasonably well to meet the objective.

- For example, if a grantee is delivering behavioral health services and in the Telehealth group 55% will receive individual therapy-60 minutes (CPT 90832) and 45% will receive group therapy-60 minutes (CPT 90853), then the In-person comparison group should receive these same types of services in approximately the same proportions.
- As another example, if the grantee is providing diabetes services and in the Telehealth group 70% will receive follow-up office visit (CPT 99211) and 30% will receive diabetes education (CPT 99202), then the In-person comparison group should receive these same types of services in approximately the same proportions.

Another data element for both the Telehealth group and the In-person comparison group will be diagnosis in the form of International Classification of Diseases, Tenth Revision (ICD-10) codes. Operationally, ICD-10 codes for both groups should match reasonably well.

- For example, if a grantee is delivering behavioral health services and the Telehealth group patients will have 60% depression (ICD-10 F32.1) and 40% anxiety (ICD-10 F41.1) as their primary diagnosis, then the In-person comparison group should be patients with the same diagnostic categories in approximately the same proportions.
- As another example, if the grantee is providing chronic care services and the Telehealth group patients will have 50% hypertension (ICD-10 I10), 28% diabetes (ICD-10 E08.9), and 22% congestive heart failure (ICD-10 I50.10) as their primary diagnosis, then the In-person comparison group should be patients with the same diagnostic categories in approximately the same proportions.

We realize an exact match for patients receiving Remote Patient Monitoring (RPM) services is impossible as there is no matching code for in-person. However, we expect grantees to find an In-person comparison group that matches with presenting complaint and/or principal diagnosis.

Specific Operational Clarification for Other Matching Variables

The NOFO definition above states, "The most important matching variables are comparable services and presenting complaint and/or principal diagnosis. Following those, the patients

should be matched, as a group, on the remaining patient characteristics…. The patient characteristics (e.g., age, gender, race, ethnicity, insurance coverage) should be similar for the two groups – Telehealth group and Non-telehealth comparison group."

Data elements for both the Telehealth group and In-person group to be considered for comparison purposes will include the following patient characteristics: age, gender, race, ethnicity, and insurance coverage. Summing across patients, both groups should be reasonably similar on major categories.

- For example, if a grantee is delivering services to a pediatric population for the Telehealth group, then the In-person comparison group should receive similar services in a pediatric population.
- As another example, if the grantee is providing services to patients who are primarily covered by Medicaid in the Telehealth group, then the In-person comparison group should include Medicaid coverage in approximately the same proportion.

As stated above, specific individual-level patient demographics are less important for creating comparable groups than CPT/HCPCS codes and ICD-10 codes, so priority should be given to matching on CPT/HCPCS codes and ICD-10 codes. But major categories of patient demographics should not vary widely between the Telehealth group and the In-person comparison group (e.g., a pediatric Telehealth group should NOT be compared to an adult In-person group).

Identification of Separate Treatment Sites/Clinics/Providers

The NOFO included language that the Non-telehealth comparison group should be identified from similar treatment sites, as follows: "Ideally, award recipients will be able to identify treatment sites that provide in-person services that are comparable to those delivered through telehealth, and to patients who are similar to those receiving telehealth services." Again, the objective is to identify an In-person comparison group that is receiving similar services. This means that the In-person comparison group is NOT comprised of patients who are offered but refuse Telehealth group participation. There are many reasons why patients who are offered telehealth treatment might refuse, which will then create sources of data bias.

- Examples of separate treatment sites could be ambulatory clinics in separate towns that offer similar services for similar types of patients, with one clinic doing so primarily through telehealth and the other clinic doing so primarily in-person.
- Another example could be separate behavioral health clinicians in the same clinic who offer similar therapeutic approaches for similar types of mental health conditions, but by different modalities (telehealth vs in-person).

Geographic Requirements

The NOFO included specific language that the Telehealth group patients must be rural, as shown below (NOFO, page 5):

> "For the purposes of this award, the originating site is the location of the patient at the time the service being furnished via a telecommunications system occurs. The originating site is

required to be solely located in HRSA-defined rural areas in order to receive funds through this award."

We understand that some grantees are providing Telehealth services to rural areas where comparable In-person services are not available. This presents a considerable challenge for some grantees for identifying an In-person comparison group that is also rural. The wording in the NOFO specifies that the Telehealth group must be rural. If identifying an In-person comparison group that is also rural is not possible, then grantees may be able to substitute an In-person comparison group that is not rural. If grantees plan to go that route, then they MUST receive written approval to do so from their OAT Project Officer.

Data Elements to be Included in Data Collection

As stated above, RTRC has been charged by OAT with identifying approaches that can be used across the EB TNP grantees to enhance the evidence base for direct-to-consumer telehealth use in rural communities. A key component of this approach will involve pooling data across the EB TNP grantees. To pool data, the specific data components must be identical. To that end, RTRC identified a set of data elements appropriate for use in this study. The data elements will include specific information that will be entered for each patient upon enrollment and for each encounter during the study period. The goal in identifying data elements was to meet multiple priorities: 1) data elements that are useful for answering important research questions that address access/utilization, cost/efficiency, and clinical outcomes; 2) prioritized for usefulness in contributing to the evidence base including that data are available from multiple grantees; 3) alignment with commonly used clinical outcome measures to permit benchmarking against published norms; 4) including demographics needed for describing the study sample and for use as covariates in analyses; and 5) availability as data fields in electronic medical records used by the grantees to reduce burden. RTRC identified candidate data elements and reviewed each with the grantees. Based on grantee feedback about data collection feasibility, RTRC selected the 27 data elements shown in Tables 1 - 3. Table 1 includes 13 data elements that will be collected at the patient level once, Table 2 includes 7 data elements that will be collected at each encounter over the 12-month follow-up period, and Table 3 includes 7 data elements representing clinical outcomes that will be collected at least quarterly on patients receiving relevant services. The data elements are described briefly below and more detail about each of these data elements are included in the Data Element Dictionary.

Table 1. Data Elements to be Collected at the Patient Level Once

These patient-level data elements are collected once for each patient who receives any health services as part of the EB TNP (for both the Telehealth and In-person groups). These data elements will be collected at enrollment (see below for more explanation). Although these data elements tend to be constant over time, it is possible that some may change during the 12-month follow-up period. However, the data entered should reflect the response options that are most accurate at the time of enrollment.

Data Element	Description of Data Element
1. Patient identification	An ID assigned to each patient that is automatically converted to a non-linkable ID when data are submitted to protect the patients' confidentiality
2. Treatment site ID	An ID assigned to each treatment site
3. EB TNP enrollment date Treatment Site ID	The date when patient enrolled in EB TNP
4. Assigned Treatment Group	Indicates whether the patient is in the telehealth group or the in-person treatment group
5. Age at intake	The patient's age at EB TNP enrollment date
6. Gender	The patient's gender
7. Race	The patient's racial group
8. Ethnicity	The patient's ethnic group
9. Language that the patient is best served in	Indicates whether or not the patient is best served in English
10. Patient's insurance status	The primary type of insurance that the patient has at time of EB TNP study enrollment
11. EB TNP primary service provided to patient ZIP code	Indicates the principal service to be provided to the patient through the EB TNP
12. Patient's residence ZIP code	5-digit ZIP code for the location where the patient resides at time of study enrollment
13. Patient travel miles to planned place of health services	Miles from the patient's residence to where the patient plans to receive health services as part of the EB TNP

Table 2. Data Elements that Are Collected at Each Scheduled Encounter

These encounter-level data elements are to be collected for each patient who receives services through the EB TNP at each encounter for both the Telehealth and In-person groups. All encounters that are scheduled to be delivered as part of the EB TNP should be entered, with the exception of remote patient monitoring data transmissions, which will only be entered once per month (see below for more information on this exception). The duration of data collection is 12 months. Grantees may, and indeed are likely to, provide services beyond the first 12 months after enrollment. But for the purposes of this data pooling effort, data will only be transmitted to RTRC representing the first 12 months of treatment.

Remote patient monitoring presents a special situation for data collection. In remote patient monitoring, multiple services and CPT codes may be billed to Centers for Medicare & Medicaid Services (CMS) monthly. These include patient data that are being monitored (CPT 99457 and 99458) and interpreted (CPT 99091) by clinicians and billed each 30 days. In addition, there are other activities that involve initial set-up and patient education (CPT 99453) and supply of device (CPT 99454) that occur once or periodically. Each of these activities, matching one of these cited CPT codes, should be treated like an encounter for data collection purposes.

Data Element	Description of Data Element
14. Scheduled encounter date	The date when an encounter was scheduled
15. Encounter modality	The modality intended for the encounter
16. Encounter status of the scheduled encounter	Whether the scheduled session was completed, or reason if it was not completed
17. Treatment service type	CPT or HCPCS code(s) for each encounter
18. Clinician type	Type of clinician seen for services during this encounter
19. Patient's diagnosis (ICD-10)	The International Classification of Diseases, Tenth Revision (ICD-10) code(s) associated with the diagnosis established to be chiefly responsible for the services during this encounter
20. Prescribed medications	Prescribed medications that are newly prescribed, modified, renewed, or discontinued during encounter using one form of medication drug code (either NDDF or RxNorm or NDC)

Table 3. Data Elements that Are Collected on Patients Receiving Related Services

These clinical outcome data elements are to be administered repeatedly during treatment to patients as appropriate to the services the patient is receiving. Generally, repeatedly means as often as clinically relevant, but quarterly at a minimum, during the 12-month follow-up period. Skip logic will be used to include these data elements that are relevant to the service the patient is receiving as indicated in the patient-level section of the data collection tool. It is assumed that these data elements will be collected at the time of an encounter. If any of these data elements are available at a time other than an encounter, treat them like they were an encounter and fill in all known data elements.

Remote patient monitoring presents a special situation for data collection. Remote patient monitoring often generates daily data values that are transmitted from the patient to the monitoring site. We do NOT want to collect a large number of such readings so we are limiting the data elements shown below to once per month since that coincides with the billing approach used by CMS.

Data Element	Description of Data Element
21. PHQ-9 depression symptoms score	Use the Patient Health Questionnaire – 9 (PHQ-9) to assess depression symptoms
22. GAD-7 generalized anxiety symptoms score	Use the Generalized Anxiety Disorder Scale – 7 (GAD-7) to assess anxiety symptoms
23. Smoking status	The patient's smoking status
24. Vaping status	The patient's vaping status
25. Blood pressure	The patient's systolic and diastolic blood pressure
26. HbA1c	The patient's hemoglobin A1c value

27. Height/weight/BMI	The patient's height, weight, and/or BMI value

Timing of Collection of Data Elements

The data elements are separated into three sections depending on the timing of data collection. The first section are data elements that are collected once, the second section are data elements that are collected at each scheduled encounter for the first 12 months of follow-up, and the third section are data elements that are collected at least quarterly for the first 12 months of follow-up, but only on those patients receiving pertinent services.

As shown in Table 1, a set of data elements including demographic data are to be collected when the patient is enrolled in the EB TNP treatment activities. Enrollment should occur directly before the initiation of treatment. Enrollment will include collection of "baseline" data that are stable over time and not expected to change during the 12-month follow-up period. Enrollment would likely be when the patient is informed about the study, agrees, and consents to participate. See 'Identification of Enrollment Date' section below.

As shown in Table 2, a set of data elements involving treatment processes are to be gathered for each scheduled encounter during the 12-month follow-up period. We understand that treatment may not extend for the full 12-month follow-up period. In fact, it may only last a few weeks or months. Nevertheless, data should be collected for the full 12-month follow-up period. We also understand that there will be patients who are lost to follow-up (i.e., ceased to seek services for any cause) during the 12-month follow-up period. The research design follows "intent to treat" principles and thus it is important that available data are transmitted for every patient who enters treatment as part of the project. If a patient is lost to follow-up because they stop using the services or move to a different, unaffiliated provider or clinic, they are still considered part of the research project and the data already collected should not be eliminated. Enter all available data on every patient that is enrolled in the study even if they are lost to follow-up and data become unavailable at some point in the 12-month follow-up period.

As shown in Table 3, a set of data elements involving clinical outcome measures will be collected periodically. Specific clinical outcome measures will only be pertinent for patients receiving related services. For example, the HbA1c measure assesses glycemic control and is only pertinent to patients with diabetes or related conditions including gestational diabetes. Pertinent measures are to be collected according to clinical guidance and reported whenever these data are available. For example, HbA1c is recommended to be measured twice yearly in well-controlled diabetics and four times yearly in poorly controlled individuals. But all clinical outcome measures must be administered and reported at least quarterly during the 12-month follow-up period. The clinical outcome assessment instruments are some of the most important data elements, and we ask grantees to make efforts to collect these measures when pertinent to the services they are delivering.

Guidance on Specific Data Elements

Patient Identification

This data element is necessary so that grantees and their treatment sites can identify patients who participate in the EB TNP data collection. It will never be uploaded or saved in the RTRC study database. It is only for grantees and their treatment site's own reference. This serves as a tracking mechanism for data management activities. The patient ID must remain consistent over the duration of the project. When data are transmitted to RTRC, an anonymous (non-linkable) case ID will be automatically assigned to the record and the patient ID used by the grantee/treatment site will never be viewable by RTRC. This patient ID should be entered for Data element number: Patient – 1. It will be entered for that data element but will be replaced by a non-linkable case ID when data transfer to RTRC occurs.

Identification of Treatment Site

A treatment site must be identified for each patient. This site is where the clinician providing the EB TNP service is affiliated. It is the clinician affiliation site and not necessarily where the patient receives any particular treatment/service. The site will be the clinic where the patient is affiliated for ID purposes. This serves as a tracking mechanism for data management activities. The name of the site should remain consistent for the duration of the study. This treatment site should be entered for Data element number: Patient – 2.

Identification of Enrollment Date

This study requires that grantees identify a beginning point for each patient. This beginning point is identified as the enrollment date. The enrollment date should coincide with when baseline data are collected. Baseline data must be collected shortly before EB TNP treatment begins. This date should be entered for Data element number: Patient – 3.

Ideally for the purposes of research, all patients would be receiving treatment for the first time, but we know that is not a realistic expectation and would drastically reduce the number of patients in the study. Thus, we expect that some patients will have received treatment previously and may be in ongoing treatment that is continued during the study, especially for patients receiving chronic care management services. Nevertheless, grantees must identify a date when patients are enrolled in this study and begin the 12-month data collection period.

Patients may only participate in data collection for a single 12-month follow-up period. Over the course of the 5-year grant funding, patients may receive EB TNP services more than once. For example, a patient may receive behavioral health services in Year 2 and again in Year 4. Or a patient may receive one EB TNP service (e.g., primary care) and then later begin to receive a different EB TNP service (e.g., maternal care) if a grantee offers multiple services. However, patients may only contribute data once to this project and only for one primary service.

Identification of Telehealth Versus In-person Treatment

For each patient, grantees identify whether the patient will be assigned to the Telehealth treatment group or the In-person treatment group at the beginning of data collection. This means that the patients in the Telehealth group will primarily receive services via telehealth and the patients in the In-person group will primarily receive in-person services. This assignment is based on intent for the primary mode of treatment. It does not mean that the patients in each group will exclusively receive services that way. There will be crossovers where patients assigned to one group will occasionally receive services akin to the other group. One data element will identify which group the patient was assigned to at the time of enrollment. A separate data element (described later) will identify the treatment modality (e.g., telehealth or in-person) for each encounter. This assignment group should be entered for Data element number: Patient – 4.

Identification of Primary Service Provided to Patient

The EB TNP NOFO identified six services as the focus of treatment activities, and the grantees indicated which services they plan to deliver. At the time of enrollment, a single, primary service must be identified for each patient. If grantees are offering multiple services, it is possible the patients will receive more than one service through the EB TNP, however only one service must be chosen as the principal service for data collection purposes. Some grantees plan to offer remote patient monitoring as part of chronic care management or maternal care services, while other grantees will offer these services without remote patient monitoring. Thus, select the response option for chronic care management and maternal care services that indicates whether or not remote patient monitoring will be part of this service. This data element will be used in skip logic to open clinical outcome data elements that are pertinent to each service and hide clinical outcome data elements that are not relevant. This primary service should be entered for Data element number: Patient – 11.

Identification of Encounter Modality

This data element captures for each encounter, whether it was in-person or via telehealth, and if by telehealth, which modality (i.e., video, phone, or remote patient monitoring). Patients in the Telehealth Group may, at times, be seen in an in-person encounter. Likewise, patients in the In-person Group may, at times, be seen in a telehealth encounter. The modality for each encounter should be entered for Data element number: Encounter – 2.

Data Collection Procedure

Data transfer and use agreements (DTUAs) will be established between RTRC and each of the EB TNP grantees. The University of Iowa Institutional Review Board (IRB) will approve the protocol for transmission of data to RTRC by the grantees. Grantees are responsible for

securing IRB approval from their own institution for data collection and transmission to RTRC, which may involve establishing DTUAs with their participating sites. OAT will submit the data elements and data dictionary to the Office of Management and Budget (OMB) for clearance.

RTRC will create a Direct-to-consumer Telehealth Evidence Collection (D-TEC) Tool which will be used for data collection and a D-TEC User Manual that will provide guidance on its use. Grantees will be responsible for capturing data relevant to the data elements, either through working with coders at their participating sites or centrally reviewing and coding patient records. Grantees are expected to input the data in REDCap® using a link provided by RTRC as requested by RTRC on a periodic basis. Secure data transmission processes will be employed.

Data Transmission Schedule

RTRC will establish a schedule for periodic data transmission with grantees. The D-TEC Tool will be designed so that encounter-level data for each patient will be entered on an on-going basis. This will aid in spreading the workload for data entry across the grant period. The D-TEC Tool will be designed so that encounter-level data can be updated at any point during the 12-month data collection period for each patient. This means that if updated or formerly missing information becomes available, it can be entered and old data can be written over, replacing the previous data with corrected or updated data. However, for patient-level data that are to be collected at the time of patient enrollment, the D-TEC Tool will be designed to "lock" the data once it is submitted.

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 inputted 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. Analyses will only be presented in aggregate form. Individual grantee, treatment site, and patient data will be kept confidential and will not be identified in manuscripts. The goal will be to contribute to the evidence base by publishing multiple peer-reviewed journal articles.

Statistical analyses will involve multiple steps. Differences in characteristics of patients who used telehealth versus in-person treatment will be described. Regression models (logistic for binary, linear for continuous variables, Poisson or negative binomial models for count data) will be used to test for differences between the telehealth and the in-person treatment groups. Models will be run for any telehealth use and also by frequency of telehealth utilization to explore dosing effects. Multivariable regression models will be used to estimate effect sizes for covariates of interest. Covariates of interest will include patient characteristics (e.g., age, sex, race, ethnicity, diagnosis, insurance) and provider/service type. Data transformations will be made when necessary to satisfy any underlying statistical assumptions. In addition to point estimates of comparative effectiveness, associated confidence intervals will be produced.

We offer this document as the protocol governing RTRC collection of data using the D-TEC Tool. If you have additional questions, please contact Kim at RTRC (kimberly-merchant@uiowa.edu).