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Research & Policy Brief

Data Element Identification and Data Collection Procedures for the HRSA Direct-to-Consumer Evidence Based Telehealth Network Program

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Introduction and Background

The shortage of available health care services in rural areas in the U.S. may be mitigated by accessing telehealth services, especially for direct-to-consumer (DTC) telehealth. DTC telehealth is defined as patient-initiated telehealth care, typically from their home. While considerable evidence supports the use of telehealth, additional well-designed studies are needed to identify the best applications of telehealth services to increase access in rural settings. To address these needs, the Office for the Advancement of Telehealth (OAT) in the Health Resources and Services Administration (HRSA) has been offering grant funding to existing telehealth networks to further expand their services to rural areas. Specific to this project, OAT released a Notice of Funding Opportunity (NOFO) (HRSA 21-082) for the Evidence Based Telehealth Network Program (EB TNP) focused on DTC telehealth. In September 2021, OAT identified 11 grantees to receive 5 years of funding. The NOFO specified that the grantees would submit data to the Rural Telehealth Research Center (RTRC) on patients who receive DTC telehealth and on a comparable group of patients who receive in-person services. The NOFO specified that RTRC would identify data collection elements and protocols, and subsequently serve as the data coordinating center for this grant program.

Key Findings

- Candidate data elements were identified through a review of previous data coordination projects and grantee service plans.
- The resulting inventory was reviewed with the 11 grantees for feasibility and applicability to their services.
- The final set of 27 data elements will be reported by the Evidence Based Telehealth Network Program (EB TNP) grantees on direct-to-consumer (DTC) telehealth and in-person services they deliver.
- The resulting data will be subjected to comparative effectiveness statistical analysis to contribute to the evidence base on DTC telehealth services.

Prior to the pandemic, DTC telehealth was the fastest growing telehealth application and was provided largely by a few commercial firms.[1] Research on this delivery model by these commercial firms has been particularly limited.[2-4] To help mitigate concern about the spread of COVID-19, a different model of DTC telehealth became widespread during the pandemic.[5] This model provides DTC telehealth through the patients' medical home in established health care 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.

Purpose

The 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 DTC telehealth and in-person care related to primary care, urgent care, behavioral health, substance use disorder, maternal care, 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 patients receiving telehealth with patients receiving treatment in-person, and publishing peer-reviewed journal articles of the findings.

Measure Criteria and Review Process

To pool data across the EB TNP grantees, 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 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 is to meet multiple priorities: (1) 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) aligned with commonly used clinical outcome measures to permit benchmarking; (4) inclusive of demographics needed for describing the study sample and for use as covariates in analyses; and (5) available as data fields in electronic medical records used by the grantees to reduce burden.

This project began with a review of published literature for studies on DTC telehealth. Few empirical studies were identified. Those in the literature were primarily from specialized business models rather than services integrated into a patient's medical home. Consequently, the data elements used in previous data collection efforts by RTRC were reviewed for applicability to this program. Categories of potential data elements were created and shared with the grantees in the form of a data element dictionary. Grantees were asked to review each proposed data element and indicate the degree to which each was feasible for data collection. This feedback from grantees was used to narrow the data element list. For example, household size and number are included variables in the Uniform Data Set (UDS) for Federally Qualified Health Clinics, but a third of grantees indicated that they did not collect data on those variables, so those elements were excluded from further consideration.

Final Selection of Data Elements

Based on grantee feedback about data collection feasibility, RTRC selected the 27 data elements shown and described briefly in Table 1. The first 13 data elements will be collected at the patient level once, the next 7 data elements will be collected at each encounter over the 12-month follow-up period, and the final 7 data elements representing clinical outcomes will be collected at least quarterly on patients receiving relevant services.

Data Collection Procedure

Data transfer and use agreements (DTUAs) have been established between RTRC and each of the EB TNP grantees. The University of Iowa Institutional Review Board (IRB) has approved the protocol for transmission of data to RTRC by the grantees. Office of Management and Budget (OMB) clearance will be obtained by OAT prior to data collection. RTRC has created a DTC Telehealth Evidence Collection (D-TEC) tool, which will be used for data collection, and a D-TEC user manual that provides 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 into an online tool developed in REDCap®, a data capture software program. Using REDCap®, de-identified D-TEC data will be available for download by RTRC for analysis. Secure data transmission processes will be employed. The D-TEC tool is designed so that encounter-level data for each patient will be entered at least quarterly. Grantees will be able to update or complete previously missing information at any time. However, patient-level data that are to be collected at the time of patient enrollment, should reflect conditions at that time and will likely remain unchanged. The D-TEC tool and D-TEC user manual underwent extensive testing by RTRC during development. Grantees reviewed both the D-TEC tool and manual and provided feedback. Adjustments were based on their feedback. Training materials will be developed prior to release once OMB review is finalized.

Table 1. Data Elements to be Collected, Their Level and Description

Data Element	Description of Data Element
Patient-Level	
1. Patient identification	ID assigned to each patient that is automatically converted to a non-linkable ID when data are submitted to protect the patient's confidentiality
2. Treatment site ID	ID assigned to each treatment site
3. EB TNP enrollment date	Date when patient enrolled in EB TNP
4. Assigned treatment group	Indicates whether the patient is in the telehealth treatment group or the in-person treatment group
5. Age	Patient's age at EB TNP enrollment date
6. Gender	Patient's gender
7. Race	Patient's racial group
8. Ethnicity	Patient's ethnic group
9. Language	Language that the patient is best served in
10. Patient's insurance status	Patient's primary type of insurance
11. EB TNP primary service provided to patient	Principal service to be provided to the patient through the EB TNP
12. Patient's residence ZIP code	Patient's residence 5-digit ZIP code
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
Encounter-Level	
14. Scheduled encounter date	Date when an encounter was scheduled
15. Encounter modality	Modality intended for the encounter (i.e., video telehealth, telephone telehealth, remote patient monitoring, in-person service)
16. Encounter status	Whether the scheduled session was completed, or reason if 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 diagnoses	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	NDDF or RxNorm or National Drug Code (NDC) for each prescription medication that was prescribed or changed during this encounter
Outcomes Collected at Least Quarterly	
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	Patient's smoking status
24. Vaping status	Patient's vaping status
25. Blood pressure	Patient's systolic and diastolic blood pressure
26. HbA1c	Patient's hemoglobin A1c value
27. Height/weight/BMI	Patient's height, weight, or BMI value

Data Management Procedure

Data monitoring and management activities will include the following: (1) overseeing the progress of the data collection process; (2) engaging in quality control measures to identify trends and areas for improvement; (3)

identifying root causes of problems; 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 available for RTRC utilization 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 be presented only in aggregate form. Individual grantee, treatment site, and patient data will be kept confidential and de-identified at submission 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. Covariates of interest will include patient characteristics (e.g., age, sex, race, ethnicity, diagnosis, insurance) and provider/service type. In addition to point estimates of comparative effectiveness, associated confidence intervals will be produced.

Significance

As telehealth use 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. Multiple studies that replicate positive findings on a common set of measures will be especially meaningful. 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. Given the growth of DTC telehealth during the COVID-19 pandemic, efforts to define a common set of data elements are timely and will contribute to establishing the evidence base examining their effectiveness.

Notes

1. Jain T, Lu R J, Mehrotra A. Prescriptions on demand. The growth of direct-to-consumer telemedicine companies. *JAMA.* 2019;322(10):925-26.
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4. Uscher-Pines L, Mulcahy A, Cowling D, Hunter G, Burns R, Mehrotra A. Access and quality of care in direct-to-consumer telemedicine. *Telemedicine and e-Health*. 2016. 22(4): 282-7.
5. Portnoy J, Waller M, Elliott T. Telemedicine in the era of COVID-19. *J Allergy Clin Immunol Pract.* 2020;8:1489-91.

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