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Research & Policy Brief

Development of metrics and a protocol to clinically evaluate the HRSA Behavioral Health Integration program within the Evidence-Based Telehealth Network Program

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Key Actions

- Performed a scoping review which revealed only a limited number of published research studies from telehealth applications that integrate primary care and behavioral health.
- Identified key data elements and instruments to support data collection efforts through reviews of existing tools, consultations with grantees funded under the Evidence-Based Telehealth Network Program (EB TNP), and engagement with the Office for the Advancement of Telehealth (OAT) within the Health Resources and Services Administration (HRSA).

Introduction

Primary health care is considered the point of entry into the health care system and is frequently the bridge to acquiring behavioral health care services.[1,2] However, many underserved and rural communities have limited access to services for behavioral health conditions (e.g., mental health, substance use disorders) within and outside of the primary health care setting.[3-6] Advances in telehealth have provided viable opportunities for accessing health care needs, including tele-behavioral health care delivery across various settings.[7-9] With this expansion of tele-behavioral health care service options, an emerging challenge is how to optimize the integration of these services into primary care to coordinate care across a patient's team of clinical providers.

Although behavioral telehealth services that are integrated into primary care have increased, research on their effectiveness has remained scant. As such, there is a critical need for well-designed studies that can inform the adoption and reimbursement for telehealth services in rural and underserved areas. To address this need, the Office for the Advancement of Telehealth (OAT) within the Health

Resources and Services Administration (HRSA) released a Notice of Funding Opportunity (HRSA 24-010) for a new Evidence Based Telehealth Network Program (EB TNP). OAT granted funding to 26 organizations across diverse settings in the U.S. to integrate behavioral health into primary care.[10] The Remote care and Telehealth Research Center (RTRC) was charged with serving as the data coordinating center for this grant program, which requires performing comparative effectiveness research in which data from all grantees are pooled to evaluate the effectiveness of behavioral health integration (BHI) in primary care settings. This research requires systematic and consistent reporting of clinical and operational measures of telehealth and in-person care models in terms of patient demographics, care processes, costs, and clinical outcomes.

Drawing on the success of nationally implemented common data models in health systems, the RTRC developed a protocol to study the practical implementation of behavioral health integration into primary care. This protocol employs a comparative effectiveness research design that aggregates data from 26 HRSA grantees using a standardized set of common data elements and validated clinical outcome instruments. By doing so, the protocol aims to enhance internal validity, by minimizing bias and ensuring data quality, and external validity by improving the generalizability of findings across diverse care settings. Here we describe the first stage of implementing this design.

Process

Overview. To identify common data elements and develop a study protocol, the RTRC took a series of steps that built on previous projects in which we pooled data and integrated feedback from the HRSA/OAT program team and the 26 HRSA grantees (Table 1). At that point, the data element dictionary and study protocol were finalized and shared with the HRSA grantees (Table 2). Data collection is set to commence as soon as clearance from the Office of Management and Budget (OMB) is obtained.

Process for Development of Data Collection. In Table 1, we describe each step of the process used to develop the data element dictionary and evaluation tools. We also describe the role of each group (i.e., RTRC, HRSA/OAT, and the grantees).

- Step 1: OAT, RTRC, and grantees started meeting in October 2024 to learn about their projects
- Step 2: RTRC worked with a research librarian to conduct a scoping review of the incorporation of telehealth into various integration care delivery models, such as the Collaborative Care Model
- Step 3: Only a limited number of studies incorporated BHI and telehealth, leading to a consensus that the RTRC would need to specify data elements designed to characterize the integration of behavioral health into primary care. RTRC began this process by identifying data elements that had successfully captured patient characteristics and encounter processes in previous similar projects. RTRC administered two rounds of surveys to the grantees to capture their feedback about the feasibility and practicality of each element.
- Step 4: The RTRC team subsequently identified a list of behavioral health instruments employed clinically for evaluation. The RTRC used this list to create an online survey and provided space for identifying other instruments that grantees planned to use. From the 27 instruments that were identified, we considered three aspects for inclusion as part of data collection:
    1) clinical value and prevalence of use among grantees;
    2) confirmation in the research literature of their validity and sensitivity to treatment effects; and

3) brevity for practical implementation across sites.

RTRC therefore proposed seven instruments for use across all sites as appropriate, meaning that only specific instruments matching each patient’s condition would be administered. RTRC drafted the initial study protocol document and data element dictionary and solicited feedback from grantees about feasibility and practicality of the protocol and each data element.

- Step 5: Adjustments were made to address grantee feedback and documents were prepared showing the specific instrument wording and instructions along with scoring directions.
- Step 6: The final study protocol document, data element dictionary, and clinical outcome instrument document were delivered to OAT for OMB review and to grantees. Throughout this entire process, OAT and RTRC met with individual grantees to answer questions, clarify processes, and work through potential challenges to data collection.

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) has approved the protocol for transmitting data to RTRC by the grantees. OMB approval for data collection will be obtained by OAT prior to data collection. RTRC will create a behavioral health INtegration Telehealth Evidence Collection (IN-TEC) tool, which will be used for data collection, and an IN-TEC user manual to provide guidance on the tool’s use. The IN-TEC tool will be developed in REDCap® (an online data capture software program) and will be used by grantees to record data elements identified in the protocol. Data input of reviewed and coded patient records will be provided either by participating grantee sites or centrally by the grantee organization. RTRC will be able to regularly download (using secure data transmission processes) a limited dataset for analysis. Grantees will receive quarterly reports detailing their data collection progress including assessments of data quality. The IN-TEC tool and IN-TEC user manual will undergo extensive testing by RTRC during development. Grantees will be given opportunities to review both the IN-TEC tool and manual and provide feedback. Adjustments will be made to both based on grantee feedback. Training materials will be developed prior to release once OMB review is finalized.

Significance

The purpose of this protocol is to develop a common data model to use across grantee sites. The goal will be to contribute to the evidence for incorporating behavioral health into primary care services by publishing multiple peer-reviewed journal article.

Table 1. Steps Involved with Protocol Development and Stakeholder Roles

Steps	**Stakeholders**			**Notes/Comments**
	RTRC	**HRSA/OAT**	**Grantees**	
1. Conduct introductory meetings with individual grantees	• Attended by all groups to review grantee's project plans, how behavioral health services would be integrated into primary care, and RTRC data collection expectations			• Provided grantees an overview of planned approach • Gave RTRC an opportunity to ask about services provided by grantees and plans for data collection
2. Perform a scoping review of behavioral health integration	• Identified integration care delivery models • Worked with a research librarian to identify studies examining integration care delivery models via telehealth • Considered how behavioral health integration would affect data elements	• Reviewed process and findings and provided feedback	• Surveyed grantees on which integration care delivery model they planned to use	• Integration care delivery models are evidence based, but literature on use via telehealth is limited
3. Identify data elements that had successfully captured patient characteristics and encounter processes in previous similar projects	• Identified data elements based on prior approaches and integrated care model concepts • Used online survey for grantees to indicate concerns about suggested data elements. • Reviewed preliminary feedback from grantees and aggregated findings to understand feasibility of data element collection	• Reviewed drafts and provided feedback	• Responded to online survey • Rated feasibility of data collection of each variable	• Candidate data elements were rated across two surveys focusing on data collected at the patient-level and encounter-level
4. Review behavioral health instruments to use as outcome measures	• Used online survey to collect list of behavioral health instruments that grantees planned to use • Reviewed behavioral health instruments against criteria (see notes) • Identified candidate instruments to use as clinical outcome measures	• Reviewed drafts and provided feedback	• Surveyed grantees on which behavioral health instruments they planned to use	• From all available instruments, we assessed: feasibility and ease of implementation, documentation in published literature, clinical relevance and meaningfulness, appropriateness for repeated application, and sensitivity to change

Table 1. Steps Involved with Protocol Development and Stakeholder Roles

Steps	Stakeholders			Notes/Comments
	RTRC	HRSA/OAT	Grantees	
5. Disseminated draft of study protocol and data element dictionary	• Drafted a data element list based on prior approaches and integrated concepts from BHI studies • Distributed online survey for grantees to indicate concerns about suggested study protocol and data elements • Reviewed feedback from grantees and made adjustments to address feasibility	• Reviewed drafts and provided feedback	• Responded to online survey	• Candidate data elements were largely approved by grantees • Grantees raised feasibility concerns with certain aspects of the study protocol; RTRC made revisions to address these concerns
6. Disseminated final study protocol document, data element dictionary, and clinical outcome instruments	• Delivered final study protocol document, data element dictionary, and clinical outcome instruments with scoring instructions to OAT for OMB clearance • Provided final versions of documents to grantees	• Reviewed and approved deliverables for dissemination to grantees		

Abbreviations: BHI = Behavioral health integration; OAT = Office for the Advancement of Telehealth; OMB = Office of Management and Budget; RTRC = Remote care and Telehealth Research Center

Table 2 – Data Elements, Level, and Description

Data Element	Description of Data Element
Patient-Level	
1. Patient identification	ID assigned to each patient. To protect the patient's confidentiality this ID is automatically converted to a non-linkable ID when data are accessed by RTRC
2. Date of program enrollment	Date when patient was enrolled in BHI EB TNP
3. Primary care site ID	ID assigned to patient's primary care site
4. Date of most recent primary care visit	Either the date of the primary care visit when program enrollment occurred or the date of the most recent primary care visit prior to program enrollment
5. Assigned treatment group	Indicates whether the patient is in the telehealth treatment group or the in-person treatment group
6. Age at enrollment	Patient's age at BHI EB TNP enrollment date
7. Sex	Patient's sex
8. Race	Patient's racial group
9. Ethnicity	Patient's ethnic group
10. Primary insurance	Patient's primary type of insurance at time of BHI EB TNP enrollment
11. Secondary insurance	Patient's secondary type of insurance at time of BHI EB TNP enrollment
12. Patient's ZIP code	Patient's residence 5-digit ZIP code
Encounter-Level	
13. Encounter type	Visit type for encounter (i.e., primary care, behavioral health)
14. Encounter date	Date when an encounter occurred
15. Encounter site ID	ID assigned to site where encounter occurred if in-person or where clinician is affiliated if via telehealth
16. Encounter modality	Modality for the encounter (i.e., video telehealth, phone telehealth, in-person service)
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	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 behavioral health medication that was prescribed or changed during this encounter
Outcomes Collected at Baseline and Repeatedly in Subsample of Patients as Applicable	
21. PHQ-9 depression symptoms score	Use the Patient Health Questionnaire – 9 (PHQ-9) to assess depression symptoms. Use the PHQ-A for ages 17 and under
22. GAD-7 generalized anxiety symptoms score	Use the Generalized Anxiety Disorder Scale – 7 (GAD-7) to assess anxiety symptoms.
23. C-SSRS symptoms score	Use the Columbia Suicide Severity Rating Scale (C-SSRS) to assess suicide risk.
24. PCL-5 PTSD symptoms score	Use the PTSD Checklist for DSM-5 (PCL-5) to assess post-traumatic stress disorder symptoms
25. NICHQ Vanderbilt Assessment Scales scores	Use the NICHQ Vanderbilt Assessment Scales to assess attention deficit hyperactivity disorder (ADHD) symptoms
26. AUDIT-C alcohol use	Use the AUDIT-C to assess alcohol use
27. DUDIT-C substance use	Use the DUDIT-C to assess substance use

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