PROJECT INFORMATION

Project Title: Using Telehealth to Deliver Developmental, Behavioral, and Mental Health Services in Primary Care Settings for Children in Underserved Areas
Project Start Date: 5/1/2013
Project End Date: 4/30/2016

Specific Aims:

Our goal is to integrate developmental, behavioral, and mental health services into pediatric primary care using a telehealth model that will be tested with children in low-income, urban communities.

Primary care clinicians should provide comprehensive, family-centered care that addresses unmet developmental, behavioral, and mental health (DB/MH) needs. However, data indicate that most children who need DB/MH services do not receive them. Access to DB/MH services is often severely limited, while a lack of communication and coordination between specialty and primary care providers often prevents optimal outcomes even for those with DB/MH access.

A patient-centered model for telehealth has the potential to transform DB/MH services by integrating them into primary care. If DB/MH providers are able to deliver services remotely, large numbers of children across multiple small but conveniently located primary care clinics can gain ready and sustainable access to DB/MH specialty providers.

In partnership with a multi-site, Los Angeles-area federally qualified health center (FQHC) consortium, North East Valley Health Corporation (NEVHC), we will use telehealth to integrate DB/MH services into primary care for low-income, publicly insured children. This new delivery model for DB/MH services will be compared to a typical in-person visit model in which children receive DB/MH specialty care through referral to community DB and MH providers. This study will examine whether a telehealth DB/MH delivery model can be an effective, efficient, and family-centered way to provide integrated DB/MH services to children in low-income communities.

Aim #1: To customize a telehealth delivery system for the provision of child DB/MH services within primary care for low-income children (ages 5-12) in a network of federally-qualified health centers. Customization will occur through qualitative interviews with FQHC parents, clinicians, and staff, and through partnership with a stakeholder advisory board.

Hypothesis #1: Parents and providers will describe needs and barriers regarding DB/MH services that can be addressed using a telehealth delivery system that integrates DB/MH into primary care.

Aim #2: To compare a customized telehealth delivery system that provides specialty child DB/MH services in a primary care clinic to a typical in-person, community-based delivery system using a randomized controlled trial study design. Primary outcomes are family-centered, parent-reported outcomes including parent experiences of care, accessibility, timeliness, and child DB/MH clinical outcomes.

Hypothesis #2: Parents using the telehealth system will report better family-centered experiences with care and better child DB/MH outcomes.

Technical Abstract:

Background: Primary care clinicians should provide comprehensive, family-centered care that addresses

PCORI RESEARCH PLAN

RESEARCH STRATEGY

Part A: Background and Significance

Impact of the Condition on the Health of Individuals and Populations (*Criterion 1*)

1. Primary care clinicians (PCCs) play a central and critical role in mental health care for children.

Over 20 preventive care visits are recommended throughout childhood and adolescence.[1, 2] At these visits, PCCs have a unique opportunity to identify and address important behavioral, developmental, and mental health issues that could have significant and lifelong impacts. This opportunity is often missed, particularly when needed developmental, behavioral, and mental health (DB/MH) services extend beyond the capability of the PCC. Children who desperately need specialty care for assessment, diagnosis, treatment, or management of DB/MH problems often get lost in a referral system that is inundated with barriers to referral completion and visit attendance.[3]

Children with obvious and clearly defined DB/MH symptoms may present to their PCC with a chief complaint of a DB/MH concern, seeking diagnosis and/or management. Pediatric patients will face a number of barriers in this scenario, including a national shortage of child DB/MH specialists, long appointment wait lists for these specialists, limited insurance coverage of DB/MH services, and a lack of specialists willing to accept patients with lower-reimbursing insurances even when services are covered.[4-7]

Most children, however, may not present to their PCC with such a clear chief complaint of a DB/MH concern. Many children with DB/MH needs can be identified through parental concerns brought up during primary care visits, as well as through the routine screening and surveillance that is an integral part of pediatric primary care preventive visits—screening for family psychosocial concerns (e.g., divorce, parental depression, parental substance abuse), and screening and surveillance for behavioral, developmental, and social problems (e.g., autism, developmental delay, behavioral problems, school failure, ADHD).[8, 9] Screening and surveillance for these concerns is a recommended part of pediatric preventive care.[1] Pediatric PCCs are critical for identifying these children and linking them with DB/MH services.

2. As many as one in five U.S. children suffer from DB/MH problems, but just a small minority of those who need DB/MH services receive them.

Child DB/MH problems were first described as the part of the "new morbidity" in 1975.[10] Public health interventions, such as immunizations, substantially decreased the incidence of infectious disease and its serious consequences in children. The leading causes of morbidity during childhood shifted away from microbes to chronic disease, unintentional injuries, violence, and psychosocial and DB/MH concerns.[11-13] Administrative data, as well as data from primary care provider and parent report suggest that many children with DB/MH concerns are not adequately identified or managed in primary care.[14-20]

Research indicates that 15- 20% of U.S. children suffer from a DB/MH disorder, but nearly 80% of those who need DB/MH services don't receive them.[8, 17, 19, 21]For many children with a DB/MH problem, the PCC may be the only professional that they see who has the potential to identify and treat the problem. Despite this critical role of the PCC for children, and the frequency that children present to their PCC with a DB/MH concern, most children leave those visits with their DB/MH problems unidentified, undiagnosed, and untreated.[8, 22]

DB/MH needs that go unaddressed have enormous consequences for child health and well-being, family functioning, and eventual adult health and productivity. For example, children who suffer from depression are more likely to encounter academic problems, suicide attempts, underemployment, and early parenthood as adults.[23]

While DB/MH concerns affect a significant proportion of the pediatric population, Black and Latino children and children living in poverty are often affected at higher rates, and are consistently less likely to receive DB/MH services.[15, 17, 24-29]

3. Most U.S. children do not have access to DB/MH specialists, either due to insurance and/or out-of-pocket expenses, or a lack of perceived need for DB/MH specialists.

The reasons for such low utilization of DB/MH services for children with DB/MH problems are likely multifactorial, particularly for children in low-income and minority populations. First, parents often lack general information about child DB/MH care. In particular, parents may be unaware of insurance coverage and benefits for DB/MH services, and how or where to find appropriate clinicians to provide these services.[4, 6] They may not recognize their child's behavioral problems as a concern to seek medical care for, and when they do, they may face barriers related to the stigma of DB/MH disorders and DB/MH specialty care clinics and clinicians.[6, 15, 24, 25, 30-33]

There are many other significant barriers to access that extend beyond parental perceptions and knowledge regarding access. First, there is a nationwide shortage of child DB/MH providers. One of the greatest shortages of pediatric subspecialists in the U.S. exists within developmental/behavioral pediatrics (DBP).[34] There is also a severe shortage of child psychiatrists across the U.S.; in urban and suburban areas, the shortage is most pronounced in high-poverty communities.[5, 35] Additionally, in these settings, many clinicians utilized to provide child mental health services are not child psychiatrists, and do not have prescribing authority.[3]

Innovation and Potential for Improvement through Research (*Criterion 2*)

Several systematic reviews, reports, studies, and commentaries on child DB/MH services have suggested that collaboration between primary care and subspecialty DB/MH providers is a key solution to improving DB/MH utilization among children who need DB/MH services.[36-40] Providing DB/MH services using primary care or subspecialty clinicians in completely separate systems of care often results in sub-optimal care for children receiving care in either setting.[41] Telehealth for DB/MH may been one way both to connect patients to subspecialty care and to create a "virtual" co-location of services in primary care settings in rural areas where access to DB/MH care is almost non-existent.[42] Data from more preliminary studies and reviews suggest that such a model could be successful in improving utilization and coordination of DB/MH services through primary care for children in urban areas that have similarly poor access to DB/MH specialty services.[43, 44]

1. Evidence suggests that telehealth is an effective tool to improve access to specialty care for previously underserved populations; however, there are no data to help clinicians and parents make informed decisions in selecting delivery models for DB/MH specialty care, or what the best delivery systems might be for providing DB/MH services in primary care settings.

Telehealth has been defined as "the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health education".[45] There are two main modalities for telehealth clinical care encounters—asynchronous (i.e., store-and-forward) and videoconferencing. Store-and-forward is an asynchronous form of telehealth that involves the collection and transmission of health-related data (e.g. school records, lab results, images, audio, video) for interpretation or analysis. In contrast, telehealth encounters that occur through videoconferencing are real-time encounters between patients and providers that are similar to traditional visits. There is some evidence from both adult and pediatric studies to suggest that outcomes related to diagnosis and management, clinical outcomes, and access to care for telehealth encounters may be comparable to in-person clinical encounters.[42, 46-49] However, the data is limited—most studies do not employ a randomized design, and those that do often have small sample sizes (<50). Further, the evidence comes from studies across various patient populations, age groups, and specialties. While the evidence on telehealth encounters in general is promising, there are simply not enough well-designed studies in the area of pediatric DB/MH to help clinicians and patients make informed decisions about the best delivery systems for care.[50, 51]

Several uncontrolled studies have demonstrated the feasibility of using telehealth for DB/MH services in the setting of pediatric primary care, parent satisfaction with the delivery system, rapport building between parents and providers, and accurate diagnostic assessments and parent utilization of services via telehealth.[44, 52-54]

To date, there are only three published, peer-reviewed randomized controlled trials that have examined telehealth videoconferencing for child DB/MH services. Nelson, et al 2003 enrolled 28 depressed children ages 8-14 and randomized them to depression treatment via videoconferencing or traditional in-person visits.[55] The children in the intervention group had significantly faster improvement in depression symptoms as measured by the Children's Depression Inventory. Elford, et al 2003 enrolled 23 children ages 4-16 to each receive a videoconference and in-person visit in a randomized order (e.g., videoconference encounter first, in-person visit second); the authors reported that the diagnoses and treatment recommendations were similar in 96% of the sessions.[56] In Glueckauf, et al, researchers found no differences in clinical outcomes among 22 rural teenagers with epilepsy and psychosocial problems receiving counseling via telehealth videoconferencing compared to in-person visits.[57]

Clearly, there are wide gaps in our understanding and knowledge regarding telehealth as a delivery model for pediatric DB/MH services. Specifically, research questions that remain unanswered are if providing DB/MH services in primary care settings through telehealth can a) enhance the family-centeredness of care, b) increase accessibility and timeliness of care, c) enrich parent experiences of care, and d) improve child DB/MH clinical outcomes.

Impact on Health Care Performance (*Criterion 3*)

This proposed project has the potential to have a significant impact on healthcare performance. The structure→ process→outcome model, developed by Donabedian, serves as the conceptual model for this proposal by demonstrating how the structure and processes of a system of care affect the eventual outcomes.[58, 59]

In the current structure of care, primary care services are in a separate location from DB/MH services. Coordination and communication between the two clinical settings is often not ideal. In the process of usual care, children with a DB/MH need present to or are identified by the PCC and receive a referral for DB/MH specialists at a separate location. The parent then must schedule an appointment with the DB/MH specialist for some time in the future, often with a long waiting period for the next available appointment. When the parent arrives at the DB/MH care location for their child's first visit, they will likely encounter unfamiliar clinic staff and settings, and an uncertainty that the specialist's recommendations will be communicated back to the PCC.

In our proposed project, the structure is fundamentally altered with the patients' interest in mind. Primary care and DB/MH services are provided in the same physical primary care setting through telehealth. Coordination and communication are improved between the two entities because of real-time brief summaries of patient visits and scheduled PCC-DB/MH specialty conferences to discuss difficult cases and referral protocols for common diagnoses. The overall experience of care for families is improved; their DB/MH visit occurs in a place that is convenient and familiar—the PCC office.

This new structure of care will lead to more patient-centered processes of care– processes of care that are more convenient and less burdensome for parents, leading eventually to improved DB/MH outcomes for children, and better experiences of care for parents.

Part B: Relevance to Patients (Criterion 4)

This proposed project has direct relevance to parents in terms of the research question, the intervention, and the outcomes that we hypothesize to be improved with the intervention. DB/MH problems are among the most commonly cited needs that parents describe when asked about their pediatric primary care experiences. In a study conducted by Drs. Coker and Chung, focus groups of low-income parents provided their perspectives on pediatric preventive care services. One of the major themes that emerged from qualitative analysis of the focus groups was that parents described a lack of help for DB problems from their pediatric providers.[60] In two separate studies of children with at least one chronic condition, parents identified behavioral health services as a top area of need.[61, 62] Our proposed project directly addresses parents' needs by focusing on a research objective to improve parents' access to DB/MH services by providing DB/MH services in primary care settings, using a delivery system that may make accessing DB/MH easier for parents.

Our proposed intervention and our proposed measurement outcomes also have direct relevance to parents. Through the intervention, our aim is to create a new system of care that can enhance parent access to DB/MH subspecialty care, increase the convenience and family-centeredness of care, and improve child DB/MH outcomes. To evaluate child DB/MH outcomes, we will focus on those parent-reported clinical outcomes that are likely most important to parents, including school performance and parent-reported child behavior. If effective, the telehealth-based model of care will illustrate a sustainable way to provide DB/MH services in the primary care setting; this model will be generalizable across a wide spectrum of primary care settings throughout the U.S.

Part C: Approach

1. Overview

The research plan has two major phases that align with the two study aims. For **Phase 1 (Aim 1, Year 1)**, we will use qualitative methods to conduct and analyze interviews with parents, clinicians, and staff at NEVHC to assess their perspectives on the delivery of child DB/MH services and on a potential telehealth-based patient visit, coordination, and clinician education system. These data will be used in a stakeholder-engaged process to customize a telehealth-based delivery system for child DB/MH services that can be integrated into primary care settings for children ages 5-12. For **Phase 2 (Aim 2, Years 2-3)**, we will compare this customized telehealth-based patient visit, coordination, and clinician education system to the usual in-person, community based referral system at NEVHC.

1a. Phase 1 (Stakeholder-Engaged Intervention Customization)

Phase 1 (Aim 1, Year 1) has two major steps: First, we will obtain an assessment of the views of key stakeholders (NEVHC parents, clinicians, and staff) on a telehealth-based patient visit and provider education system for the provision of DB/MH specialty care in primary care settings to children ages 5-12. Second, we will present our findings to a NEVHC community-partnered project advisory board and work together to modify the intervention to address the stakeholders' concerns and conduct a small pilot of the telehealth system.

Step 1 (Assessment of Stakeholder Views)

We will recruit 7-10 parents of children ages 5-12 at NEVHC who have been referred to in-person community-based DB/MH specialty care. We will conduct one-on-one interviews with these parents to understand the process that they went through after initial referral. We will ask them to describe any barriers or facilitators encountered in this process of accessing services. We will also ask them to describe the overall quality of care received, the level of coordination with their primary care provider, and the overall satisfaction and experiences with care. Finally, we will present to them a brief description of a telehealth intervention "template" to improve DB/MH services at NEVHC. We will obtain their perspectives on potential challenges and advantages of such an intervention to parents. At the same time, we will conduct one-one-one interviews with 5- 7 pediatric clinicians (pediatricians, family physicians, and nurse practitioners), and 5-7 administrative and clinical support staff at NEVHC to obtain their perspectives on the referral process, access issues, and the overall quality of DB/MH care provided through specialty referral, as well as the level of communication and coordination with DB/MH professionals. We will also obtain their views on the feasibility, acceptability, and effectiveness of the telehealth intervention template and how it might be adjusted to fit the needs of NEVHC. We will use these findings to customize the telehealth delivery model to the needs of the NEVHC population.

Step 2 (Customization of the Telehealth Model)

To customize the delivery model for NEVHC, we will work with a NEVHC project advisory board to modify the intervention template, conduct a workflow analysis, and conduct a pilot test of 5 referrals to identify and troubleshoot operational, technical, and clinical problems that arise. There are three main parts to the basic template of this telehealth intervention:

1. **Real-time videoconference patient visits.** Patients who need a specialty visit with a child psychiatrist or developmental/behavioral pediatrician will be scheduled for a telehealth visit (with the patient at the primary care clinical site and the subspecialists located at a UCLA telehealth site).
2. **Enhanced clinician communication and patient coordination.** Providers will use telehealth capabilities to communicate with each other about patient care and coordination issues, including diagnostic decisions, management strategies, and other patient care coordination activities.
3. **Clinical educational sessions for clinicians.** The telehealth equipment will also be used for real-time videoconference educational sessions to help primary care clinicians and specialty care clinicians share knowledge and experience that can translate into greater improvements for patient care.

1b. Phase 2 (Randomized Controlled Trial (RCT)

The goal of study phase 2 (Aim 2, Years 2-3) is to evaluate this new telehealth-based system at NEVHC. Children ages 5-12 who are referred by a NEVHC PCC to either developmental/behavioral pediatrics (DBP) or to child psychiatry will be eligible for study enrollment. Enrolled children will be randomized to intervention or control. The control group children will receive the usual community-based referrals for DB/MH concerns (depending on whether the PCC referred the patient to DBP or child psychiatry). Patients randomized to the intervention group will receive a telehealth appointment with one of the UCLA-based study specialty physicians: a developmental/behavioral pediatrician (DBP), or child psychiatrist, in accordance with the PCC referral. Children will remain in the study for 6 months, and parents will be asked to complete surveys at enrollment, and at 3-, and 6-months post-enrollment. PCCs will have monthly videoconferencing sessions with the study DB/MH specialists to discuss difficult cases (e.g., children with multiple DB/MH co-morbidities, complicated psychosocial factors), problems with coordination and/or communication among the three groups of clinicians (PCCs, developmental/behavioral pediatrician, and child psychiatrist) and basic diagnostic/management concerns that can be handled without official referral. PCCs and DB/MH clinicians will have the opportunity to communicate with each other via secure messages for patient care concerns that may arise before or after the telehealth visit.

We will enroll 400 children (200 intervention and 200 control) into the study. We will collect data on outcomes of 1) accessibility of care, 2) delivery-related quality of care (timeliness, family-centeredness, coordination, and parent experiences of care, 3) parent satisfaction, 4) child DB/MH clinical outcomes, and 5) quality of life.

2. Phase 1 Methods

The objective of this study phase is to understand the perspectives of NEVHC parents, PCCs, and staff on the shortcomings of the current community referral-based system for DB/MH services at NEVHC, and their perspectives on a proposed template for a telehealth intervention. We want to understand the current process and how it affects parents' ability to receive high-quality, timely, convenient, and family-centered care for their child's identified DB/MH needs. Similarly, we want to obtain information from NEVHC PCCs regarding needs for communication and coordination with DB/MH specialists that they are referring patients to, as well as information from NEVHC staff on the referral process and workflow. Finally, we want to assess the perspectives of parents, clinicians, and staff at NEVHC on our proposed telehealth intervention template, and what aspects may need to be adjusted to meet the needs of NEVHC stakeholders. This phase will inform the telehealth-based system to be customized for the randomized controlled trial (RCT) in Phase 2. We will conduct 60-minute, one-on-one qualitative interviews of NEVHC parents, PCCs, and staff.

2a. Sample Selection

We will first meet with Dr. Christine Park (NEVHC Pediatric Medical Director) to identify pediatric clinicians and staff at NEVHC for interviews. We will interview at least one full-time PCC (including at least one nurse practitioner, pediatrician, and family physician) and clinical staff member (staff involved in the referral process, e.g., referral coordinator, front office staff) at each of the seven clinical sites. Each clinician will be sent a letter of invitation describing the purpose of the study, followed by a phone call to schedule an interview. Each participating clinician will be asked to identify three patients, ages 5-12 that they referred for DB/MH specialty care over the past 12 months. NEVHC staff will contact these patients and obtain their permission to be contacted by UCLA study staff. Parents will be invited to participate in one-on-one interviews at a time and place that is convenient to them. We will conduct interviews with 7-10 parents who agree to participate, selecting for diversity by site and demographic characteristics.

2b. Incentive

All participants (clinicians, staff and parents) will receive a $75 gift card for their participation in the interviews.

2c. Study Procedures

Prior to the interview, participants will be provided with an information sheet providing informed consent materials. We will obtain oral consent prior to the interview. The interviews will be scheduled ahead of time at the participant's convenience. To accommodate the participants' work and family schedules, interview times during lunch breaks will be available, as well as in the early morning and later in the evening. Interviews for clinicians and staff will be held in private rooms at each clinic site, and interviews for parents will be held at a location of the parents' choosing (home, clinic, or other location). Interviews will be conducted by the Project Director (Dr. Coker, PI) and the Project Manager (Ms. Thomas). Both individuals have extensive experience in conducting surveys and interviews, and in qualitative studies.

2d. Interview Protocol

We will conduct the interviews using a semi-structured protocol, in English for the clinicians and staff, and in Spanish or English for parents (depending on parent language preference). We will conduct two pilot interviews with a pediatric clinician and parent at a separate clinic (unaffiliated with NEVHC) prior to the first NEVHC parent or clinician interview. Based on these pilot interviews, the UCLA research team will adjust the wording, timing, or order of the interview protocol. In particular, we will be looking for unclear, confusing, or misleading questions.

Introduction

Each interview will begin with a welcome and introduction to the purpose of the interview. We will describe why the participant was chosen for the interview, and the confidentiality of the interview.

Parent Interviews

- **Initial Referral and Visit Process**

Parents will be asked to describe the entire process that they went through after the referral was first made by the PCC to a DB/MH specialist. They will be asked to detail their experiences in calling the specialist for the first appointment, attending the first visit, and coordinating follow-up visits, and any other needs, such as medication refills. Parents will be asked how much time elapsed between first referral and fist specialty visit, and the reasons for delay, if any. We will ask what barriers and facilitators parents encountered in accessing services. Examples of questions from the interview protocol are:

1. *Can you describe what happened after [PCC'S NAME] referred you to see [SPECIALIST'S NAME]?*
2. *What exactly did you have to do to make that first appointment?*
3. *Did you face any problems in making that first appointment with [SPECIALIST'S NAME]? Any problems in making further appointments with [SPECIALIST'S NAME], or communicating with him/her for other things you needed or questions you had between appointments?*

- **Timeliness, Convenience, and Family-Centeredness.**

We will ask how parents perceived the referral process to be in terms of timeliness, convenience, and family-centeredness. Next, we will ask parents what expectations they have in terms of timeliness and convenience. We are interested if their initial referrals were completed within an acceptable period of time and if the location and timing of the specialist visit was convenient enough to not cause a burden on their family. Finally, we will ask which, if any elements of the referral process were inconvenient and how that could be improved in a new system. Examples of questions from the parent interview protocol:

1. *How much time passed between the day that [PCC'S NAME] referred you to [SPECIALIST'S NAME] and your first visit? Were you satisfied with that amount of time?*
2. *What was your experience at the [DB/MH CLINICAL SITE]?*
3. *What could have been done at either [PCC's] practice, or at [SPECIALIST'S] practice to have made your overall experience better?*

- **Follow-up, Coordination, and Communication**

Parents will be asked to discuss the experiences that they had with the specialist after the initial visit. We will probe for information on how follow-up visits or communication with the specialist was arranged, how much the PCC was involved, and whether the parent felt that coordination between the two clinicians helped with their child's condition. Parents will be encouraged to also discuss any problems with receiving any needed follow-up, including medication refills.

1. *Did you have additional visits with [SPECIALIST'S NAME] for [CHILD'S] [DB/MH PROBLEM]? How were they scheduled or arranged? What was that process like for you?*
2. *Did you have any questions about your child's condition after the first visit with [SPECIALIST'S NAME] If so, what was your experience in getting answers to those questions?*
3. *How much do you think that [PCC'S NAME] and [SPECIALIST'S NAME] communicated about or worked together to help with your child's healthcare? In what ways (if any) do you think that more communication between the doctor's offices would have helped your child?*

- **Telehealth Intervention Template**

We will briefly describe what a potential telehealth intervention might include at NEVHC. This intervention will be presented to parents as a basic template for an intervention that is open to their criticisms and suggestions. Using our conceptual model, Donabedian's structure→process→outcome model, we have designed a general framework to guide this part of the parent and clinician interviews (Table 1).

1. *Intervention structure*. We will begin by describing the basic structural elements involved in the proposed telehealth intervention: the format of the visit (real-time videoconference), the location (the primary care clinic), and the providers (DB/MH specialty providers). Parents will be asked to assess the advantages and disadvantages of this new structure of care, compared to usual care, and any potential solutions that they can think of to the major challenges of this new structure of care.
2. *Intervention process.* Next, we will describe the proposed processes, including the process of the actual visit, which follows the American Telehealth Association Guidelines, and are modeled after a protocol previously used by Dr. Soares (project co-investigator and telehealth DBP specialist) for several years in Kentucky.[42] Again, parents will be asked to describe if and how these new processes of care could improve their overall experiences in receiving care.
3. *Intervention outcomes.* We focus on the outcomes related to the changes in the structure and process of care. We will describe the meaning of each of these outcomes in simple terms (e.g., timeliness = how quickly a parent can get a visit), and then ask parents how these outcomes might be impacted by the new structure and processes under telehealth.

Examples of questions to parents under each category (intervention structure, process, outcomes) include:

1. *How would you feel about receiving care for [CHILD'S NAME] [DB/MH PROBLEM] in this new way?*
2. *How would this change your relationship with [SPECIALIST'S NAME]?*
3. *What are some reasons why this would or would not be a good way to receive care for [CHILD'S NAME]?*

Table 1. Framework for Qualitative Interview Section on Telehealth Intervention

	Participant			Questions		
	Parent	Provider	Staff	Advantages	Disadvantages	Solutions
Intervention Structure						
1. Telehealth videoconferencing	✓	✓	✓			
2. Primary care clinic location- specialty care location	✓	✓	✓			
3. Specialty providers	✓	✓				
a. Developmental/behavioral pediatrician						
b. Child psychiatry						
c. Non-medical mental health professionals						
Intervention Processes						
1. Appointment scheduling	✓		✓			
2. Videoconference visit	✓	✓				
a. Intake						
b. Provider visit						
c. Visit wrap-up						
3. Educational sessions		✓				
a. Specialty provider-primary care provider						
4. Communication and coordination	✓	✓				
a. Parent-specialty provider						
b. Primary doctor-specialty provider						
Intervention Outcomes						
1. Visit quality (related to delivery of care)	✓	✓	✓			
a. Timeliness						
b. Family-centeredness of care						
c. Coordination						
d. Parent/family experiences of care						
2. Parent convenience	✓	✓	✓			
3. Parent satisfaction	✓	✓	✓			
Other issues/concerns	✓	✓	✓			

Note: checkmarks indicate which participants will discuss the topic.

Clinician Interviews

• Usual Practice for Referrals

We will collect information on the referral process from the clinician's perspective. We will ask participants which DB/MH problems they most commonly provide referral for, and which problems they manage in the primary care setting, without specialty referral. We will also ask participants under what circumstances (e.g., comorbidities) they will either manage patients that they would otherwise refer, or refer patients that they would typically manage. Next, we will ask participants what process they follow in referring a patient to specialty DB/MH services, and if and how they receive information on the outcome of the referral. Participants will have the opportunity to share any challenges that they have in getting specialty providers to see their patients for DB/MH care. Examples of interview questions are:

1. *What are the most common DB/MH problems for which you refer children to either DBP or child psychiatry? What are common exceptions to these diagnoses?*
2. *How has your experience been when referring patients to each of these clinical specialties? How often do you receive information from the specialty provider?*
3. *What are the major challenges that you have in managing children with DB/MH problems?*

• Coordination and Communication with PCC

Participants will be asked what, if any, information they usually receive from the DB/MH specialists regarding the patient's visit. We will ask participants to describe their own needs with regards to communication and coordination with the specialty provider. Specifically, clinicians will be asked what method and frequency of communication they would prefer to use in information sharing with specialists regarding patient care concerns (e.g., emailed letter, emailed recorded message, consultation note placed into EHR, or phone conversation). Finally, participants will be asked if there are any other goals for communication with the specialist providers, such as clinician education on how to manage symptoms or diagnoses that do not require referral. Examples of interview protocol questions include:

1. *What type of information do you usually receive regarding your patients after a DB/MH referral?*
2. *What do you think would be the best ways to receive information from the DB/MH specialists regarding your patients? What methods of communication would you prefer? (Probe with various options, including 2-minute emailed video summary)*

• Telehealth Intervention Template

As described for the parent interview, we will use the interview framework in Table 1 to assess participant perspectives on the proposed telehealth intervention. This section of the interview will proceed in a similar fashion as described above, with the addition of questions related to the educational element of the intervention. Examples of questions to clinicians under each category (intervention structure, process, outcomes) include:

1. *Would these changes to care be feasible in your clinic? Why or why not?*
2. *Would this type of telehealth system change your patterns of referral for DB/MH problems? If so, how?*
3. *How could the educational sessions best serve your needs?*

Staff Interviews

• Referral and Follow-up Process

We will collect information on the referral process from the perspective of the staff who are involved in obtaining referrals, insurance authorizations, and in arranging appointments for patients. We will ask participants to detail the referral process from the time of physician referral. We will focus on barriers to obtaining insurance authorization, scheduling appointments, contacting patients, tracking utilization, and arranging follow-up specialty visits. We will ask participants to discuss how the procedures differ for DBP compared to child psychiatry referral, and how the process may differ based patient insurance type. Participants will have the opportunity to share ways in which a telehealth system for care can be customized to minimize many of the challenges they currently face in arranging referrals. Examples of interview questions are:

1. *What is the current process, step-by-step, that you typically follow after a child is referred to either DBP or child psychiatry? What are the major challenges that you or parents face in this process?*
2. *What has your experience been like when communicating with the offices for each of these subspecialties?*
3. *When and how do patients "fall through the cracks" in this process? What can be done to prevent that?*

• Telehealth Intervention

As described for the parent and clinician interviews above, we will use the interview framework in Table 1 to assess participant perspectives on the proposed telehealth intervention. This section of the interview will proceed in a similar fashion as described above; however, only topics related to NEVHC non-clinical staff will be discussed. Examples of questions to staff include:

1. *How would this change the current referral process?*
2. *Would this type of telehealth system be logistically feasible at the clinic? Why or why not? What would be the major problems that you would anticipate?*
3. *How would this affect clinic communication with the offices for each of the subspecialties?*

Interview Wrap-Up

At the end of the interview (parents, providers, and staff), we will ask participants if they have any final suggestions to add. We will then summarize and verify their perspectives on the initial referral process, timeliness, convenience, and family-centeredness of care received; on follow-up, coordination, and communication with providers; and on the advantages of, disadvantages of, and solutions for the telehealth intervention template.

2e. Data Analysis

All interviews will be digitally recorded, transcribed, and imported into Atlas ti 7 (text management software) for analysis. The goal of this qualitative data analysis is to identify and describe the experiences and perspectives of parents and clinicians on improvements to the structure and processes of a DB/MH referral at NEVHC. To achieve this goal, we will use a coding procedure based in grounded theory.[63] We will perform 3 steps to analyze interview transcripts. The qualitative analysis will be led by the project Qualitative Methods Advisor, Dr. Bromley.

Step 1: Identify themes

Themes are abstract constructs that can be identified from relevant literature, previous experiences of researchers, or from the qualitative research data itself.[64] As interviews are completed, the research team (Dr. Coker and two UCLA/RAND research assistants) will independently read the transcripts and identify themes using an open-coding process. In identifying themes, we will focus on processes, actions, assumptions, and consequences.[64] The research team will then meet together after independently reading the transcripts, discuss and refine the themes that were identified, and read through sections of transcripts to identify any additional themes.

Step 2: Develop a codebook and code transcripts

The themes identified in Step 1 will be compiled into a codebook. This will help us to improve the inter-coder reliability and the validity of the findings. This codebook will list each theme with a code to identify it, a detailed definition, inclusion and exclusion criteria, and an example of the theme from the actual text. The research team will then practice using the codebook to code the transcripts. We will begin by independently coding a random sample of transcript sections using the codebook. The team will continue practicing coding until all three coders demonstrate consistent identification of themes across the sample texts. Next, two members of the research team will sequentially code each remaining transcript as the interviews are completed. We will calculate a kappa statistic as a measure of inter-coder agreement; kappa statistics ≥ 0.70 suggest good inter-coder consistency. This analysis will be done using the constant comparative method of qualitative analysis, where the emerging themes and coding paradigm are continuously revised as the researchers revisit the original data, comparing one interview to another, and as theory emerges, comparing data to theory.[65]

Step 3: Describe themes and patterns

After the completion of all interviews and coding, we will examine all instances of themes in the text, describe the frequency and distribution of the themes, and describe each theme by using direct quotes from the text. We will also look for patterns of themes that both unify and divide the different interviewees by participant role (parent, clinician), child age (preschool age, school age), and referral source (developmental/behavioral pediatrics, child psychiatry).

Stakeholder Engagement Process

The data from the parent, clinician, and staff interviews will be used to modify and adapt our proposed telehealth-based delivery system. We can anticipate the qualitative interviews will reveal the following specific areas of focus for intervention customization:

Intervention Structure

1. Locations: (e.g., alternative NEVHC locations for telehealth visit for patient, potential telehealth "hubs")
2. Providers: (e.g., involvement and role of non-physician mental health professionals; telehealth coordinator role)

Intervention Process

1. Visit process (e.g., language interpretation services, discharge instructions, medication prescription methods)
2. Educational sessions (e.g., timing of sessions, focus of topics, real-time vs. recorded sessions)
3. Communication and patient coordination activities (e.g., secure e-messaging, store-and-forward document transmittal, recorded video summaries; capacity for e-referrals or "curbside" communication only when a visit is not needed)

We will organize a NEVHC community-partnered project advisory board (PAB) during Phase 1. The PAB (~9 members) will include clinical and administrative leadership from NEVHC and clinicians, clinical support staff from the primary care clinical sites, and parent representatives (nominated by the clinics). Each PAB member will receive an honorarium for each project year.

The major PAB activities during Phase 1 will be organized around monthly meetings, supplemented by ad hoc meetings, phone conferences, and e-mails. We will continue to communicate with PAB members frequently throughout Years 2-3 of the project, and will also have quarterly meetings to discuss the RCT plans and progress.

The PAB will be responsible for working with the research team over a series of 6 meetings over a 6-month period to modify the proposed telehealth intervention to address the major themes identified during the stakeholder interviews. The PAB and research team will then review the clinic workflow to accommodate and implement the new delivery system of DB/MH care, and will work with the research team to conduct a small pre-intervention pilot test for 3-5 referred children. The PAB and the PAB process are described in detail in the ***Stakeholder Engagement Plan*.**

3. Phase 2 Methods

To examine the effectiveness of this telehealth-based system for DB/MH within a primary care setting, we will conduct a randomized controlled trial. The trial will be conducted at all seven clinical sites of NEVHC. Currently, referrals to DB and MH specialty services occur through two different processes. Since mental health is a carved-out benefit for most publicly-insured patients at NEVHC, parents are simply given a list of local community mental health clinics to contact when a child mental health visit is needed. Following the existing community mental health clinic workflow, children have initial contact with a social worker for intake at these mental health clinics and subsequently receive an appointment to see a child psychiatrist, a clinical psychologist, or both, depending on the intake assessment of patient need. Referral to DBP does not fall under the mental health carve-out, but instead uses the typical referral authorization process under managed care. Once the authorization for referral is received by NEVHC, the referral staff will help the parent make the appointment with the community-based DBP specialty physician.

3a. Enrollment and Procedures

Once enrollment starts, NEVHC will use a different process for referral to DBP and child psychiatry to enable patient randomization to intervention and control arms. When the PCC decides that a referral is warranted for DB/MH specialty care, he/she will fill out a study-specific referral slip with the child's name, and the parent's name and contact phone number. In addition to this, PCCs will continue to request authorization from the managed care plan for DBP referrals. The PCC will then tell the parent that he/she will receive a phone call within 24-48 hours to arrange a referral for child psychiatry, and within 4-5 days for DBP (to allow time to receive authorization).

Referral

All study-specific referral forms will be faxed to a NEVHC referral coordinator. This will be a NEVHC staff member who will manage all DB/MH referrals from the 7 NEVHC clinics for children ages 5-12. This NEVHC staff member will be budgeted on the NEVHC subcontract to cover his/her time on study enrollment. Once the referral is received, the coordinator will call the parent within 24 hours of receiving either the child psychiatry referral or the notification of insurance authorization for DBP referral. The coordinator will call the parent to arrange the referral.

Enrollment

During this initial phone contact, the NEVHC referral coordinator will assess whether the parent is willing to participate in the study (see Appendix, Figure 1). The coordinator will inform all parents that, if they agree to participate in the study, they will be randomized to telehealth or usual care and asked to complete an enrollment interview and two follow-up interviews with a UCLA research coordinator.

If the parent meets eligibility criteria and consents to participate (see Appendix, Figure 1), the coordinator will assign the child to DB or MH in accordance with the referral, and then use a computer-generated random number to randomly assign the parent to intervention or control within the DB or MH stratum. Depending on the group assignment, the program coordinator will either a) schedule the next available (or most convenient) telehealth DBP or child psychiatry visit, or b) schedule the next available (or most convenient) mental health clinic visit or community DBP appointment.

If parents decline to participate in the study, the coordinator will proceed to schedule an in-person visit with the community DBP or the community mental health clinic per usual care.

Baseline Data Collection

The UCLA Project Manager/Program Coordinator (Ms.Thomas) will receive an email message from the referral coordinator with the contact information for the participating parent. Ms. Thomas will contact the parent within 24 hours to conduct the 40-minute baseline data collection survey.

Telehealth Visit Procedure

The telehealth visit encounter procedure follows the American Telehealth Association Guidelines and is modeled after a protocol previously used by Dr. Soares (project co-investigator).[42]

Patients scheduled for a telehealth visit will receive a phone or text reminder the day before the visit. The location of the telehealth visit will be at the same clinic location as the index PCC visit. Upon arrival for their telehealth visit, parents will be sent to a typical patient encounter room at the clinical site. The room will be set up for a telehealth visit with a Cisco Telepresence XV Clinical Assistant unit, two chairs for the parent(s) and a small table with chairs and toys for the child and any siblings that arrive with the family. The Cisco camera/screen will be set up to allow the specialty provider to have full view of the examination room. The Cisco system uses a multifunctional camera with zoom and pan (side to side) capabilities; we will utilize a high-speed internet connection at NEVHC for optimal connection speed.

A bilingual (Spanish and English) telehealth coordinator will greet the parents and coordinate the visit at the NEVHC end. The telehealth coordinator will receive web-based telehealth coordinator training through a HRSA-funded Telehealth Resource Center (Southeastern Telehealth Resource Center). The telehealth coordinator is present at the NEVHC end of the telehealth visit for the duration of the visit. The telehealth coordinator ensures that the camera and microphones are operating correctly, positions the camera as necessary, conducts a volume and vision check, and as the exam proceeds provides Spanish language interpretation if necessary. The telehealth coordinator takes basic vitals at the beginning of the visit, including heart and respiratory rate and blood pressure.

The clinical encounter proceeds as a typical "in-person" encounter. Dr. Soares will perform the DBP specialty telehealth visits, and Dr. Zima (co-Investigator), a health services researcher and child psychiatrist for UCLA and Los Angeles County Department of Mental Health, will identify a UCLA-based child psychiatrist during the first year of the project to deliver the telehealth psychiatry visits. The child psychiatrist will be trained by Dr. Soares to conduct telehealth visits. Each specialty provider will dedicate one half to one full clinic day to the telehealth visits, with the typical 1-hour slot for new patients and 30 minutes for established patients. The telehealth specialty physician will conduct the typical history, review of information brought by the parent to the visit, focused behavioral observations, and a general visual inspection physical examination, with assistance from the telehealth coordinator on the distal end. At the end of the visit, the telehealth coordinator will assist the physician in setting up any follow-up plans with the family, and providing any prescriptions (via phone or fax, or mail-in for controlled Schedule II substances). Once the family leaves, the telehealth coordinator will help the specialty clinician record a brief (2 minute) video visit summary and will immediately email the encrypted video visit summary to the PCC. The telehealth coordinator will then prepare for the next scheduled patient. Dr. Soares will bill for the visit as he would for a similar in-person visit, as allowed by California telehealth laws. Since child psychiatry is a carve-out in Medicaid managed care plans in California, the telehealth child psychiatrist will not bill for visits; these visits are budgeted as outpatient care services in the project budget.

DB/MH–PCC Communication and Coordination Components

The intervention will also include several components to enhance communication and coordination between specialty physician and PCCs. First, the PCC will receive a secure video message summarizing the child's specialty visit and the specialty physician's overall assessment and plan (described above). In addition, the PCC will be able to communicate with the telehealth specialty clinician through secure messages. Specialists and PCCs can use this mechanism to communicate recommendations for patient care, to ask patient-specific questions, and to transfer back to primary care or to specialty care management.

Usual Care Procedure

The referral process for usual care will follow the procedure described above. We will continue to use the same DB/MH specialty providers and clinics currently used for referrals at NEVHC. For DBP referrals, once the authorization is obtained, the NEVHC referral coordinator will schedule the visit with the community DBP practice. For child psychiatry, the program coordinator will schedule a visit with one of three area mental health clinics.

Telehealth Educational Sessions

As part of our ongoing stakeholder engagement process, we will hold a telehealth primary care-DB/MH educational session via videoconference every other month during the study period. The session will include the study DBP and child psychiatrist, and the NEVHC PCCs; each session will be held during the clinic's lunch hour for 30-45 minutes, based on the NEVHC PCC availability. The telehealth equipment at each NEVHC site will be placed in a conference room for the purposes of the telehealth education session. During the 18- month intervention period (12 month enrollment period + 6 months length of intervention per patient), there will be 9 sessions. The first 4 sessions will focus on referral indications and recommendations for the most common child DB/MH symptoms. The sessions will focus on areas of interest that we elicited from the NEVHC clinicians during Aim #1. Tentative topics include: ADHD, Autism, Developmental Delay, Child Depression, Anxiety, and Behavior Problems in Children and Adolescents. During each brief lunchtime session, the

DBP and child psychiatrist will discuss 1) when referral is indicated, 2) to whom (DBP or child psychiatry) the referral is most appropriate for, and 3) when and how the PCC can manage the patient without referral. Dr. Zima, Soares, Coker, and Chung will work together during Study Phase #1 to create provider summaries of each session and a session guide for the session moderators (based on preferences from NEVHC Phase #1 interviews). Dr. Soares and Dr. Zima will review the materials prior to the intervention and make any necessary adjustments or edits to the documents. The PCC handouts and recorded presentations will be available in each of the NEVHC clinics for any clinicians who could not attend that session.

3b. Data Collection

The study program coordinator and research assistants (RAs) will collect baseline data from one parent (preferably the child's primary caregiver) at the time of the first referral phone contact. The parent will be asked to participate in three surveys: at enrollment (baseline), 3 months after the initial referral, and at 6-month follow-up.

Baseline, Three-Month Follow-Up, and Six-Month Follow-Up Interviews

Upon enrollment, parents will participate in a 40-minute phone interview. In addition to the data collection on measures described below for the three and six-month surveys, we will also collect baseline demographic data on the child, parent, and household. Parent (and spouse/partner) data will include age, educational attainment, English language proficiency, literacy level, country of birth, years living in US, and social support. Family data will include household income, household composition, primary language spoken at home, age of other children in household, and home zip code. Child data will include medical history, developmental history, medication use, school performance, current DB/MH symptoms, severity, and impairment, and whether the child meets criteria for CSHCN (using the CSHCN screener).[66]

At each of these follow-up surveys, parents will participate in a 20-minute phone interview. We will use a modified version of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey, the Pediatric Quality of Life Inventory, and the Strengths and Difficulties Scale, with selected questions to obtain parent-reported data on 1) Access, 2) Quality *(Timeliness, Family-Centeredness, Coordination, Parent Experiences of Care)*, 3) Parent Satisfaction, 4) Child BD/MH Outcomes, and 5) Quality of Life (Table 2).[67-69]

- **Access, Quality, and Parent Satisfaction**

We will collect data on the time from referral to initial visit, the distance traveled to reach the specialist appointment, out-of-pocket costs, and missed work, school, or child care duties to attend the visit. We will utilize a modified version of CAHPS to collect data on access, timeliness, coordination, satisfaction, and overall experiences of care. We will include CAHPS questions for the following topics: 1) timely appointments, care, and information (4 items), 2) provider-parent communication (6 items), 3) helpful, courteous, and respectful office staff (2 items), 4) parent's overall rating of the provider (1 item), and 5) provision of follow-up information.

We will also collect data on the receipt of family-centered DB/MH care; to do this we will use a family-centered care measurement scale used in the National Survey of CSHCN and the National Survey of Children's Health. This scale was developed under the leadership of The Maternal and Child Health Bureau, in collaboration with the National Center for Health Statistics (NCHS).[70] The scale includes six questions assessing receipt of family-centered care for parents who report a visit for their child in the previous 12 months. We will use the scale to specifically ask about family-centered care provided in the DB/MH specialist visits. Parents will be asked if the specialist clinician: 1) spent enough time with the child and family, 2) listened carefully to the family during the visits, 3) provided care that was sensitive to the family's values and customs, 4) provided needed information, 5) helped the family feel like a partner in their child's care, and, 6) utilized interpreter services if needed. Parent response choices include that over a given time period, this care was received never, sometimes, usually, or always. We will use a composite index for assessing the level of family-centered care received. Two of these questions overlap with the CAHPS questions (spending enough time and listening carefully); we will use the family-centered care version for these two questions.

- **Child Behavioral Outcomes**

To assess child behavioral outcomes, we will examine the change in score on the Strengths and Difficulties Questionnaire (SDQ) at baseline and study completion.[69] The SDQ is a brief behavioral screening questionnaire that asks parents of children ages 3-16 about 25 child attributes. There are five scales in the SDQ—four of the scales screen for symptoms of different categories of mental health problems; these include emotional symptoms (5 items), conduct problems (5 items), hyperactivity/inattention (5 items), and peer relationship problems (5 items). A composite "difficulties" score is calculated as a total of the 20 items across these four scales. The fifth scale focuses on positive attributes of prosocial behavior (5 items). We will ask 2 additional questions about school performance, focusing on academic performance (e.g., teacher reports, grades) and classroom behavior.

- **Health-Related Quality of Life**

Finally, we will use the Pediatric Quality of Life Inventory 4.0 (PedsQL), a well-validated instrument designed to measure changes in the child's quality of life.[71] There is a parent-reported PedsQL 4.0 for children ages 5-7 and 8-12. We will use the age-specific questions from each version for emotional functioning (4 items), social functioning (3 items), school functioning (3 items), and physical functioning (5 items). Respondents are asked how much of a problem each item has been during the past one month with five response options (*never a problem, almost never a problem, sometimes a problem, often a problem, almost always a problem)*. Items are reverse scored (so that higher scores represent better quality of life) and linearly transformed to a 0-100 range.

Table 2. Outcome Measures

Major Outcome Variables	**Parent-Report (# of survey items)**	**Utilization data**
1. Access		
Time from Referral to First Visit	Newly-created items (1)	Time from referral to: –Authorization (DBP) –Initial screening (Psych) –Specialty visit
Out-of-pocket costs to related to first visit	Newly-created items (2)	
Selected CAHPS items	CAHPS (2)	
2. Quality		
Timeliness	CAHPS (4)	
Family-centered care	MCHB (5)	Parent- DB/MH communication –Outside of visit –After hours
Coordination	CAHPS (1)	PCC–DB/MH: –Communication after first visit –Communication after additional visits –Patient hand-off –Additional DB/MH referrals after initial Medication prescription pharmacy data
Parent experiences of care	CAHPS (6)	
3. Parent Satisfaction	CAHPS (2)	
4. Child Behavior and School Performance		–PCC visits for same problem
Mental health disorder symptoms	SDQ (5)	
Conduct problems	SDQ (5)	
Hyperactivity and inattention	SDQ (5)	
Emotional symptoms	SDQ (5)	
Peer relationship problems	SDQ (5)	
School performance	newly-created items (2)	
5. Pediatric Quality of Life		
Emotional Functioning	PedsQL (4)	
School Functioning	PedsQL (3)	
Social Functioning	PedsQL (3)	
Physical Functioning (modified)	PedsQL (5)	

3c. Quantitative Analysis

Statistical Analysis

We will compile descriptive statistics on all outcome variables, composite scores, and covariates. We will report means, medians, and standard deviations for continuous variables, create graphical displays to visualize distributions, and transform variables with non-normal distributions. We will develop weights to account for subject attrition, using logistic regression models that compare study completers and dropouts. These weights will be derived as reciprocals of the predicted probability of study completion from the logistic regressions.[72, 73] We will carefully inspect patterns of missing data in each data point and consider using multiple imputation to account for item non-response and uncertainty in the imputed values.[74, 75] We will use bivariate associations to assess the success of random assignment. If there are significant differences between intervention and control subjects, these will be included as covariates in all regression models. To improve the precision of the estimated intervention effect, we will conduct a series of bivariate analyses to identify the potential covariates to be considered for a multiple regression model. Confounding will be assessed by comparing the unadjusted coefficient for treatment condition with the adjusted coefficient. Next, we will use bivariate and multivariate analyses to examine differences between the control and experimental groups on the measures described above. From these analyses, we will also estimate intervention effects, the feasibility of measures, and intervention and comparison group attrition rates.

Assessing Intervention Effects

We will conduct an intention-to-treat analysis, which includes all participants randomly assigned to the intervention and comparison conditions, regardless of whether they completed the intervention. The primary analyses will compare intervention versus control on the five main outcome variables (Table 4); we will compare intervention and control group scores on these variables at baseline, 3-, and 6- months post-intervention. Quality of life scores will be calculated according to the PedsQL manual, using a 0-100 possible range. The CAHPS and SDQ scales will be linearly transformed to the same 0-100 range. We will use ANCOVA[76] for group comparison with intervention status as the main independent variable, adjusted for the baseline measure for that variable as a covariate plus potentially confounding covariates. We will fit logistic regression for binary variables (e.g. utilization data). Analyzing 3-month outcomes will allow us to assess early, preliminary differences; six-month outcomes will address study hypotheses, based on pre-assigned Type 1 rates. To examine the intervention effects using longitudinal data using 3- and 6-month data controlling for baseline, we will add to the regression model individual-level random effects to account for repeated measurements within individuals and include interactions between time and intervention indicator variables. We will examine the intervention effects at each time point, the difference between intervention effects between two follow-ups, and the average intervention effects over time. We will also conduct MANCOVA analyses to test each hypothesis simultaneously for five main outcome measures, and separate ANCOVA analyses for each outcome measure as discussed above. Assuming similar effects across specific outcome measures, MANCOVA is usually more powerful than ANCOVA for a single outcome measure as the information from multiple outcome measures are combined in MANCOVA.

Statistical Power

We conducted power calculations for the primary endpoint with power ≥80%, assuming two-sided tests with the Bonferroni adjusted alpha level .01, and assuming that tests are conducted without controlling for the covariates, a conservative assumption. The power is anticipated to be higher for MANCOVA and longitudinal analysis than the power shown below for a two sample t-test (Table 3). For end-status analysis, we have power to detect small/medium effect size (.37-.38).

Table 3. Minimum detectable effect sizes for main analyses (80% power (alpha=0.01), two-sided test)

	Sample size/ group at 6 months follow-up	Effect Size†
Assuming 85% retention rate at 6 months	170	0.368
Assuming 80% retention rate at 6 months	160	0.384

†Detectable effect size (mean difference between two groups divided by the standard deviation). (Cohen J: Statistical power analysis for the behavioral sciences: Lawrence Erlbaum, 1988.)

4. Study Limitations, Avoidance of Bias, and Possible Barriers to Completion

Contamination of Control Group

Since the NEVHC PCCs will be involved in educational sessions with the telehealth DBP and child psychiatrist, they might change their management of DB/MH problems, referral patterns, or communication and coordination with DBP and MH specialty providers for control patients. If this contamination is substantial, we will be less likely to find significant differences between the intervention and control children in child behavioral and quality outcomes. To reduce the likelihood of this type of bias in our study, we will focus the proposed educational sessions on DB/MH concerns for young children and adolescents, not on the age group (5-12 years) that is the focus of the RCT. This will allow us to include DB/MH education as part of the telehealth intervention (an expressed priority by NEVHC in planning this proposal) but avoid some of the bias potentially associated with educational sessions focused on the study population.

Although contamination of the control group by the DB/MH specialty providers is also theoretically possible, we have chosen to use two specialty providers who otherwise would not be involved in providing services to NEVHC patients. This greatly reduces the bias introduced by contamination because the telehealth DBP and child psychiatrist will not provide care to or have any contact with control group children.

Variation of Care for Child Psychiatry Referral

Intervention group children who receive a referral for child psychiatry will be scheduled for a telehealth visit with the telehealth child psychiatrist. Control group children will be referred to the community mental health center, where children will receive an appointment to see the child psychiatrist, a clinical psychologist, or both, depending on an intake assessment of patient need conducted by a social worker. There may be a wider variation in the types of mental health providers for the control group compared to the intervention group. To address this, the telehealth child psychiatrist will have the ability to recommend telehealth visits with a clinical psychologist for subsequent visits with the child for therapy-related needs, such as cognitive-behavioral therapy.

Sustainability of the Intervention and Models for Reimbursement

In California, reimbursement for telehealth visits by public and private insurance must be equivalent to in-person visits, by law. Thus, there is an inherent sustainability in telehealth for clinics once implementation, support, and success in terms of outcomes are ensured. Because of an existing contract between UCLA and the largest Medicaid managed care plan in California, Dr. Soares will be able to bill for the majority of DBP visits. We have budgeted for patient care funding for the minority of telehealth DBP visits for children who have a different managed care plan. For telehealth child psychiatry, since these services are a carved-out benefit for most Medicaid managed care plans, our telehealth child psychiatrist will not bill for most visits as part of the study. The anticipated patient care costs for child psychiatry (and clinical psychology) have been included in the budget. Despite this payment arrangement during the study for child psychiatry, NEVHC and the Los Angeles County Department of Mental Health have verified the feasibility and sustainability of reimbursement for this telehealth system. If this system proves successful, it will be disseminated widely for NEVHC, utilizing the carved-out mental health benefits for Medicaid-insured children. This is described in more detail below, under ***Dissemination and Implementation Assessment.***

Part D: Inclusiveness of Different Populations (Criterion 6)

This study will focus primarily on children and their parents from low-income families, and of racial/ethnic minority status. The vast majority of children will be publicly-insured, and all will have a DB/MH need.

While these patients are not necessarily “hard to reach” (given that they represent a highly prevalent population in the most populous county in the US), they are clearly underserved and face major barriers with respect to access and convenience of services. NEVHC, as one of the nation’s largest community health centers with seven clinics covering a mostly urban area of roughly 150 square miles within Los Angeles County, will likely draw a population that is both highly diverse and highly representative of the county’s underserved communities. Even though the focus of this study is on children with DB/MH needs and their families, it is highly likely that the lessons drawn from this telehealth study will be applicable to other underserved populations. The access and convenience problems addressed by this intervention are universal, and allowing patients and PCCs to connect with remote specialty providers regardless of their primary care environment or their physical distance from specialists is one of the inherent putative advantages of telehealth services.

REFERENCES CITED

1. Hagan JF, Shaw JS, Duncan P, editors. Guidelines for Health Supervision of Infants, Children, and Adolescents. 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2008.
2. Bright Futures/American Academy of Pediatrics. *Recommendations for Preventive Pediatric Health Care*. Elk Grove, IL: American Academy of Pediatrics; 2008.
3. Bringewatt EH, Gershoff ET. Falling through the cracks: Gaps and barriers in the mental health system for America's disadvantaged children. *Children and Youth Services Review*. 2010;32:1291-1299.
4. Huang L, Stroul B, Friedman R, et al. Transforming mental health care for children and their families. *Am Psychol*. 2005;60:615-627.
5. Thomas CR, Holzer CE. National Distribution of Child and Adolescent Psychiatrists. *J Am Acad Child Adolesc Psychiatry*. 1999;38:9-15.
6. Children's Defense Fund. The barrers: Why is it so difficult for children to get mental health screens and assessements? Available at: http://www.childrensdefense.org/child-research-data-publications/data/barriers-children-mental-health-screens-assesments.html. Published 2009. Accessed December 7, 2012.
7. Pfefferle SG. Pediatrician Perspectives on Children's Access to Mental Health Services: Consequences and Potential Solutions. *Administration and Policy in Mental Health and Mental Health Services Research*. 2007;34:425-434.
8. Briggs-Gowan MJ, Horwitz SM, Schwab-Stone ME, Leventhal JM, Leaf PJ. Mental Health in Pediatric Settings: Distribution of Disorders and Factors Related to Service Use. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2000;39:841-849.
9. Jensen PS, Goldman E, Offord D, et al. Overlooked and Underserved: Action Signs for Identifying Children With Unmet Mental Health Needs. *Pediatrics*. 2011;128:970-979.
10. Haggerty R, Roghmann K, Pless I. *Chid Health and the Community*. New York, NY: John Wiley Sons; 1975.
11. American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health. The new morbidity revisited: A renewed commitment to the psychosocial aspects of pediatric care. *Pediatrics*. 2001;108:1227-1230.
12. American Academy of Pediatrics. Committee on Psychosocial Aspects of Child and Family Health: The pediatrician and the "new morbidity". *Pediatrics*. 1993;92:731-733.
13. American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health: Pediatrics and the psychosocial aspects of child and family health. *Pediatrics*. 1982;70:126-127.
14. Costello E, Costello AJ, Edelbrock C, et al. Psychiatric disorders in pediatric primary care: Prevalence and risk factors. *Arch Gen Psychiatry*. 1988;45:1107-1116.
15. Coker TR, Elliott MN, Kataoka S, et al. Racial/Ethnic Disparities in the Mental Health Care Utilization of Fifth Grade Children. *Academic Pediatrics*. 2009;9:89-96.
16. Coker TR, Shaikh Y, Chung PJ. Parent-Reported Quality of Preventive Care for Children At-Risk for Developmental Delay. *Academic Pediatrics*. 2012;12:384-390.
17. Kataoka SH, Zhang L, Wells KB. Unmet need for mental health care among U.S. children: variation by ethnicity and insurance status. *Am J Psychiatry*. 2002;159:1548-1555.
18. Gardner W, Kelleher KJ, Pajer KA, Campo JV. Primary Care Clinicians' Use of Standardized Tools to Assess Child Psychosocial Problems. *Ambul Pediatr*. 2003;3:191-195.
19. US Public Health Service. Mental Health: A Report of the Surgeon General. Rockville, MD: US Department of Health and Human Services Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health.; 1999.

20. US Public Health Service. Mental Health: Culture, Race, and Ethnicity (a Supplement to Mental Health: A Report of the Surgeon General). Rockville, MD: US Department of Health and Human Services Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health.; 2001.
21. Leaf PJ, Alegria M, Cohen P, et al. Mental Health Service Use in the Community and Schools: Results from the Four-Community MECA Study. *Journal of the American Academy of Child & Adolescent Psychiatry*. 1996;35:889-897.
22. Committee on Psychosocial Aspects of Child Family Health Task Force on Mental Health. The Future of Pediatrics: Mental Health Competencies for Pediatric Primary Care. *Pediatrics*. 2009;124:410-421.
23. Fergusson DM, Woodward LJ. Mental health, educational, and social role outcomes of adolescents with depression. *Arch Gen Psychiatry*. 2002;59:225-231.
24. Zimmerman FJ. Social and economic determinants of disparities in professional help-seeking for child mental health problems: evidence from a national sample. *Health Serv Res*. 2005;40:1514-1533.
25. McMiller WP, Weisz JR. Help-seeking preceding mental health clinic intake among African-American, Latino, and Caucasian youths. *J Am Acad Child Adolesc Psychiatry*. 1996;35:1086-1093.
26. Sturm R, Ringel JS, Andreyeva T. Geographic disparities in children's mental health care. *Pediatrics*. 2003;112:e308-.
27. Hough RL, Hazen AL, Soriano FI, Wood P, McCabe K, Yeh M. Mental health care for Latinos: mental health services for Latino adolescents with psychiatric disorders. *Psychiatr Serv*. 2002;53:1556-1562.
28. Cunningham PJ, Freiman MP. Determinants of ambulatory mental health services use for school-age children and adolescents. *Health Serv Res*. 1996;31:409-427.
29. Howell E. Access to Children's Mental Health Services under Medicaid and SCHIP. Washington, DC: Urban Institute; 2004 August 31, 2004.
30. Cuffe SP, Waller JL, Cuccaro ML, Pumariega AJ, Garrison CZ. Race and gender differences in the treatment of psychiatric disorders in young adolescents.[see comment]. *J Am Acad Child Adolesc Psychiatry*. 1995;34:1536-1543.
31. Lambert MC, Knight F, Weisz JR. Over- and under-controlled clinic referral problems of Jamaican and American children and adolescents: The culture general and the culture specific. *J Consult Clin Psychol*. 1989;1989:467-472.
32. Weisz JR, Suwanlert S, Chaiyasit W, Walter BR. Over- and undercontrolled clinic-referrral problems among Thai and American children and adolescents: The wat and wai of cultural differences. *J Consult Clin Psychol*. 1987;55:719-726.
33. Gonzalez M. Access to mental health services: The struggle of poverty affected urban children of color. *Child and Adolescent Social Work Journal*. 2005;22:245-256.
34. National Association of Children's Hospitals and Related Institutions. Pediatric subspecialist physicians shortages affect access to care. Alexandria, VA: NACHRI; 2009.
35. Thomas CR, Holzer Iii CE. The Continuing Shortage of Child and Adolescent Psychiatrists. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2006;45:1023-1031.
36. Olfson M. Evaluating the Quality of Community Care for Attention-Deficit/Hyperactivity Disorder. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2010;49:1183-1185.
37. Sarvet B, Gold J, Bostic JQ, et al. Improving Access to Mental Health Care for Children: The Massachusetts Child Psychiatry Access Project. *Pediatrics*. 2010;126:1191-1200.
38. Gruttadaro D, Markey D. Integrating mental health and pediatric primary care. Arlington, VA: National Alliance on Mental Illness; 2011.
39. Williams J, Shore SE, Foy JM. Co-location of Mental Health Professionals in Primary Care Settings: Three North Carolina Models. *Clin Pediatr (Phila)*. 2006;45:537-543.
40. Ford J, Steinbert K, Pidano A, Honigfeld L, Meyers J. Behavioral health services in pediatric primary care. Farmington, CT: Child Health and Development Institute of Connecticut; 2006.
41. Zima BT, Bussing R, Tang L, et al. Quality of Care for Childhood Attention-Deficit/Hyperactivity Disorder in a Managed Care Medicaid Program. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2010;49:1225-1237.e1211.
42. Grady B, Myers KM, Nelson EL, et al. Evidence-based practice for telemental health. *Telemedicine and e-Health*. 2011;12:131-148.

43. Soares NS, Langkamp DL. Telehealth in Developmental-Behavioral Pediatrics. *J Dev Behav Pediatr*. 2012;33:656-665.
44. Yellowlees PM, Hilty DM, Marks SL, Neufeld J, Bourgeois JA. A Retrospective Analysis of a Child and Adolescent eMental Health Program. *Journal of the American Academy of Child & Adolescent Psychiatry*. 2008;47:103-107.
45. US Department of Health and Human Services Health Resources and Services Administration. Telehealth. Available at: http://www.hrsa.gov/telehealth. Published 2012. Accessed December 9, 2012.
46. Pesamaa L, Ebeling H, Kuusimaki M-L, Winblad I, Isohanni M, Moilanen I. Videoconferencing in child and adolescent telepsychiatry: a systematic review of the literature. *J Telemed Telecare*. 2004;10:187-192.
47. Hersh WR, Hickam DH, Severance SM, Dana TL, Krages KP, Helfand M. Diagnosis, access and outcomes: update of a systematic review of telemedicine services. *J Telemed Telecare*. 2006;12:3-31.
48. Hersh W, Helfand M, Wallace J, et al. Clinical outcomes resulting from telemedicine interventions: a systematic review. *BMC Med Inform Decis Mak*. 2001;1:5.
49. Hersh W, Helfand M, Wallace J, et al. A systematic review of the efficacy of telemedicine for making diagnostic and management decisions. *J Telemed Telecare*. 2002;8:197-209.
50. Monnier J, Knapp RG, Frueh BC. Recent advances in telepsychiatry: an updated review. *Psychiatr Serv*. 2003;54:1604-1609.
51. Hailey D, Roine R, Ohinmaa A. Systematic review of evidence for the benefits of telemedicine. *J Telemed Telecare*. 2002;8:1-7.
52. Myers KM, Valentine JM, Melzer SM. Child and adolescent telepsychiatry: utilization and satisfaction. *Telemedicine and e-Health*. 2008;14:131-137.
53. Diamond JM, Bloch RM. Telepsychiatry assessments of child or adolescent behavior disorders: a review of evidence and issues. *Telemedicine and e-Health*. 2010;16:712-716.
54. Ekeland AG, Bowes A, Flottorp S. Effectiveness of telemedicine: A systematic review of reviews. *Int J Med Inf*. 2010;79:736-771.
55. Nelson E, Barnard M, Cain S. Treating childhood depression over videoconferencing. *Telemedicine and e-Health*. 2003;9:49-55.
56. Elford R, White H, Bowering R, Ghandi A, Maddiggan B, John KS. A randomized, controlled trial of child psychiatric assessments conducted using videoconferencing. *J Telemed Telecare*. 2000;6:73-82.
57. Glueckauf RL, Fritz SP, Ecklund-Johnson EP, Liss HJ. Videoconferencing-based family counseling for rural teenagers with epilepsy: phase 1 findings. *Rehabilitation Psychology*. 2002;47:49-72.
58. Donabedian A. The quality of care. How can it be assessed? *JAMA*. 1988;260:1743-1748.
59. Donabedian A. Evaluating the quality of medical care. *Milbank Mem Fund Q*. 1966;44:Suppl:166-206.
60. Coker TR, Chung PJ, Cowgill BO, Chen L, Rodriguez MA. Low-Income Parents' Views on the Redesign of Well-Child Care. *Pediatrics*. 2009;124:194-204.
61. Perrin EC, Lewkowicz C, Young MH. Shared Vision: Concordance Among Fathers, Mothers, and Pediatricians About Unmet Needs of Children With Chronic Health Conditions. *Pediatrics*. 2000;105:277-285.
62. Farmer JE, Marien WE, Clark MJ, Sherman A, Selva TJ. Primary Care Supports for Children with Chronic Health Conditions: Identifying and Predicting Unmet Family Needs. *J Pediatr Psychol*. 2004;29:355-367.
63. Glaser BG, Strauss AL. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Chicago, IL: Aldine Publishing Company; 1967.
64. Ryan G, Bernard H. Data management and analysis methods. In: Denzin N, Lincoln Y, editors. *Handbook of Qualitative Research*. 2nd ed. Thousand Oaks, CA: Sage Publications; 2000. p. 769-802.
65. Miles MB, Huberman AM. *Qualitative Data Analysis: An Expanded Sourcebook*. 2nd ed. Thousand Oaks: Sage Publications; 1994.
66. Bethell CD, Read D, Stein RE, Blumberg SJ, Wells N, Newacheck PW. Identifying children with special health care needs: development and evaluation of a short screening instrument. *Ambul Pediatr*. 2002;2:38-48.
67. Agency for Healthcare Research and Quality. Topics and related items in the CAHPS Health Plan Survey 4.0 Core Questionnaires. Available at: https://www.cahps.ahrq.gov/content/products/PDF/PROD_HP4_Core.htm. Published 2006.

68. Varni JW, Seid M, Kurtin PS. PedsQL (TM) 4.0: Reliability and validity of the Pediatric Quality of Life Inventory (TM) version 4.0 Generic Core Scales in healthy and patient populations. *Med Care*. 2001;39:800-812.
69. Goodman R, Scott S. Comparing the Strengths and Difficulties Questionnaire and the Child Behavior Checklist: is small beautiful? *J Abnorm Child Psychol*. 1999;27:17-24.
70. Child and Adolescent Health Measurement Initiative. 2005-2006 National Survey of Children with Special Health Care Needs Indicator Data Set, Data Resource Center for Child and Adolescent Health. Available at: http://www.childhealthdata.org. Accessed May 12, 2009.
71. Varni JW, Seid M, Kurtin PS. PedsQL(TM) 4.0: Reliability and Validity of the Pediatric Quality of Life Inventory(TM) Version 4.0 Generic Core Scales in Healthy and Patient Populations. *Medical Care*. 2001;39:800-812.
72. Groves R, Dillman D, Eltinge J, Little RJA. *Survey nonresponse*. Hoboken, NJ: Wiley-Interscience; 2002.
73. Korn E, Graubard B. *Analysis of health surveys*. Hoboken, NJ: Wiley-Interscience; 1999.
74. Schafer JL. *Analysis of incomplete multivariate data*: Champman & Hall/CRC; 1997.
75. Rubin D. *Multiple imputation for nonresponse in surveys*. Hoboken, NJ: John Wiley & Sons; 1987.
76. Neter J, Kutner M, Nachtsheim C, Wasserman W. *Applied linear regression models* 3rd ed. Chicago, IL: Irwin Inc.; 1996.
77. Israel BA, Schulz AJ, Parker EA, Becker AB, Allen AJ, Guzman JR. Critical Issues in Developing and Following Community Based Participatory Research Principles. In: Minkler NW, editor. *Community-Based Participatory Research for Health*. San Francisco: Jossey-Bass; 2003.