

Mental Health Services Act

Collaborative Statewide Early Psychosis Program Evaluation

Deliverable 1:

Summary Report of the Contracting and IRB Process Undertaken to Support the Activities of the LHCN

Draft submitted June 1, 2019

Final version submitted June 30, 2019

Prepared by:

University of California, Davis

This report was supported by:



Table of Contents

Summary Report of the Contracting and IRB Process Undertaken to Support the Activities of the LHCN..... 1

Background 3

Deliverable 1: 3

Methods: 3

Writing and submitting the IRB..... 3

 Table 1: Type of data and relevant documentation for IRB protocol 4

Contracting process 5

 County and One Mind Contracts..... 5

 Application Developer Selection and Contract..... 6

Developing the Advisory Committee 6

Discussion 7

 Next Steps..... 7

Appendix I: Flyer to advertise for advisory committee 8

Appendix II: Summary of Consultations with County and Program Staff 10

DRAFT

Background

Multiple California counties, in collaboration with the UC Davis Behavioral Health Center of Excellence, received approval to use Innovation or other Prop 63 funds from 4 counties (Solano, San Diego, Los Angeles and Orange) to develop infrastructure for a sustainable learning health care network for early psychosis (EP) programs. The One Mind Foundation has also contributed \$1.5 million in funding to support the project. This Innovation project seeks to demonstrate the utility of the network via a collaborative statewide evaluation to clarify the effect of the network and these programs on the consumers and communities that they serve. This project, led by UC Davis in partnership with UC San Francisco, UC San Diego, University of Calgary and multiple California counties, will bring consumer-level data to the clinician's fingertips for real-time sharing with consumers, and allow programs to learn from each other through a training and technical assistance collaborative. This Statewide EP Evaluation and LHCN primarily aim to 1) increase the quality of mental health services, including measurable outcomes, and 2) introduce a mental health practice or approach that is new to the overall mental health system. The proposal must comply with the regulatory and funding guidelines for evaluation as stipulated by the applicable MHSA funding regulations, contract deliverables, and best practices.

There will be three components to the data collected for the Learning Health Care Network: County Level, Program Level, and Qualitative data. Each component of the proposal must be reviewed by an Institutional Review Board (IRB) and approved before commencement of data collection. Further, aspects of the data design will be shaped by the input of stakeholders, including mental health consumers and family members.

This proposal was approved for funding using Innovation Funds by the OAC in December of 2018. Following the approval, we began the process of establishing contracts with counties and writing the IRB to support research activities. This is the first deliverable of ten, which is described in the scope of work that each county has or will have with the University of California, Davis team. The first deliverable is as follows:

Deliverable 1:

The contractor will submit a progress report summarizing: 1) submission of the IRB protocol covering all aspects of Learning Health Care Network and statewide evaluation data collection; 2) identification of an external company to develop LHCN platform application; 3) recruitment for external advisory committee and focus groups.

The participating EP Programs will support access to stakeholders for feedback. Support recruitment of external advisory committee. Participate in outcome of interest prioritization process.

The participating Counties will: Participate in outcome of interest prioritization process. Support access to other relevant community- or state-level stakeholders for feedback. Submit report that identifies key staff for data collection and transfer.

Methods:

Writing and submitting the IRB

Starting in January of 2019, staff at UC Davis began preparing an IRB protocol to cover all aspects of work that will be performed as part of the Learning Health Care Network and statewide evaluation. As described above, we will collect three main elements of data for the Learning Healthcare Network.

The main components of the County Level data will be to compare program utilization, emergency department/crisis, and non-EP behavioral health care utilization and associated costs across EP and

comparator programs (CG) serving EP consumers (with similar age, diagnosis, services received). We will do this by using de-identified county-level data from each of the participating counties.

The vast majority of the Program Level “Learning Health Care Network” data will be detailed outcome data (symptoms, functioning, satisfaction, etc.) collected on a tablet-based application from consumers receiving care from an EP program in participating counties. We will also assess EP program fidelity as well as consumer and provider skills, beliefs and attitudes around measurement-based care. We will interview consumers and providers to understand the use of LHCN in service delivery (pre- and post-LHCN implementation).

The Qualitative data will come from focus groups, stakeholder meetings & qualitative interviews with consumers, families, county and state staff, relevant community groups, and EP program staff. The results from these interviews and focus groups will be used to inform outcome selection, inform implementation of LHCN and the evaluation, present findings, and assess satisfaction.

During the writing process, the team had several consultations with the IRB staff on how to properly set up the activities for this project. There will be colleagues from at least two other universities (UCSF and UCSD) conducting research activities on this project. The participants will be consumers, families, staff from county EP clinics, and community stakeholders across the state of California. Thus, our IRB was submitted as a single IRB for multi-site research. This is a type of reliance agreement. The IRB will have a CORE (maintained at UCD) with IRBs of record for the participating research sites (UCD, UCSF, UCSD). Any research that will involve all of the sites will be covered by documents in the CORE. If there are additional activities that are unique to a site, they will be submitted to the IRB of record for that site. All of the planned procedures and activities were described in detail and all relevant documentation was submitted with the IRB protocol (see Table 1). This initial application was submitted for review to University of California’s, Davis IRB on April 17th, 2019. UC Davis is actively working with the UC Davis IRB and collaborators at UCSF and UCSD to submit all relevant forms and address questions. IRB approval is pending.

Table 1: Type of data and relevant documentation for IRB protocol

Data Type	Relevant documentation
Self-Reported Clinical Outcomes Collected on Tablet*	
Modified Colorado Symptom Index (CSI)	Electronic Tablet Screening Form; Client-Family Demographic Form
The Questionnaire about the Process of Recovery (QPR)	
Personal Well-being Index	
Glasgow Antipsychotic Side-effect Scale (GASS)	
Systemic Clinical Outcome Routine Evaluation (SCORE-15)	
Burden Assessment Scale (BAS)	
The National Survey on Drug Use and Health (NSDUH) 2014 Questionnaire	
At-Risk of Homelessness Indicator	
MHSIP Youth Services Survey	
Recovery Self-Assessment (RSA)	
Treatment Satisfaction Survey	
Qualitative Interviews	
Evaluation of EP services	Client and Family consent form, Client assent form, Provider consent form for Evaluation Qualitative Interview

Barriers and Facilitators to Tablet Implementation	Client and Family consent form, Client assent form, Provider consent form for Barriers and Facilitators Qualitative interview
Focus Groups	
Wireframe	Focus group guide for Wireframe, client version; Focus group guide for Wireframe, provider version; Client and Family consent form, Provider consent form
Application and Dashboard	Focus group guide for Dashboard, client version; Focus group guide for Dashboard, provider version; Client and Family consent form, Provider consent form
Outcomes Selection	Focus group guide for Outcomes, client version; Focus group guide for Outcomes, provider version; Client and Family consent form, Provider consent form
Cognitive Testing	
Penn Computerized Neurocognitive Battery (CNB)	Client and family consent and client assent forms for surveys and cognitive testing
Matrix Reasoning Test (PMAT)	
Word Memory Test (PWMT)	
Digit Symbol Substitution Test (DSST)	
Surveys	
Perceived Effect of Use	Consent form for Provider surveys; Client and family consent and client assent forms for surveys and cognitive testing; Consent form for Client surveys
Treatment Alliance (STAR-C & STAR-P)	
Comfort with Technology	
Satisfaction with MOBI Platform	
Insight into Illness	

*These are subject to change after the Outcomes Selection focus groups.

Contracting process

County and One Mind Contracts

UC Davis had drafted a common scope of work that encompasses language that is agreeable to each county and the One Mind Foundation. We had decided, in collaboration with the counties, to have a separate contract for each county using the common scope of work with UC Davis, as opposed to one master agreement for all counties. At the time of this deliverable, only Solano county and the One Mind foundation have an executed contract with UC Davis. San Diego, Los Angeles, and Orange County are at various stages of approval for their contracts. San Diego county has submitted their contract to our Office of Research and we are in the process of finalizing the terms of the contract. San Diego and other participating counties have stressed the need for the language in the executed contracts to address data storage and privacy concerns because PHI is involved and MHSA dollars would be used. To that end, we have had multiple consultation meetings between our team and San Diego county and their county run program, Kickstart, to ensure the contract for all counties includes strict protections to meet HIPAA compliance and the data privacy needs required by each county are included in the software development process (see Appendix II). The developer has also been on these calls with IT/data specialists from each county review the language in the scope and contract before approving the agreement. After some discussion, we created a document that covers all human subjects concerns from an IT/data standpoint.

Los Angeles and Orange county have chosen to contract through the Joint Participation Agreement (JPA) with CalMHSA rather than directly with UCD. CalMHSA is working with the counties to draw up a contract that then needs to be approved by each county's board of supervisors. This process has taken longer than anticipated and both counties are actively working to obtain approval by their board of supervisors and develop a contract with CalMHSA. To address the delay, staff here at UCD have amended Los Angeles and Orange county's scope of work to still include the original 10 deliverables but on a compressed timeline so that we hit the original planned evaluation and research targets. To do this, there will be two deliverables for Los Angeles and Orange county in the first six months of the project, and their total contract length will be reduced by six months.

Application Developer Selection and Contract

One of the goals of the project period was to identify and select an external company to develop the LHCN platform and application. We have proposed Quorum technologies as our developer as they have already built two applications for research purposes with UC Davis. Quorum is a Sacramento-based company that specializes in health care application development and creating integrated specialty applications for large health systems. Additionally, it should be noted that we also reached out to multiple development companies in the past to obtain quotes to develop the prior apps (described below) and no one responded but Quorum.

We have previously contracted with Quorum to build two applications - MOBI and the DUP app - for research purposes. Currently, UCD holds the rights to the MOBI application, which was previously developed by Quorum and will serve as the foundation for the LHCN application. Due to its prior knowledge of MOBI, Quorum has participated in multiple calls with stakeholders and worked with IT teams across the state to address security needs for MOBI to work for this project. Quorum has an established team located in Sacramento that is ready to modify MOBI for the current project. Their knowledge of the healthcare landscape of California, local staff that can be deployed for project meetings or stakeholder engagement related to the project, and intimate knowledge of the MOBI app makes them uniquely capable of executing this project.

The UCD team is working with UCD contracts to determine if we can have a sole source contract with Quorum. While we do have funds in place from One Mind and Solano county to begin paying the developer to begin work on the wireframe and app development, we are not able to spend these funds until the university approves the quote, contract, and sole source justification. This has prevented us from spending funds allocated for the 18-19 fiscal year.

Developing the Advisory Committee

One of the stated goals of the LHCN project is to have an advisory committee. Prior to data collection, an Advisory Committee consisting of 2-3 former consumers, 2-3 family members of service users, EP providers (1 admin, 1 non-management/direct service provider), researchers and county (program monitor + data support person) and state representatives (OAC) will be recruited with the aim of providing input at each stage of the project. This Advisory Committee will convene every 6 months, and additionally when needed, to provide input at the initiation and submission of the major project deliverables detailed below. One of the goals of the advisory committee is to ensure diversity across linguistic, racial/ethnic, sex, gender identity, LGBTQ+, and socioeconomic status factors. During this period, we have begun the process of recruiting for the Advisory Committee. This first step is to create materials to advertise the opportunity to potential volunteers that will fill the role of the family members and service users. We have created a flyer to disseminate to the county programs for them to recruit mental health consumers and family members from their clinics (see Appendix I). This flyer will be distributed in participating clinics after IRB approval.

We have also identified possible members that may fill the other roles on our Advisory committee.

Discussion

Over the past 6 months, the UC Davis-led team has worked hard to address each of these three deliverables. It should be noted that the LHCN represents the first partnership between the University of California, multiple California counties and a foundation to build and implement a collaborative and integrated Innovation project. Through this endeavor, all parties hope that we can have a larger impact on mental health services than any one county can create on their own. While the project has experienced some initial obstacles in contracting and implementing a new IRB method, the team feels confident that we are making excellent progress.

Next Steps

The UC Davis team will continue to collaborate with Los Angeles, Orange County and CalMHSA to establish a contract for the LHCN. Progress with the IRB is ongoing and approval should be obtained in the coming months. Once IRB approval is in place, the team will begin to work with the counties that have established contracts so that progress can be made toward project goals.

DRAFT

Appendix I: Flyer to advertise for advisory committee

DRAFT

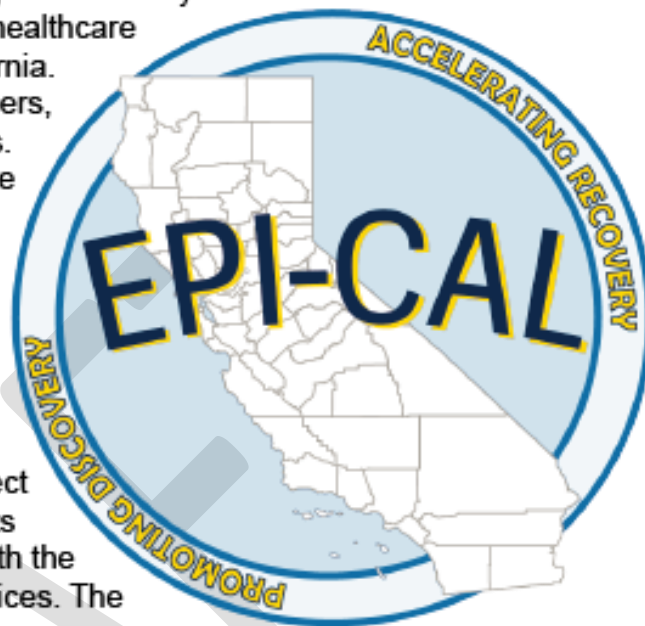
EPI-CAL California Early Psychosis Collaborative: Learning Healthcare Network and Statewide Evaluation

Are you interested in joining our Advisory Committee?

The clinic is looking for volunteers for a new project's Advisory Committee. This project will develop a learning healthcare network for early psychosis clinics across California. The Committee will include clients, family members, clinicians, researchers and state representatives. The Committee will give feedback on every stage of the project.

What is the Learning Healthcare Network?

The project will bring together early psychosis programs across California to share information and coordinate collection of outcomes data. A customized electronic tablet application will collect data from clients and families in the clinic. Clients and families can see their data when working with the clinical team and use the data to make care choices. The data will help us learn how to support clients to reach their goals.



What does being a member of the Advisory Committee entail?

In the Advisory Committee, a diverse group of clients and family members will share their experiences using mental health services. They will view presentations on the project, review the electronic tablet application and project materials, review findings from the evaluation and provide feedback. The advisory committee will meet for few hours twice a year for 5 years. You would be paid for travel or may join via phone.

If you are interested in joining or would like more information, please contact:

Clinic Contact name, Title
Phone Number, Email Address



Appendix II: Summary of Consultations with County and Program Staff

Date	County/Countries	Attendees	Summary of call
6/21/2019	Solano	Tara Niendam, Valerie Tryon (UCD); Tracy Lacey (Solano County)	Call to discuss delays in spending down first period of Solano County contract funds and plans for moving forward. We will contact the OAC to roll unspent funds over to the next fiscal year.
6/17/2019	San Diego	Valerie Tryon, Brooke Herevia (UCD); Mandi Duarte, Cecily Thornton-Stearns, Elaine Sanders (SD County)	Call to clarify and discuss the terms of the contract between SD county and UCD. Each objective of the deliverable has an invoiceable amount. Invoicing will occur twice annually.
5/24/2019	Solano	Brooke Herevia (UCD), Jacquelyn Holley-Young (Solano County)	Call to discuss how invoicing is to be performed between UCD and Solano county.
5/9/2019	San Diego	Tara Niendam, Valerie Tryon (UCD); Binda Mangat (Quorum Tech); Mary Ellen Baraceres, Hope Graven, Marni Orsbern, Stephany Rogers, Shan Sejkora, Joseph Edwards, Katherine Lee (Pathways); Mandi Duarte, Cecily Thornton-Stearns, Elaine Sanders, Liane Sullivan (SD County)	Call to clarify the data entry process and discuss the security of the MOBI platform and how to test this once a contract is in place. Update on the county contract process.
5/9/2019	Orange	Tara Niendam, Valerie Tryon (UCD); Sharon Ishikawa, Flor Yousefian-Tehrani, Mark Lawrenz, Raquel Tellez (Orange County), Rhonda Bandy (Modoc)	Call with Orange county to check-in on their progress with contracting. We also used the call as a platform to introduce the LHCN project to Modoc county behavioral health representative Rhonda Bandy. Modoc county has expressed interest in joining the LHCN.
4/2/2019	Los Angeles	Valerie Tryon (UCD), Samantha Wettimuny (LA county)	Call between UCD and LA county to discuss amending their scope of work to start 7/1/2019 instead of the original planned 1/1/2019. The call was used to discuss how to update the deliverable timeline and it was decided that the first two deliverables would occur in the first 6 months of the updated scope.
3/1/2019	San Diego	Tara Niendam, Valerie Tryon (UCD); Mandi Duarte, Cecily Thornton-Stearns, Elizabeth Miles, Cara Evans Murray (SD County)	Call to clarify how to proceed with the IRB process for the county programs. This will be a multi-site study with UCD as the "CORE" site containing study-wide documentation. SD county usually does not require IRB for activities such as these.
1/7/2019	San Diego	Tara Niendam, Valerie Tryon, Jessica Hicks	Call to discuss how to organize contract between SD county and UCD. The contract will be a fixed price,

(UCD); Mandi Duarte,
Cecily Thornton-Stearns,
Elaine Sanders (SD
County)

deliverable based contract. SD county plans to submit a
contract template to UCD's Contracts and Grants
department for review.

DRAFT