COUNTY OF LOS ANGELES-DEPARTMENT OF MENTAL HEALTH

MHSA INNOVATION 8 PROJECT
EARLY PSYCHOSIS LEARNING HEALTH CARE NETWORK

The Need

Research has demonstrated that intervening within 18 months of the onset of psychotic symptoms significantly improves recovery rates, overall prognosis and a client's quality of life. These findings coupled with a legislative focus on early psychosis services (AB 1315, SB 1004), has served as a catalyst for the delivery of these early intervention services across the state that includes a focus on early identification and treatment of clients experiencing psychotic symptoms. Of the 58 California counties, 23 counties reported implementing early psychosis (EP) programs. However, these programs were started county by county, with little collaboration in training or implementation. As a result, many counties and programs have implemented programs in isolated and struggle to get the training and technical assistance needed to keep their EP program flourishing. Additionally, no statewide outcome data currently exists to document the impact these programs have on the clients served, their families and on the local mental health systems.

Los Angeles County, through its MHSA Prevention and Early Intervention (PEI) plan, implemented an early psychosis program developed through the UCLA Center for the Assessment and Prevention of Prodromal States (CAPPS). While the program to date has provided a full course of services to 186 clients (representing 43% of those who started the practice) and achieved a 30% improvement in mental health functioning and a 60% reduction in prodromal symptoms, a portion of the provider cohort reduced or eliminated their use of the practice and the developer moved the center to the east coast.

As part of a comprehensive review and addition to the Department's PEI plan contained in the MHSA 3 Year Program and Expenditure Plan for Fiscal Years 2018-18 through 2019-20, there was a plan to increase early psychosis services. After a comprehensive review of evidence-based coordinated specialty care models, the Department selected the Portland Identification and Early Referral (PIER) model. The Department issued a solicitation on June 29, 2018 and has identified a cohort of directly operated programs to implement the PIER model. Through this Innovation proposal, LACDMH proposes to participate in a learning health care network that will aid in the consistent and successful implementation and sustainment of coordinated specialty care early psychosis services that will involve the collection, reporting, analysis and use of consistent outcome data through a state portal.

Project Overview

Research has demonstrated that treating psychotic symptoms within 18 months of their emergence results in significantly better functional outcomes and quality of life. The proposed Innovation program seeks to 1) develop an EP learning health care (LHCN) network to support ongoing learning and development across the state and 2) demonstrate the utility of the network via a collaborative statewide evaluation to clarify the effect of these programs on the clients and communities that they serve.
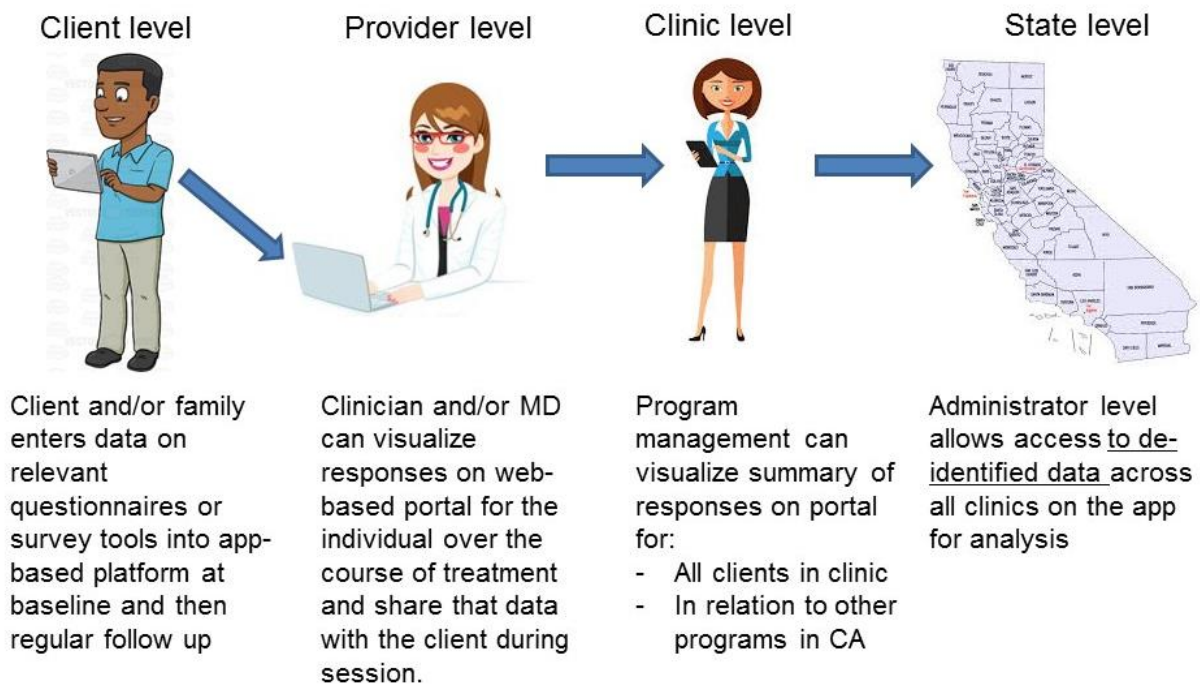
The Los Angeles County Department of Mental Health, in collaboration with the UC Davis Behavioral Health Center of Excellence, is seeking approval from the Mental Health Services Oversight and Accountability Commission (MHSOAC) to use Innovation Funds to develop the infrastructure for a sustainable learning health care network for EP programs, the utility of which will be tested through a robust statewide evaluation. The evaluation would assess effectiveness and cost-effectiveness of EP programs across the state and allow counties to adjust their programs based on lessons learned

through interdisciplinary methods. This project, led by UC Davis in partnership with UC San Francisco, UC San Diego, University of Calgary and a number of California counties, will bring client-level data to the clinician's fingertips, allow programs to learn from each other, and position the state to participate in the development of a national network to inform and improve care for individuals with early psychosis across the US.

Background: Positioning California to Lead Early Psychosis Treatment to Optimize Outcomes

The foundation for the proposed California EP learning health care network and associated evaluation was developed through a prior MHSOAC funded project, which sought to develop a method for evaluating publically funded EP programs across the state. Based on the current research literature, cumulative findings of the previous project, and stakeholder input, it became clear that EP program clients, providers and county supports wanted to have immediate access to their data so they could learn and improve in real time (see Figure below). Through a collaborative county-led process, we identified potential outcomes that could be regularly measured at a client level and then made available immediately for a variety of uses. For example, a client could review their own data while in session with their provider, to understand factors that may be contributing to treatment progress. The clinic manager or county administrator could visualize data across the program and compare program averages to a statewide benchmark, which will be based upon data from all programs using the network. Finally, de-identified data will be available at the state level to support large scale analysis. Within the proposed project, we would test the utility of this network though a cross-county evaluation of outcomes. Further, the network utilizes self-report data from clients on valid measures that have been selected for use in early psychosis programs (www.phenxtoolkit.org). In this way, clients are empowered to share their experiences with their clinical team and providers have the ability to obtain this additional information without asking their clinicians to perform lengthy assessments.

Figure 1. Proposed Learning Health Care Network for CA Mental Health Programs

Client level	Provider level	Clinic level	State level
Client and/or family enters data on relevant questionnaires or survey tools into app-based platform at baseline and then regular follow up	Clinician and/or MD can visualize responses on web-based portal for the individual over the course of treatment and share that data with the client during session.	Program management can visualize summary of responses on portal for: - All clients in clinic - In relation to other programs in CA	Administrator level allows access to de-identified data across all clinics on the app for analysis

With the support of this innovative learning health care network, EP programs and their associated counties recognized the unique opportunity to have longitudinal patient- and service-level clinical data available to providers and their clients in real-time that can be used as part of the consultation. However, they also recognized that this network would allow them the opportunity for improved outcome recording and reporting, which can be used for services planning and improving standards of care via comparison to a statewide benchmark. These stakeholders proposed that this could serve as the basis for an EP learning collaborative, through which programs or counties could use the data to identify areas of unmet clinical or training needs, identify which service components drive outcomes in a particular area, collaborate to hold trainings, and learn from each other's successes and struggles. Through the network, these otherwise disparate programs could come together to learn, grow and improve.

Furthermore, this Innovation project would leverage the California LHCN to support our participation in a national early psychosis learning health care network, which will be funded by the National Institute of Mental Health (NIMH). In fall 2017, NIMH convened key leaders across the country, including leaders in California and in Los Angeles County, to promote best practices for treating first episode psychosis or those deemed at high risk for developing schizophrenia and to identify common metrics that can be used to evaluate outcomes associated with such services across the country. At this meeting, it was noted that California has demonstrated the largest dissemination of EP services in the US. Therefore, California and its EP programs are in a prime position to contribute to national efforts to evaluate the impact of EP care.

The standardized outcomes that have been proposed for consideration for inclusion in the NIMH network have been identified by the MHSA as core outcomes to be measured in programs receiving MHSA funds and are aligned with the SAMHSA Mental Health Block Grant. The NIMH is interested in developing a national network of EP program – currently named EPINET – but participation in this national network requires the participating states to have established infrastructure for large scale data collection and reporting. In this area, California is poised to contribute the most data, yet we lack the infrastructure to participate. By systematically designing outcome reporting for counties across the state, the value of the proposed network moves beyond simple program level evaluation and lays the groundwork for linking data on both a state and national level.

The participation of the counties and programs co-authoring this proposal demonstrates the anticipated value of the LHCN and statewide evaluation. We have a unique opportunity to build a coalition of counties, their partnered programs, and leading researchers in psychosis to share lessons about what works for patients across the state using interdisciplinary methods. With this innovative proposal the state will have thematic evidence from consumers, family members and clinicians as well as quantitative impacts such as service utilization, hospitalizations, and crisis utilization. The learning health care network and the statewide evaluation dovetail to inform early psychosis care across the state. It is our aim to use the LHCN as a resource and a tool for the counties before, during and after a formal evaluation, and to sustain the network beyond the 3-year project for ongoing benefit to the counties involved and the state of California.

Implementation Plan
Priorities for implementation of this learning health care network and statewide evaluation were identified in a series of stakeholder meetings conducted in 2017 and 2018 with relevant county and program leaders, as well as well as individuals with lived experience of psychosis and family members of those with lived experience. Three common themes were prevalent in all conversations – utility, sustainability, and relevance to real-world outcomes. It became apparent during conversations with program and county staff that they saw immediate value in the utility of the tablets and the ability to display outcomes data at the individual level for use during clinical visits, at the program level for

internal quality improvement, and at the state level for system level learning. Because of this, the evaluation team has prioritized the utility of the data collected in real-time. The program and county stakeholders were acutely aware that plans for sustainability after the project end date will be very important for their ongoing interest. As part of the project, we will calculate true costs to programs for implementation of tablets and daily operations to inform future decisions around sustainability. Beyond this project, there may be opportunities to explore implementation of the outcomes reporting protocols across county programs. All stakeholders, especially individuals and family members, wanted to prioritize outcomes relevant to them and real world outcomes. Therefore, the initial list of measures (to be developed further during the project) has focused on client-driven input.

Data on costs and utilization – at the program, crisis/ED and hospital levels – represent key areas of interest for county and state level stakeholders. The ability to understand how EP programs yield differential utilization of high-cost services versus standard outpatient care is essential to clarify the impact of these programs on the communities that they serve. In combination with the EP program level data, the evaluation associated with this project will help counties and programs understand the client- and program-level factors that contribute to increased utilization of high-cost services, thereby enabling targeted decisions around program level changes to mitigate those costs.

The qualitative arm of the proposal includes multiple opportunities for feedback from county, program, client, and family stakeholders. The three-stage, iterative nature of the prospective evaluation is designed to integrate ongoing stakeholder involvement and create an operationally sustainable tool that will be just as valuable to the individual counties as the state as whole. We aim for the tablets to be accessible to interested counties across the state and plan to incorporate additional counties for qualitative feedback throughout the project with an eye for statewide implementation.

The counties affiliated with this proposal and their respective program partners have agreed to engage with the evaluation team at UC Davis to participate in one or more components of the evaluation component and participate in ongoing stakeholder groups for the learning health care network.

Overall Goals
1. Implement a learning health care network (LHCN) for early psychosis programs across multiple California Counties.
2. Develop a learning health care network implementation strategy that could be adopted by EP programs statewide, utilizing principles and practices from implementation science and continuous quality improvement.
3. Demonstrate the utility of the learning health care network through a multilevel evaluation of: a) the potential differences in service utilization (EP program, ED/crisis, hospital) and costs between EP programs and standard care, b) the EP program components associated with improved client level outcomes, and c) the client, family and program staff experiences related to participation in at LHCN.

Primary Purpose and Qualification as an Innovation Project
The proposed Innovation Project will ***make a change to an existing practice in the field of mental health*** by introducing a collaborative learning health care network to support quality improvements, client engagement and provider use of measurement-based care in early psychosis programs. This learning health care network will produce real-time data at the individual, clinic, county and state levels to inform client- and program-level decisions and develop learning opportunities. The associated evaluation would quantify costs of implementation and utilization and support statewide efforts for early identification and treatment of psychosis. This project proposes a new approach to state-level learning and real-time outcomes monitoring. ***Aligning with a primary purpose for an Innovation project as***

identified by the MHSOAC, this project seeks to increase the quality of services, including measurable outcomes.

The proposed project meets a variety of unmet needs across the state:
1. Provides client-level data across a variety of recovery-oriented measures to directly inform day-to-day service provision. Training and technical assistance will be provided to support the ability for clinicians to use the LHCN data in practice, transforming these services to measurement-based care.
2. Provides immediate access to relevant outcome data for program leadership that can be shared immediately with stakeholders, the county, or the state. Rapid dissemination of program outcomes has historically been a challenge for county-based programs.
3. Provides infrastructure for an EP Learning Collaborative across counties, in which common challenges can be identified and "lessons learned" can be quickly disseminated, creating a network of programs that rapidly learn from and respond to the changing needs of their clients and communities.
4. Evaluation of the LHCN will provide information on how to incorporate measurement based care into mental health services, and demonstrate impact of the LHCN on the recipients and providers of care.

Target Population
The target population or intended beneficiaries/users of this learning health care network are:
- Individuals at increased risk or in the early stages of a psychotic disorder
- Family Members or other support persons
- EP program providers
- County and EP program leadership
- State authorities and policy makers
- National networks (EPINET)

Overarching Learning Questions
Through the development of the learning health care network and the associated evaluation, we will answer the following questions:
1. Are there differences in utilization and costs between EP programs and standard care?
2. How do utilization and cost relate to client level outcomes within EP programs?
3. What are the EP program components associated with client-level outcomes in particular domains?
4. Within EP programs, what program components lead to more or less utilization (e.g. hospitalization)?
5. To what extent do California EP programs deliver high fidelity to evidence-based care, and is fidelity related to client-level outcomes?
6. What are the barriers and facilitators to implementing a learning health care network across EP services?
7. What are the client, family and provider experiences of submitting and utilizing data obtained through the learning health care network during routine clinical care?
8. Does a technology-based learning health care network increase use of client-level data in care planning?
9. Does use of client-level data increase insight into treatment needs, alliance with the treatment team, or improve satisfaction with care?
10. What will be a viable strategy to implement a statewide learning health care network for EP programs?

Proposed Implementation and Dissemination Strategies

To implement the learning health care network and statewide EP evaluation, the UC Davis led evaluation team will draw on experiences from the previous MHSAOAC evaluation including a pilot conducted with Sacramento County. Implementation of the tablets for client-level outcomes reporting and analysis of county data on cost and utilization will be piloted in two counties in order to establish methods for cross-county data integration before implementing the strategy across all partner counties. There will be qualitative interviews at each stage to identify outcome selections that are feasible and appropriate for stakeholders, focus groups to refine the software, and interviews to determine barriers and facilitators to successful implementation.

Dissemination is an integral piece of the learning health care network and has been identified as one of the strongest reasons for county participation. Dissemination would include access to data via designated portals for providers, county and program leadership. Such data will be easily summarized and visualized for county and state stakeholders. The collaboration between researchers and providers, clients and family members, which is a central theme of this proposal, will inform ongoing improvements to support ongoing usability and promote participation of other counties. We will present stakeholders with main findings as part of the qualitative component of the project, and support access and opportunities for counties to communicate and collaborate. We intend for the software to be available to other California providers through a phased onboarding process. Dissemination of lessons learned and opportunities for EP programs will be disseminated more broadly through the publication of main findings.

Evaluation

The Utility of the Learning Health Care Network on Early Psychosis Programs

To examine the impact of the LHCN on clients and providers, the evaluation will examine the impact of the LHCN on the counties and their services. We predict that the easy-to-use technology-based LHCN and on-demand access to results that providers can share with clients will increase the use of data in treatment planning and care decisions, moving the system toward measurement-based care. Further, our previous experience implementing mobile health technology in community-based EP programs [Niendam TA, Tully LM, Iosif AM, et al., 2018; Kumar D, Tully LM, Iosif AM, et al., 2018] suggests that this project will improve client satisfaction with care, increase insight into their illness and treatment needs, and enhance their alliance with the treatment team.

To address this question, the evaluation will gather information from EP clients and program staff at study entry, 6 month follow up and 12 month follow up to examine the impact of the LHCN on care. Clients will be asked to complete self-report questionnaires about Insight into illness, Perceived Effect of Use for the LHCN, and Comfort with Technology. Providers will complete questionnaires on prior use of data in care, Perceived Effect of Use for the LHCN, and Comfort with Technology. At follow up, clients and providers will complete self-report questionnaires on treatment alliance; clients will also rate their satisfaction with the program. This data will be combined with stakeholder feedback and qualitative results to understand the impact of the LHCN on the client and provider experience.

### Evaluation of EP Program Fidelity

Each participating clinic will undergo a fidelity assessment to determine their adherence to evidence-based practices for first-episode services using a revised version of the First Episode Psychosis Services Fidelity Scale (FEPS-FS). The FEPS-FS represents a standardized measure of fidelity to EP program best practices [33]. The FEPS-FS was developed using an international expert consensus method, focused on six domains: (1) population-level interventions and access, (2) comprehensive assessment and care plan, (3) individual-level intervention, (4) group-level interventions, (5) service system and models of intervention, and (6) evaluation and quality improvement. This scale was tested

for reliability in six EP programs in the United States and Canada, and an accompanying FEPS-FS 1.0 Fidelity Review Manual was developed for future program review. The FEPS-FS has been recently revised to meet the agreed upon standards of EP care in the US and allow large-scale fidelity evaluation. In the proposed statewide evaluation, each EP program will participate in an assessment of EP program components using the revised FEPS-FS, which will be completed on-site or via web-based teleconference. The resulting score will be used as part of the statewide analysis. These assessments will be conducted in consultation with Don Addington, M.D. from the University of Calgary, author of the FEPS-FS scale. Dr. Addington will serve as a Co-Investigator on this project and provide oversight and support for the fidelity evaluations and interpretation of other outcomes data related to components of care. The ability to evaluate the impact of service-level factors on patient-level outcomes collected by tablets is a key component of adopting features of a learning healthcare network. This will provide us with important new insights into what particular components of the EP program of care are associated with improved outcomes in different domains. These findings can then be disseminated across the network (and beyond), further informing care and shaping service delivery.

Impact of EP Programs on Costs and Outcomes

This portion of the evaluation is divided into three data components: program-level, county-level, and qualitative (See Figure 2 below). The first component, which serves as the foundation for the LHCN, utilizes a prospective, longitudinal approach to gather client level data elements for EP programs on core outcomes in six-monthly intervals across 18 months, starting at their intake assessment. The second component, modeled after a pilot analysis in Sacramento County, will focus on county level Medi-Cal data related to client's program service utilization, crisis/ED utilization, and psychiatric hospitalization and costs associated with these utilization domains, compared between EP and comparator outpatient programs in that county who serve similar clients. These comparator programs will be identified by input from county staff, and an evaluation of county level data to identify where first-episode psychosis clients are typically treated in their county outside of the EP program. The third component incorporates qualitative interviews, stakeholder meetings and focus groups with providers, clients, family members, county representatives and regulators to determine which outcomes should be incorporated into the program-level evaluation, inform the design of the program-level data collection system, identify challenges and solutions to implementing the LCHN, and to provide their experiences of delivering or receiving services under this model of care. Taken together, we believe these 3 components will provide a rich, comprehensive summary of the impact of EP programming in California where counties and programs across the state can learn from each other about what works and what can be improved. Each evaluation components is explained in detail on the following page.

Figure 2. Three components of the evaluation associated with the Statewide LHCN.
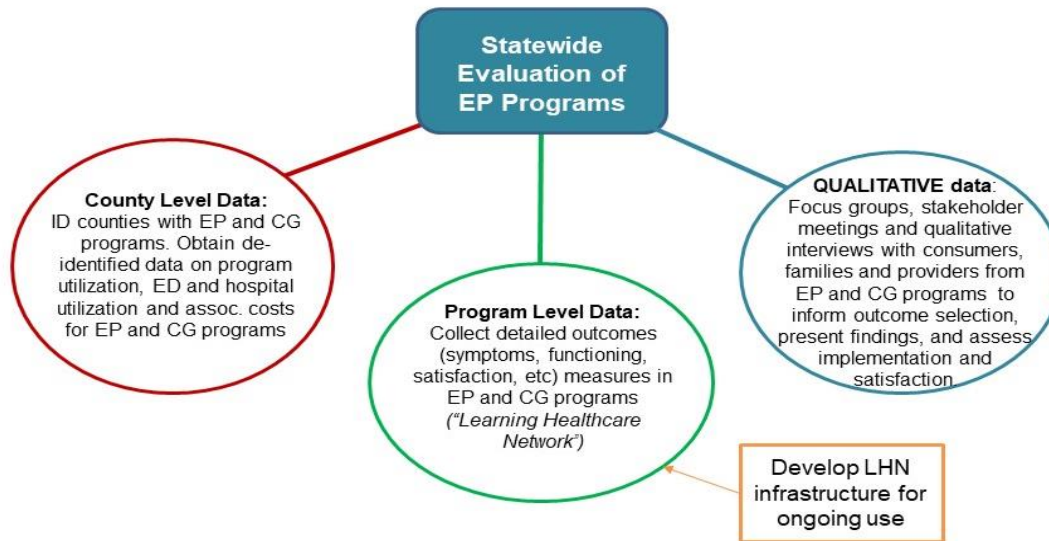
Program-level Data Component

This component of the statewide evaluation will focus on a longitudinal, prospective study of core data elements for EP, which will serve as the foundation for the statewide LHCN. This component includes identification of core data elements, which are considered appropriate and useful by EP programs via stakeholder engagement discussions, and determination of appropriate methods for data collection. Recovery-oriented data elements will be included to understand program impact across additional domains that are important to stakeholders and may not be reflected in more traditional outcome measures. As noted in stakeholder feedback, clients and families will directly provide data via questionnaires, which would reduce burden on clinic staff. If data elements are seen as useful metrics of program goals, the collection of outcomes data in this method could increase motivation for participation by EP programs and address stakeholder's desire to participate in the learning health care network.

In this component, EP programs will be engaged to identify measures of potential outcomes identified from the PhenX Early Psychosis Toolkit ((https://www.phenxtoolkit.org/index.php) and those currently in use by the national MHBG 10% evaluation of EP programming. (see Table 3 on Outcomes below). Once measures are selected by the stakeholders, a prioritization process will be used to identify core outcome domains and measures that can be collected across EP programs. A method of data collection will be developed that aligns with EP program workflows, to reduce burden on program staff, clients and families. EP programs would complete the outcomes evaluation at baseline, and every 6 months thereafter (18 months total). Programs will also provide information on each participating client's diagnosis demographics. All information will be de-identified at the program level before being submitted to the evaluation team.

A primary incentive for county participation is the technologically innovative component of the program-level analysis, which will serve as the foundation for the LHCN. Clients will self-report outcomes from the PhenX toolkit on tablets, with access to discuss the results directly with clinicians, increasing client satisfaction and involvement in the data collection process and reducing clinician burden. That data will be visualized in real-time on a web-based clinician-facing dashboard. Clinicians will receive support in how to utilize this data during client sessions to illustrate their progress toward recovery and inform

collaborative treatment planning. The dashboard will also provide summaries at the program level to aid in program decision-making based on patterns or trends. A core set of outcome measures will be collected uniformly across the six counties, a program's data can also be compared to a statewide average, to provide guidance on where training or technical assistance could be helpful to improve program outcomes.

Based on estimated numbers from our previous descriptive summary of programs in California, across the counties we estimate enrolling and obtaining 12-month outcome data on approximately 2,000-2,500 individuals, with a subset of individuals providing outcome data at 18 months. Los Angeles County expects to serve approximately 700 clients. Outcome on each domain will be modeled longitudinally within the EP group, controlling for any demographic differences between counties (e.g. age, gender, race/ethnicity). Similarly, scores on the program fidelity assessment will be tested as moderator outcomes.

Application and Dashboard Development
The program level data will be acquired on an application and dashboard built specifically for the program and county needs. In the first year of the proposal, we will be contract with an outside vendor to develop this application. We will get feedback from program staff, stakeholders, and focus groups during each step of the development process. Our team has previous experience in implementing this type of technology in the UC Davis Early Psychosis Programs and has found that health applications are useful to both clients and program staff to assess and monitor patient outcomes of interest. The application and web-based dashboard will be developed with all appropriate protections for client information according to HIPPA. Additional protections for data privacy are described below.

Qualitative Data Component
Numerous stakeholder meetings have emphasized the importance of selecting outcomes that are meaningful for clients, providers, and funders in any statewide evaluation of EP programs. This has extended to recommendations that the outcomes be recovery orientated, with an emphasis on functional change. These recommendations are consistent with the aims of the Mental Health Services Act (MHSA), which seeks to reduce specific negative outcomes that may result from untreated mental illness, including: (1) suicide, (2) incarcerations, (3) school failure or dropout, (4) unemployment, (5) prolonged suffering, (6) homelessness, and (7) removal of children from their homes (MHSA, 2015). The outcomes selected will be relatively brief, be feasible to integrate within current clinical practice, and not require extensive external training or ongoing supervision to administer appropriately.

The project proposes integrated engagement of county, program, client, and family stakeholders across all levels. The three-stage, iterative nature of the prospective evaluation is designed to integrate ongoing stakeholder involvement and create an operationally sustainable tool that will be just as valuable to the individual counties as the state as whole. We aim for the tablets to be accessible to interested counties across the state and plan to incorporate additional counties for qualitative feedback throughout the project with an eye for statewide implementation.

In order to recognize both the feedback provided by stakeholders and the treatment aims of the MHSA, the statewide evaluation would incorporate focus groups with providers, clients, family members, county representatives and regulators to assist in selecting outcomes that most appropriately meet these requirements. In addition to providing guidance on what outcome measures to use, consideration of data collection procedures, including how particular types of information may be sourced; the methods to obtain the necessary information; and the recording, storage and amalgamation of data across sites will be merited.

Following the enrollment of the first cohort, an evaluation of the implementation of the LHCN will be conducted in order assess the feasibility of the current strategy, and to identify any barriers which may need to be addressed. In-depth, semi-structured interviews with clients, family members, and providers will be conducted, with the recorded interviews transcribed and analyzed adopting a rigorous qualitative methodology. The project will aim to evaluate the acceptability of the LHCN procedures to both clients and providers; identify any facilitators that have been found to improve the implementation of the LHCN at a site level; and identify any significant barriers to successful implementation, with a proposal of strategies to address such barriers.

MHSA programs strive to provide services to clients with a patient-centered focus to clients' treatment goals (MHSA, 2005). With this in mind, it is important for the evaluation to address the experiences of participants and family members. As part of the analysis, the evaluation would include in-depth, semi-structured interviews with participants and their families receiving EP care, with a comparison of their experiences analyzed using an appropriate qualitative methodology. Given the significant changes in working practices for clinicians, this study will also include the experiences of providers involved in delivering both interventions, with a particular focus on clinician experience of the team approach and evidence-based practices, their perceptions of client engagement in the treatment programs, and their broader experiences of delivering the intervention.

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Finally, the evaluation will convene a stakeholder meeting with clients, family members, providers, county representatives and funders in order to present the preliminary findings, and receive further feedback regarding the implementation of the LHCN procedures.

County-level Data Component

The proposed analysis is based on the pilot work conducted in Sacramento County, scaled to multiple counties. It would focus on client level data related to program service utilization, crisis/ED utilization, and psychiatric hospitalization and costs associated with these utilization domains. First, EP individuals entering the EP programs during a specified period will be identified. Individuals with EP diagnoses, within the same age group, who enter standard care outpatient programs during that same time period will be identified as part of the comparator group (CG). Categories of service utilization will include, at a minimum, outpatient, inpatient and emergency services. It may also include justice system mental health use, if those data are available. Next, costs per unit of service will be assigned to each type of service, per provider, based on cost reports submitted to the Counties from the provider clinics. All information will be de-identified at the program level before being submitted to the evaluation team.

Analyses of service utilization for both groups (EP and CG) will focus on two time periods: 1) the three years prior to the start of this project (e.g. July 2015 – June 2018) to enable data harmonize data across counties and 2) for the 1.5 year period contemporaneous with the prospective program level data to account for potential historical trends during the evaluation period. Mean service utilization, by service type, will be modeled longitudinally between EP and CG groups, controlling for any demographic differences between groups (e.g. age, gender, race/ethnicity). Similarly, costs associated

with service use would also be modeled longitudinally between groups. Scores on the FEPS survey will be tested as a moderator of both service use and costs, within the EP clinics.

The evaluation team would establish a shared database with harmonized data from multiple counties. This requires partnering closely with county staff, EP and CG programs. This process will be linked closely to the qualitative component of the evaluation to identify barriers and problem-solve solutions to those barriers, such as how to make the data export most efficient for counties. The collection of county-level data would overlap with the program-level data component described below. We anticipate that each county formats their utilization and cost data somewhat differently, so that each individual county's data would require analysis to clean the data and create a common format for all data elements across participating counties. This would enable the final analysis to combine data across counties, using a modeling approach that adjusts for the clustering of data within counties. Multiple stakeholders will be involved in all stages of the analysis, regarding study design, analysis and obtaining feedback on results of both the pilot and full study phases.

Protecting Privacy and Confidentiality

Counties will provide de-identified information on client-level utilization and associated costs for the fiscal years specified in the proposal. This will be for individuals in the EP program as well as individuals identified in comparator programs within the county. EP programs will enroll individuals in the online data collection system ("learning healthcare network app") that will collect data on a variety of self-report questionnaires as well as basic demographic data (sex, race/ethnicity, year born – see PHI note below) that is tied to their participant ID. Clients will complete these surveys at baseline and every 6 months thereafter until the end of the study. This data will be available to the clients and EP program staff on the dashboard (via visualizations and data sheets) at an individually identifiable level, but only de-identified data will be available at the UCD level. Stakeholders (clients, families, providers, county staff) will be asked to provide feedback throughout the project, including participation in focus groups and qualitative interviews, that will ask their opinion and experiences as part of the project. Participants' responses will be recorded via handheld digital recorders or via secure conference lines (via ReadyTalk). All response audio files will be de-identified, removed of all 18 PHI identifiers, and then transcribed to document responses prior to analysis. Individuals participating in interviews are notified of this process at time of scheduling and prior to starting the interview.

Any data that is shared with UCD will have all PHI (protected health Information) identifiers removed except for zip code. We will work to ensure that we have enough demographic information to do meaningful analysis, but avoid combinations of PHI that could identify the individual. For example, we would ask for client age and their year of birth, but not their DOB (please see https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/hipaa/ for more information). We will work with each county to develop a unique participant ID that will be tied to each client in the data. UCD will be provided with the participant IDs only, but the county and EP program will be able to link that to the specific person. We tend to call this the "participant ID list."

Data will be stored at UCD; some data will also be stored at UCSF and UCSD at similar protections outlined below. The study investigators and primary research team are the only ones who will have access to the data. It will not be released to others. For the electronic files and data sets, copies of each file will be maintained on the Project Manager's password-protected computer, and backup copies, will be kept on a password-protected removable computer drive. All copies of these electronic file will also be encrypted. All Windows-based computers are locally protected by Windows Firewall, and by the use of IPSec security policies that block external access to the computers. The UCDHS Sacramento campus uses a border firewall to block incoming access to their subnets. The CHPR computers are thus "doubly-secured," falling under the protection of both the UCDHS physical firewall and machine-based security policies. The hard drives of all computers at the Center are protected by

Private Key Full-Disk Encryption, rendering all data unreadable in the event the computer is accessed without permission or removed from the Center. Data will be stored for 48 months after the end of the project to allow ongoing data analysis and publication.

Data will not contain PHI related to patients, but it will contain the names and contact information of program staff who completed the surveys and interviews. This identifying data will be removed during the transcription process to de-identify the program level data. These individuals will not be identified by name in any reporting of results – only summary themes will be reported. In addition, we will utilize all standard protections to safeguard all of this data. Investigators will follow applicable University policies (UC Davis Hospital Policy 1313, UCDHS P&P 2300-2499, and UC Business and Finance Bulletin on Information Security (IS-3) For the electronic files and data sets, copies of each file will be maintained on the Project Manager's password-protected computer, and backup copies will be kept on a password-protected removable computer drive. All copies of these electronic files will also be encrypted. Beyond data coding in the study electronic data files, additional steps will be taken to further ensure study data security. One will be to ensure that only authorized staff will have access to the data files, as determined by the PI. Another will be to ensure that all authorized staff have undergone appropriate briefing from the PI and project manager on techniques for maintaining electronic data security and confidentiality before they are allowed to access and use the data files. The third step will be that only the study project manager, Dr. Tara Niendam, and Dr. Joy Melnikow will be allowed to provide data files to other individuals. The fourth will be to minimize e-mailing of electronic study data files by any personnel. E-mailing of files will only be allowed if data is de-identified and can be sent via encrypted, password protected messaging. All Windows-based computers are locally protected by Windows Firewall, and by the use of IPSec security policies that block external access to the computers. The UCDHS Sacramento campus and UCSF Department of Psychiatry use a border firewall to block incoming access to their subnets. The CHPR computers are thus "doubly-secured," falling under the protection of both the UCDHS physical firewall and machine-based security policies. The hard drives of all computers at the Center are protected by Private Key Full-Disk Encryption, rendering all data unreadable in the event the computer is accessed without permission or removed from the Center

Innovation Project Sustainability and Continuity of Care
First, information gained from the project, including quantitative outcome data from the county and program level as well as qualitative data on the experiences of clients, family members and providers, plus feedback from other counties in the network. Specifically, the project will provide estimates of the cost and staff time required for the technology-based LHCN. These estimates will inform the decision as to whether the EP program will continue ongoing participation in the LHCN, and to inform allocation of necessary resources from non-INN funds, such as PEI funds. The additional counties involved in the qualitative component only at this stage will utilize the project results to determine whether they will join the LHCN in the next phase. Overall, we will work to develop a plan to sustain and enhance the web-based LHCN via ongoing funding through contracts with the EP programs and their associated counties, and to add new counties in the next phase.

Second, information from the LHCN will be used to develop training and technical assistance for the affiliated counties, enabling participants to develop new approaches through a learning collaborative, join together for larger trainings, or seek consultation from programs who have developed approaches that yield positive outcomes. Throughout and at the conclusion of the learning health care network project, Los Angeles County in collaboration with stakeholders and EP providers, will assess the value of the learning network on client outcomes. The overall relative value of each metric and instrument collected will be reviewed to determine which measures had optimal utility and should continue to be collected. It is hoped that this decision will help shape or be made in collaboration with state and federal EP initiatives.

Finally, individuals with SMI who receive services from the EP program in Los Angeles County will continue to do so regardless of whether the LHCN is continued due to the fact that those programs are funded through MHSA Prevention and Early Intervention.

Alignment with MHSA Core Principles

This project is meets the MHSA general standards set forth in Title 9 California Code of Regulations, Section 3320 related to the following:

- Community Collaboration: This project represents an opportunity to enhance community collaboration through a multi-county learning health care network where county leaders, evaluators and providers learn from each other about the best practices in identifying and treating first episode psychosis.
- Cultural competency: Through our prior project and the development of the current project, we have work to engage stakeholders across all areas, including clients served by EP programs and their families, the leadership and clinical providers within EP programs, county and state leadership, as well as community organizations (e.g. NAMI). Meaningful stakeholder engagement has helped to create the proposed county collaborative LHCN and the associated evaluation. To date, stakeholders have influenced the structure of the LHCN, outcomes to be included, and the evaluation approach. The Qualitative component of the proposed project seeks to continue stakeholder engagement throughout the 3-year proposed project, both in the forms of gathering insights and input – as well as helping to interpret the information that is learned. California's EP programs serve a diverse community and we anticipate that our stakeholders will guide us on how best to serve their community. For example, the proposed measures for the LHCN come in a variety of language and these will be available for both clients and their family members who are participating in the project.
- Client and family driven: Family involvement in services is a critical component of the coordinated specialty care approach as well as the evaluation of the project. Family members and clients will be incorporated into the learning network to help inform service effectiveness and to understand, first hand, the best strategies to engage and treat clients.
- Wellness, recovery and resiliency focused: The coordinated specialty care approach
- Integrated service experience: The coordinated specialty care approach ensures service integration from care entry points such as schools, law enforcement, hospitals, Urgent Care Centers to first episode psychosis programs.

Stakeholder Involvement

This project was publically posted on March 23, 2018 as part of the Department's AB 114 spending plan for Innovation funding. No public comment was received as part of that public posting. The Board adopted the AB 114 spending plan, along with the MHSA Fiscal Year 2018-19 Annual Update on June 6, 2018. LACDMH reviewed this project twice with the System Leadership Team, the Department's systemic stakeholder body.

Communication and Dissemination Plan

LACDMH, in conjunction with UC Davis, will communicate the results of this project in a variety of ways:
1. Results of the evaluation will be communicated with stakeholders via webinars, 1-page briefs, or larger presentations based on the needs of the stakeholders. The UC Davis-led team will assist stakeholders in developing their own presentations of the project findings for local groups (e.g. via presentations or newsletters).
2. Findings from the qualitative component will be disseminated via webinars or conference calls to support the learning collaborative of EP programs who are participating in the project.

3. Results of the evaluation will also be published in peer-reviewed academic journals or presented at conferences to share our findings with the larger community.
4. Annual reports will be shared with the MHSOAC and other county or state groups.
5. Products from this project (e.g. webinars, written products, presentations) will be available on the UC Davis Behavioral Health Center of Excellence website.
6. Report to local stakeholders at specific intervals regarding the status of the evaluation.
7. Utilize reports in local provider meetings to improve service quality and monitor performance.
8. Incorporate reports into LACDMH MHSA Annual Updates and 3 Year Plans, including reporting annually to the MHSOAC.

Budget

The Early Psychosis services utilizing the Portland Identification and Early Referral (PIER) model are being funded through MHSA Prevention and Early Intervention and include staff to support the collection and entry of outcome data associated with participation in this Learning Health Care Network. LACDMH, through this Innovation project, is budgeting a Supervising Psychologist position to oversee the data collection and entry work at the 7 PIER service sites and to be the primary evaluation contact with UC Davis.

Year 1:
Evaluation and administration of the LHCN: $786,147
Supervising Psychologist (coordinate and direct the program data $213,041
Collection at each of the 7 PIER service sites)
Year 2:
Evaluation and administration of the LHCN: $519,732
Supervising Psychologist: $213,041
Year 3:
Evaluation and administration of the LHCN: $477,592
Supervising Psychologist: $213,041
Year 4:
Evaluation and administration of the LHCN: $498,860
Supervising Psychologist: $213,041
Year 5:
Evaluation and administration of the LHCN: $498,860
Supervising Psychologist: $213,041

Total   **$3,846,395**

Project Timeline

(YEAR 1: period 1)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Contracting with County -Build platform for app -Prioritize outcomes and measures to be used -UCD IRB preparation and submission	-Contracting and MOUs with UC Davis -IRB preparation and submission	-Recruit for external consumer advisory group and focus groups. -IRB submission	-Contracting and MOUs with County -Support access to stakeholders for feedback -Support recruitment of external consumer advisory board	-Contracting and MOUs with UC Davis and EP Programs -Identify key staff for data transfer

(YEAR 1: period 2)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Select outcomes and measures to be used -Update data collection method -Review wire frame and data visualization with stakeholders - UCD IRB approval	-Discuss methods and identify available data for 5-county-integrated evaluation -IRB approval by counties	-Focus groups; outcome selection and feedback on wireframe and data visualization -Begin external consumer advisory group meetings	-Provide feedback on outcome measures Participate in prioritization process -Support access to stakeholders for feedback	-Participate in prioritization process -Identify key staff for data transfer

(YEAR 2: period 1)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Finalize outcomes and measures to be used -Beta test of app for data collection -Pilot testing in 2 EP programs begins	-Finalize methods for 5-county-integrated evaluation	-Fidelity assessments -Focus group on app and dashboard	-Provide feedback on outcome measures - Participate in prioritization process -Support access to stakeholders for feedback	-Participate in prioritization process -Identify key staff for data transfer

(YEAR 2: period 2)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Training in data collection -Pilot testing in 2 EP programs	-Obtain data from prior 3-year timeframe for preliminary 5-	- Fidelity assessments - Focus groups on app	-Pilot of app in 2 EP clinics -Provide feedback during interviews	-Send data from prior 3-year timeframe for EP and CG

				EP Program Staff	County Staff
-Incorporate feedback into application	county integrated evaluation for both EP and CG programs			-Support access to stakeholders for feedback -Participate in fidelity interviews	programs -Provide feedback during interviews

(YEAR 3: period 1)

Evaluation Team			EP Program Staff	County Staff
Program	County	Qualitative		
-Training and implementation of outcomes measurement in 5 EP programs	-Analyze and report findings on data from preliminary 5-county integrated evaluation	-Barriers/ facilitators to implementation -Focus groups on app and dashboard	-Participate in training for outcomes measurement and app implementation -Support access to stakeholders for feedback -Provide feedback during interviews -Participate in fidelity interviews	-Provide feedback and report problems to evaluation team

(YEAR 3: period 2)

Evaluation Team			EP Program Staff	County Staff
Program	County	Qualitative		
-Prospective data collection begins in 5 EP programs	-Identify and resolve problems for county-level data for statewide analysis	Barriers/facilitators to implementation -Interviews with EP stakeholders about data collection experience thus far	-Support access to stakeholders for feedback -Ongoing use of app and issue reporting -Provide feedback during interviews	-Assist county-level research collaborators in identifying and resolving issues -Provide feedback during interviews

(YEAR 4: period 1)

Evaluation Team			EP Program Staff	County Staff
Program	County	Qualitative		
-Prospective data collection in 5 EP programs	-Support infrastructure and access to next round of data	-Interviews with EP stakeholders about experience in EP treatment programs	-Support access to stakeholders for feedback -Ongoing use of app and issue reporting -Provide feedback during interviews	-Assist county-level research collaborators in identifying and resolving issues -Provide feedback during interviews

(YEAR 4: period 2)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Prospective data collection in 5 EP programs	-Obtain and analyze second round of county-level data for preliminary 5-county integrated evaluation (EP/CG programs)	-Analyze data from focus groups and stakeholders	-Support access to stakeholders for feedback -Ongoing use of app and issue reporting -Provide feedback during interviews	-Send second round of data for 5 EP Programs -Provide feedback during interviews

(YEAR 5: period 1)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Prospective data collection in 5 EP programs	-Continue obtaining and analyzing county-level data for preliminary 5-county integrated evaluation (EP/CG programs)	-Presentation of findings; summary of experiences and feedback from all stakeholders	-Support access to stakeholders for feedback -Ongoing use of app and issue reporting -Provide feedback during interviews	-Send second round of data for 5 EP Programs -Provide feedback during interviews

(YEAR 5: period 2)

Evaluation Team			EP Program Staff	County Staff
Program	**County**	**Qualitative**		
-Obtain and analyze program-level outcomes data collected from Year 3 Period 2 to Year 5 Period 1	-Continue analyzing county-level data for preliminary 5-county integrated evaluation (EP/CG programs)	-Presentation of findings; summary of experiences and feedback from all stakeholders	-Support access to stakeholders for feedback -Ongoing use of app and issue reporting -Provide feedback during interviews	-Provide feedback during interviews

Proposed Outcomes, Sources of Outcome Data, and Costs Associated with Outcomes

COUNTY LEVEL DATA VARIABLES			
Potential Outcomes of Interest	**Sources of Data on Relevant Outcomes**	**Levels of Analysis**	**Sources of Cost Data associated with Outcomes**
Inpatient hospitalization for mental health concerns	• County hospitalization records	• Number/proportion of individuals hospitalized per group • Number of hospitalizations per group • Number of hospitalizations per individual • Duration of each hospitalization (days) • Total duration of hospitalizations (days) per individual	• Daily rate paid by County • Daily rate Medi-Cal reimbursement
Emergency Department or Crisis stabilization	• County crisis stabilization unit records	• Number/proportion of individuals with crisis visits per group • Number of visits per group • Duration of each visit (hours)	• Hourly rate paid by County
Outpatient service utilization	• Service unit records by outpatient program from County	• Service type • Number of service units (minutes)	• Contract service unit rates

PROGRAM-LEVEL DATA VARIABLES			
Potential Outcomes of Interest	**Potential Measures**	**Assessed Areas**	**Specifications**
Psychiatric Symptoms	Modified Colorado Symptom Index (CSI)* [35, 36]	Frequency of positive, mood, and cognitive symptoms	*Self-report designed for adults 18+*
	Brief Psychiatric Rating Scale (BPRS)* [37]	Comprehensive evaluation of positive, negative, and affective symptoms	*Clinician-administered*
Psychosis Recovery	The Questionnaire about the Process of Recovery (QPR) [38]	Patient perception of recovery from psychosis	*Self-report designed for adults 18+*
Social and Role Functioning	Global Functioning: Social and Global Functioning [39]	Current social functioning, and highest and lowest functioning in the year prior to assessment	*Clinician-administered for adolescents and adults 12+*
	MIRECC Global Assessment of Functioning (GAF)* [40]	Occupational functioning, social functioning, and symptom severity	*Clinician-administered*
Personal Well-being	Personal Well-being Index [41, 42]	Satisfaction with standard of living, health, life achievement, personal relationships, personal safety, community connectedness, and future security	*Self-report with both adult and child forms*
	Lehman Quality of Life Scale* [43]	Quality of life in chronic mental illness	*Clinician-administered*
Antipsychotic Medication Side Effects	Glasgow Antipsychotic Side-effect Scale (GASS) [44]	Patient's viewpoint about suffering due to excessive side effects from antipsychotic medication	*Self-report designed for adults 18+*
	Extrapyramidal Symptom Rating Scale (ESRS) [45]	Drug-induced movement, balance, and muscle tone related side effects	*Clinician-administered for adults 18+*

PROGRAM-LEVEL DATA VARIABLES			
Potential Outcomes of Interest	**Potential Measures**	**Assessed Areas**	**Specifications**
Antipsychotic Medication Adherence	Brief Adherence Scale (BARS) [46]	Patient's medication taking behaviors	*Clinician-administered for adults 18+*
Family Functioning	Systematic Clinical Outcome Routine Evaluation (SCORE-15) [47]	Family difficulties, strengths, and communication	*Self-report*
Family Burden of Mental Illness	Burden Assessment Scale (BAS) [48]	Burden on families with family members that are experiencing severe mental illness	*Self-report designed for adults 18+*
Incarceration	The National Survey on Drug Use and Health (NSDUH) 2014 Questionnaire [49, 50]	Arrests, legal contact, and probation information for the year prior to assessment	*Self-report with both adult and child forms*
Physical Activity	The International Physical Activity Questionnaire (IPAQ) [51]	Physical activity in the week prior to assessment	*Clinician-administered for adolescents and adults 15+*
Mental Health Services Satisfaction	MHSIP Youth Services Survey (YSS) [52]	Patient's viewpoint on service satisfaction	*Self-report for adolescents ages 13-18*
	Recovery Self-Assessment (RSA) [53]	Perceptions of recovery, quality of services, and staff helpfulness and responsiveness	*Self-report for adults 18+, with family member and provider variants*

*These measures are currently used by the MHBG 10% Study

References

Niendam TA, Tully LM, Iosif AM, et al.: Enhancing early psychosis treatment using smartphone technology: A longitudinal feasibility and validity study. J Psychiatric Res 96:239-46, 2018

Kumar D, Tully LM, Iosif AM, et al.: A Mobile Health Platform for Clinical Monitoring in Early Psychosis: Implementation in Community-Based Outpatient Early Psychosis Care. JMIR Mental Health 5:e15, 2018