A Mobile Personal Health Record for Behavioral Health Homes

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Project Summary/Abstract

Poor quality of medical care is a major contributor to excess medical morbidity and premature mortality in persons with serious mental illnesses (SMI). To address this problem, community mental health providers are increasingly partnering with safety net medical providers to develop behavioral health homes, integrated clinics in which persons with SMI receive coordinated medical and mental health care. However, behavioral health homes have faced logistical and privacy challenges in integrating electronic medical records across organizations. This application proposes to develop and test a mobile Personal Health Record (mPHR) to overcome this problem while more fully engaging patients in their health care. The mPHR will have the capability to access medical and mental health medication and lab data in real time; to help clients set and maintain health and lifestyle goals; to provide medication and appointment prompts and reminders; and to facilitate communication with providers via asynchronous communication with the EHRs.

This three-phase study will develop, test, and disseminate the mPHR. During the first phase, we will develop the app building on experience and preliminary data from a PC-based PHR project, and link it to the medical and mental health EHR in a behavioral health home. During the second phase, we will conduct a randomized trial of the mPHR in 300 subjects randomized to the mPHR or usual care. The study will use an adaptive design, which will implement the app in five 6-month cohorts of 60 subjects. After each cohort, the app will be updated based on feasibility and acceptability findings, new research and commercial developments in PHR apps, and changes in usual care in the clinic and community practice. Analyses will examine overall effects of the intervention, and whether there is a change in its benefits across study cohorts. Study outcomes will include quality of preventive and cardiovascular care; patient activation and provider management of chronic illness; and service use including medication compliance, missed appointments, emergency department use, and costs of care from a societal and managerial perspective. During the final phase of the intervention, the app will be disseminated to behavioral health homes across the country through a national technical assistance center.

The proposed study will apply a novel technology that has not previously been studied in mental health settings, will be conducted in a new organizational model of care that is anticipated to become widespread in community mental health in the coming years, and will use an innovative adaptive design that will ensure that the intervention remains relevant and updated throughout the study period. A multidisciplinary team including mental health services researchers, experts in information technology and app design, and policymakers with expertise in public sector integration will help ensure that the study results will help transform care delivery in mental health safety net settings.

Project Narrative

This study will be the first to test a mobile PHR for use in behavioral health homes. If successful, it will provide a vital tool for empowering patients and improving quality of care in these emerging models of service delivery.

II. SPECIFIC AIMS

A long literature has demonstrated that persons with serious mental illnesses have poor quality of medical care, [1] which is a major contributor to excess medical morbidity and premature mortality.[2] In response to this public health problem, an emerging model of care has developed - the behavioral health home – a clinic based in a community mental health center, typically developed in partnership with a safety net medical provider, where persons with serious mental illnesses receive coordinated medical and mental health care.[3] While these are promising models of service delivery, they have faced challenges reaching their full potential to improve quality and outcomes of health care. [4] A 2011 survey of 56 behavioral health homes in a national demonstration program found difficulties in integrating electronic medical records across facilities to be the single largest challenge in successfully implementing these clinics.[5] Furthermore, there have also been limitations in fully engaging consumers in their care delivery,[4] one of the most important features of organized models of care delivery. [6]

In general medical populations, electronic Personal Health Records (PHRs) have shown considerable promise in reshaping healthcare by shifting the ownership and locus of health records from being scattered across multiple providers to an approach that is longitudinal and person-centered. With the growing use and capabilities of smartphones even amongst disadvantaged sectors of the population, there is an opportunity to develop PHRs for mobile platforms, or mobile Personal Health Records (mPHRs).[7] By communicating with patients' medical and mental health Electronic Health Records (EHRs), mPHRs can deliver real-time information, assist in adherence to medication regimens and appointments, and facilitate communication between patients and providers.[8] As such, mPHRs have the potential both to help foster better coordination of services and consumer engagement in care and hold great promise for individuals with serious mental illness.

This application proposes to develop and test a mPHR designed to improve quality of care in behavioral health homes. The mPHR will have the capability to access medical and mental health medication and lab data in real time; to provide medication and appointment prompts and reminders; to help clients set and maintain health and lifestyle goals; and to facilitate communication with providers. An adaptive randomized design,[9] incorporating updates to the intervention reflecting developments in mobile health technologies and in the organization of behavioral health home services, will be used to optimize relevance and effectiveness of the intervention throughout the study period.

The proposed project will address three specific aims:

Specific Aim 1: Develop a smartphone Android application (app) that will link the medical and mental health EHRs in a behavioral health home.

Specific Aim 2: Evaluate, using an adaptive, randomized controlled study design, the effects of the mPHR on patient and provider indicators in a sample of 5 sequential cohorts of 60 subjects, half of whom will receive the mPHR (300 subjects total).

H1: As compared with the treatment as usual group, subjects with an mPHR will have higher performance on indices of cardiometabolic and preventive quality of care.

H2: As compared with the treatment as usual group, subjects with an mPHR will have greater improvement in patient activation and provider management of chronic illness. Patient activation and provider management of chronic illness will partly mediate the relationship between the intervention and quality of care.

Specific Aim 3: Evaluate the impact of the mPHR on service use and costs of care.

H3: As compared with the treatment as usual group, subjects with a mPHR will have better medication compliance, fewer missed appointments, fewer ED visits, and have a modest increase in costs. Medication compliance, missed appointments, reduced ED use, and regular mPHR use will, in part, mediate the relationship between the intervention and costs of care.

The proposed study is highly innovative in the intervention, the setting, and the study design: 1) This study applies a novel technology that has not previously been studied in mental health settings; 2) The research will be conducted in a new organizational model of care, the behavioral health home, that is anticipated to become widespread in community mental health in the coming years[4]; and 3) This research uses an adaptive research design that will ensure that the intervention remains relevant using periodic updates throughout the study period.[9] The potential impact of the intervention is supported by pilot data suggesting feasibility, acceptability, and potential benefits of PC-based PHRs, and a dissemination plan that will allow for widespread use of the mPHR in behavioral health homes and, more broadly, in community mental health centers nationwide. The multidisciplinary team of researchers, leaders from the community behavioral health field, and technology experts is uniquely qualified to conduct the proposed project to maximize its potential to transform care in safety net behavioral health settings.

III. RESEARCH STRATEGY

IIIA. Background and Significance

A literature extending back more than 70 years has demonstrated the high rates of medical morbidity and excess mortality in persons with serious mental illness (SMI).[10] Mortality due to general medical conditions is elevated by two to three times in persons with severe mental disorders,[11, 12] and this differential mortality gap appears to be increasing over time.[13, 14] These troubling statistics have led to efforts among federal and state policymakers, clinicians, and mental health consumers to seek to identify opportunities to improve health and reduce mortality in this population.[15, 16] Improving quality of medical care is a first critical step in reducing cardiovascular mortality in particular and extending lifespans of persons with serious mental illnesses.[17, 18]

Because of the specialized needs and challenges in accessing primary care clinics, there has been a recent growth of interest by policymakers and clinical leaders in developing behavioral health homes --clinics based in mental health settings where persons with serious mental illnesses receive coordinated medical and mental health care.[3] In 2009, SAMHSA began funding a series of demonstration projects through its Primary Care Behavioral Health Integration (PBHCI) initiative.[19] By the end of 2012, 96 such homes will be funded nationwide through the PBHCI program. More than three-quarters of these specialty homes have been developed as partnerships between community mental health centers (CMHCs) and primary care provider organizations, the majority of which (67%) are Federally Qualified Health Centers (FQHCs).[5] Outside of this demonstration project, a growing number of CMHCs are developing partnerships with safety net medical providers as a means of caring for their patients' medical needs. In Georgia alone, 16 out of the state's 27 CMHCs have developed partnerships with public sector medical providers with the goal of jointly caring for patients' medical and mental health needs. Missouri was recently awarded one of the nation's first Medicaid demonstration health home waivers, which will develop health homes for patients with comorbid conditions through partnerships between CMHCs and FQHCs.[20]

While specialty mental health homes present a unique opportunity to improve physical health care for persons with serious mental illnesses, they have also faced challenges in implementation. While all CMHC and FQHC partners in these homes are required to have EHRs, CMHCs and FQHCs rarely use the same health record vendors; thus, communication across clinics, even when they are in the same building, is limited by both technical and medico-legal barriers and ultimately translates to obstacles in serving the consumer. These organizations typically have different procedures for order entry and charting (e.g. note sign offs) and separate privacy policies governing access to, and use of, the records. A 2011 RAND survey of the first two cohorts of PBHCI grantees found that difficulties in integrating electronic medical records across facilities was the single largest challenge in implementing behavioral health homes.[5] Finally, these sites have generally used a medical model with a limited focus on recovery and self-management. It is therefore a priority to look for opportunities to more fully engage consumers in their health care.[4]

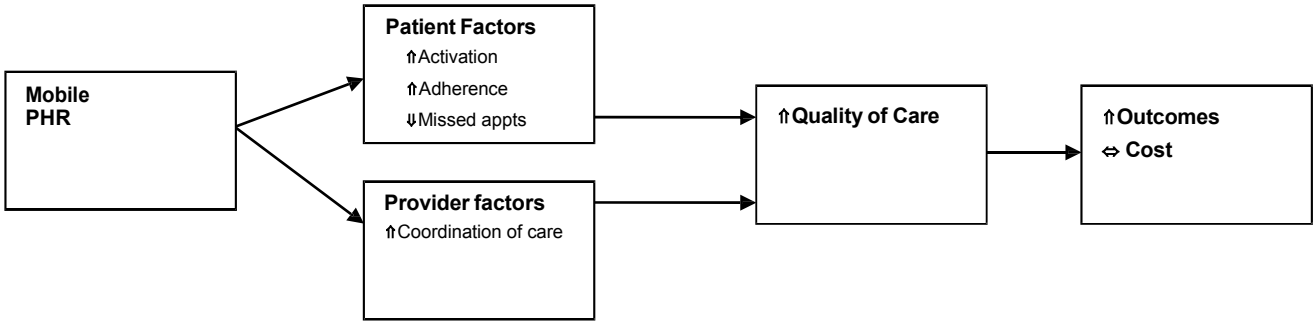
PHRs hold promise for linking services in fragmented and under-resourced public sector settings.[21] The Markle Foundation has defined a personal health record as "An electronic application through which individuals can access, manage, and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment."[22] Although the empirical literature on PHRs is limited, existing studies show promise for PHRs as tools for improving care. In a qualitative study by Tang et al, patients reported that providing printed summary information to patients at the end of a clinic visit improved their understanding of their care, enhanced their relationships with providers, improved their satisfaction with care, and motivated them to adhere to treatment plans.[23] Jerden and Weinehall found that 25% of patients who received a PHR booklet reported making one or more lifestyle change, most commonly by increasing physical activity or improving diet.[24] PHRs that have been developed as extensions of EHRs within particular health systems have had higher rates of uptake than freestanding PHRs that do not automatically provide consumers access to health data. [32] Similarly, patient portals, extensions of EHRs that provide patients with access to the most current laboratory and medication information, have been shown to increase patient and provider interaction leading to better management of chronic illness including chronic depression. [33, 34] While no existing studies have been conducted with mobile PHRs via smartphone, these would be expected to be particularly beneficial for poor populations who may have limited access to personal computers with high speed internet access.[25]

Mobile PHRs might be expected to help improve quality of care for patients with serious mental illnesses by overcoming patient and provider barriers to care seen in public sector mental health settings. [17] (see Figure 1). Patient factors include lack of familiarity with current treatments, cognitive limitations that may lead to missed appointments or medication dosages, and difficulty in effectively communicating with providers.[1, 17] These constructs can be summarized in Hibbard's concept of patient activation, which

comprises an individual's capacity to manage his or her own illness and work effectively within the formal health system. [26-28] PHRs are hypothesized to help enhance activation by improving knowledge and engagement with care and allowing the patient to set and track health goals. Reminders and prompts can help patients improve adherence to medications and upcoming appointments.

At the provider level, while most behavioral health homes have co-located services, they are not fully integrated, and providers face challenges in accessing EHRs from partner organizations largely due to technical incompatibilities in the EHR systems [4, 5] Mobile PHRs can help address these provider barriers by providing a single, consumer-controlled record that spans multiple systems of care, and facilitating communication across organizations and between patients and providers.

Figure 1: Conceptual model for mPHR



A 2011 survey found that 72% of persons with SMI from a large rehabilitation facility owned and regularly used a cell phone or smartphone, suggesting the appropriateness of the use of mobile apps to improve care in these populations.[29] However, we are not aware of any PHRs in that have been developed for this population in the research literature or commercial space.

IIIB. Approach

IIIB1. Overview of Proposed Research Project and Potential Innovation

IIIB1a: Overview: The proposed project will develop and test a mobile PHR to improve quality of medical care in behavioral health homes. In the initial stage, a mobile PHR will be developed for the Android platform, building on pilot data from a PC-based PHR developed by the study team. Subsequently, the app will be studied using an adaptive randomized controlled study among patients treated in a behavioral health home, updating the app every 6 months based on data on feasibility and acceptability. In the final phase of the project, we will work through the National Council for Community Behavioral healthcare to disseminate the app to behavioral health homes and other CMHCs nationwide.

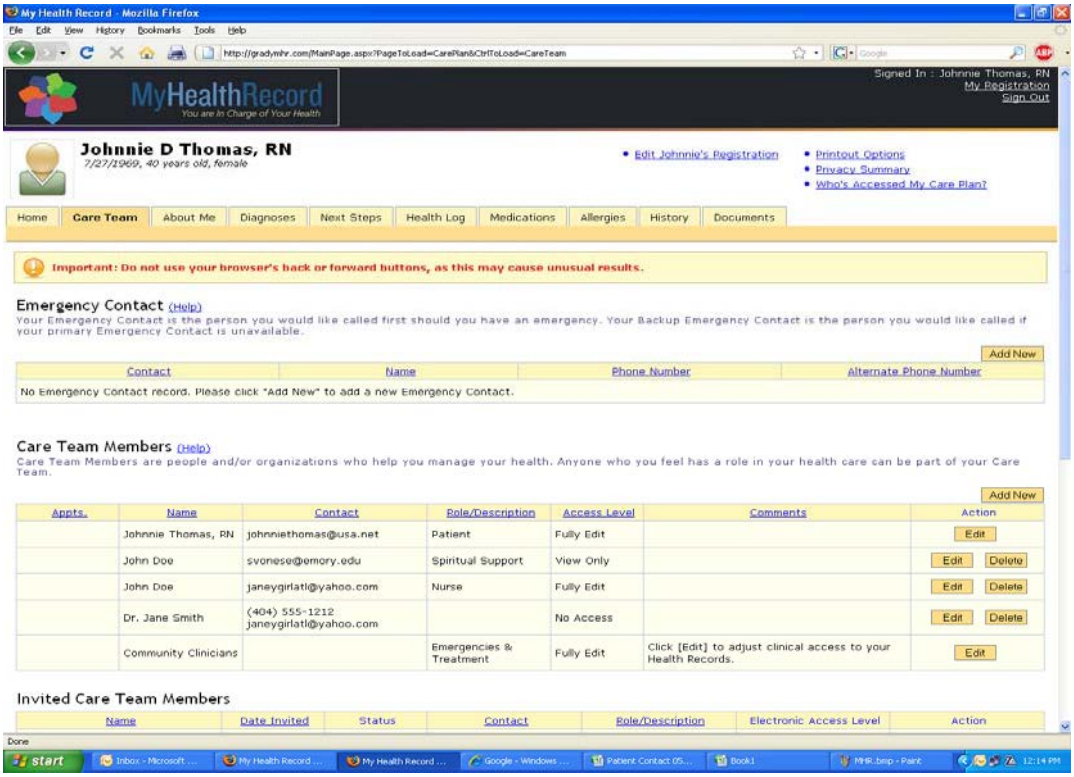
IIIB1b. Innovation: The proposed study is innovative in at least three ways: 1. It will apply a novel technology that has not previously been used in behavioral health homes or other mental health settings. 2. It will be conducted in a new organizational model of care, the behavioral health home, that is anticipated to become widespread in community mental health settings in coming years and 3. It uses an innovative, adaptive research design that will ensure that the intervention remains relevant throughout the study period.

IIIB2: Preliminary Data

IIIB2a. Study team experience and expertise: The study team includes a unique blend of researchers, information technology experts, and policymakers that will optimize the potential both for successful completion and maximal public health impact. Benjamin Druss MD, the principal investigator, is a psychiatrist and professor of health policy at the Rollins School of Public Health at Emory University whose work focuses on improving health and healthcare for persons with serious mental illnesses. He is the principal investigator on the HOME study, a randomized study of a partnership-based behavioral health home for persons with serious mental illness, and the AHRQ-funded My Health Record study, which developed and pilot tested the first PC-based PHR for patients with serious mental illness. He was a member of the planning group for the NIMH/AHRQ sponsored conference "Mental Health & Health IT Research: The Way Forward," which helped define gaps in research in information technology in mental health. Silke von Esenwein, PhD has worked on all of these projects as a co-investigator; she has presented extensively about the use of health information technology among persons with serious mental illnesses. Paul Weiss, MS is a biostatistician with extensive experience in analyzing clinical trials as well as in mobile app design. Ellen Zegura, PhD is professor and Chair in the Department of Computer Science at the Georgia Institute of Technology. She is an expert in developing and testing technology interventions including mobile applications in underserved populations. Elaine Warren, M.S.C., is an IT consultant with over ten years of experience in development and operation of information

systems including mobile application design. Michael Lardiere MSW is the Vice President of Health Information Technology and Strategic Development for the National Council for Community Behavioral Healthcare and one of the nation's experts in the use of IT in safety net health and mental health settings, as well as in newly emerging behavioral health home models.

IIIB2b. Developing and pilot-testing a PC-based Personal Health Record for persons with SMI: "An Electronic Personal Health Record for Mental Health Consumers" developed and pilot-tested the first PHR for persons with SMI and medical comorbidity, called My Health Record. This PHR was developed as a collaborative effort between Emory investigators, experts in development and implementation of medical PHRs, and mental health consumer leaders. Because it was implemented in a CMHC without an EHR, it was developed as a standalone program, in which patients entered all data into a PC-based PHR with the help of their care manager.



IIIB2c. Computer literacy curriculum: At baseline, approximately 1/3 of clients reported low levels of computer literacy. Therefore we developed a curriculum to increase computer literacy for persons with serious mental illness, including those with cognitive impairment. In a pre-post test of the curriculum, a majority of participants greatly increased their knowledge of the internet, ability to access health information and community resources, needing an average of 2.2 hours to complete the training modules.

IIIB2d. Feasibility: A total of 170 subjects were successfully randomized, and there has been a greater than 90% retention rate in the study through the 1-year follow up. Using online tracking of accessing the PHR, 71/85 (83.6%) subjects in the intervention group have accessed the PHR at least monthly to obtain health information using computers at public libraries, in their own home, and at internet cafes.

IIIB2e. Potential effectiveness in improving patient activation and quality of care: The two primary outcomes for this pilot study were patient activation and use of preventive services (as recommended by the US Preventive Services Taskforce). Each was balanced at baseline, but showed clinically and statistically significant improvements at 12-month follow-up. At 12-month follow up, patients in the PHR intervention had an average patient activation score of 59.9 (out of a possible score of 100) compared to 55.2 for the control group. The total proportion of recommended preventive medical services was double that in the case versus the control group (40% versus 20%, p<0.001) (See Table 1).

Table 1: Outcomes of PC-Based Personal Health Record Pilot

	Wave	Control (n=85)	Case (n=85)	p value
Patient Activation	Baseline	55.6 ± 14.4	55.1 ± 14.3	0.83
	12-Month	55.2 ± 14.6	59.9 ± 12.5	0.043
Total Preventive Services	Baseline	0.27 ± 0.09	0.26 ± 0.10	0.22
	12-Month	0.20 ± 0.11	0.40 ± 0.13	<0.001

IIIB2f. Focus Groups: We conducted two focus groups with participants in the PHR study, one with participants who used the PHR monthly throughout the study (83.7% of the intervention group), to assess acceptability and experience in using it. We conducted a second focus group among non-users of the PHR (16.3% of the intervention group). The groups were convened and conducted using standard procedures as described by Krueger et al.[30 31-34] Acceptability among PHR Users: Among regular PHR users in the first focus group (n=8), clients expressed a high degree of enthusiasm for the PC-based PHR. They described using it to track treatments and appointments: "It's great, I use it to stay on top of my meds and appointments with my doctor." They described how it made them more aware of their self management needs. "It helps me remember to take my blood sugar and work on keeping it down." Finally, several described it as supporting their broader recovery goals. "I feel like it lets me make progress on my whole heath, helps me keep the physical together with the mental and spiritual." Reasons for not using the PHR among non-users: In the focus group of participants who did not use the PHR at least once per month (n=7), we examined the reasons for non-use. The two most common reasons for non-use were 1. Difficulty/time spent in entering PHR data "It's a good idea, but it takes too much time trying to put everything in about my meds and all." and 2. Lack of easy access to a computer "I use the one at the library, but the library closes at 7. How am I supposed to look at it after that?"
Acceptability of using mobile phone interventions and potential interest in using a mobile PHR in the population: In both of the groups, participants were asked about potential interest in a smartphone-based mobile PHR as an alternative to the PC-based PHR. Participants who did not own smartphones (11/15 total) generally found it easy to use the demonstration smartphone in the focus group and found the interface relatively easy to use. Participants reported, "This is like a computer but it's easier to use." "It's easy to see since it's all lit up". Those who used PHRs felt that a mobile platform could provide added ease of accessibility "I'd like that since I could always have it in my pocket." Those who did not use their PHR felt that it could help overcome the barriers to use. "Yeah, if I didn't have to write all that in there it would help….I wouldn't have to find a computer to use it…"
IIIB2g. Summary: Preliminary qualitative and quantitative data using a PC-based PHR suggest high potential feasibility and acceptability, along with potential benefits on patient activation and quality of primary medical care. The primary barriers to use of the PHR – time and effort needed in entering data, and common lack of access to a computer – could both be overcome by using a mobile PHR platform.

IIIB3 Study Site

The Four Corners clinic in Austell, Georgia was established in 2010 as one of the first behavioral health homes in the country funded under SAMHSA's Primary Care Behavioral Health Integration (PBHCI) grants. The clinic is a satellite clinic of the West End Medical Center Federally Qualified Health Center (FQHC), co-located within the Cobb County Community Mental Health Center (CMHC). The Four Corners clinic is staffed by a full time nurse practitioner and RN from the FQHC, and two care coordinators who are paid for by the CMHC. It provides comprehensive primary and preventive care to patients with one or more cardiometabolic risk factor (high blood pressure, diabetes, elevated cholesterol). This partnership model between an FQHC and a CMHC is the most prevalent organizational model used in behavioral health homes. [5]

Table 2 presents the demographic and clinical characteristics of patients who are currently seen in the Four Corners behavioral health home. A total of 420 patients have been enrolled since 2010, with an enrollment rate of approximately 200 new patients per year. The target enrollment goal will be 1,000 patients. A majority of the sample have elevated BMI (60%), blood pressure (77%), and elevated LDL cholesterol (64%).

Table 2: Characteristics of Four Corners Clinic

Variable	%
Demographics	
Female	65%
African-American	22%
Age 25 to 34 years old	17%
Age 35 to 44 years old	43%
Age 45 to 54 years old	16%
Cardiometabolic Risks	
Borderline or High BP	77%
Borderline or High HgB A1C	41%
High cholesterol	50%

Characteristics of the EHRs: Both the West End Medical FQHC and the Cobb County CMHC have fully functional EHR; however, these EHRs do not currently have the ability to share data or information across the two organizations. Clinicians in the Four Corners clinic enter notes into the West End Medical Clinic record, then make electronic copies of the notes, and then, cut and paste these into the Cobb County EHR.

The Cobb County CMHC uses Carelogic, a behavioral health EHR that is in use in over 100 CMHCs in 26 states. West End Medical Center uses NextGen Ambulatory EHR, one of the most widely used ambulatory EHRs in FQHCs nationwide.[35] Each of the two EHRs has a patient portal feature that allows extraction of selected fields from the record to a website or server. Fields that can be selected include laboratory values, medications, and upcoming appointments. Each

of the patient portal features also has the capability to provide asynchronous email communication with the provider team. The portals are protected by firewalls and allow for HIPAA-compliant, secure data transfer.

IIIB4: Specific Aim 1: Develop a smartphone Android application (app) and link it to the medical and mental health EHR in a behavioral health home. The application will be developed during the first 9 months of the study. After hiring staff and establishing the study team, a beta version of the app will be constructed, incorporating and building on features developed for the PC-based PHR, then subsequently refined using qualitative techniques focusing both on design and content of the mPHR.

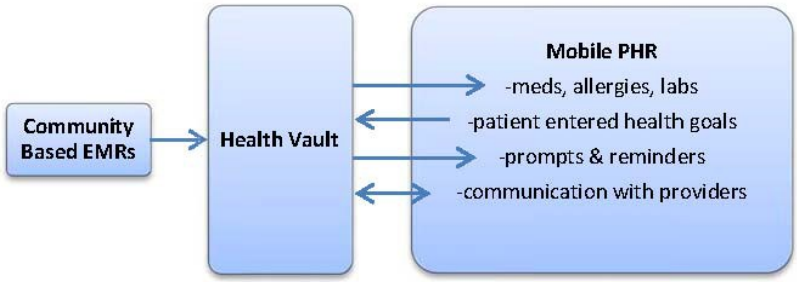
IIIB4a. App Development:The app will be programmed in Android, an open-source, Linux-based operating system for smartphones with a Java programming interface. The mobile Android app will be developed using the Android Software Development Kit. [36] The app will be developed to link with the mobile version of Microsoft HealthVault, a web-based platform developed by Microsoft to store health information for PHR. HealthVault supports a number of exchange formats including all major industry standards, making it possible to integrate with most electronic PHRs. The HealthVault security system works with cryptographic constructs available more widely on smartphones to preserve user privacy. HealthVault supports mobile platforms by providing open-source, community-supported client libraries.[37] An app developer supervised by Elaine Warren M.S.C. will develop this app.

Data fields from the EHR from each of the participating sites will be uploaded to the HealthVault server using the patient portal feature on each of the EHRs. Data are stored in XML format; with user consent, multiple user records can be downloaded from the HealthVault servers for aggregate analysis.[37] Each enrolled patient will be invited to register in the system and given a unique identification and an encrypted password. Passwords are a minimum of eight characters and are required to use mixed case letters, numbers, and punctuation. This information will be used to populate fields on the handheld device from data in the CMHC EHR and the FQHC EHR using a user-friendly interface tailored to the needs and potential cognitive limitations of the population. To ensure privacy and safety of data, no health data will be stored on the mobile device – all will be maintained on the HealthVault server.

IIIB4b Mobile PHR structure:

The mPHR will comprise four sections: 1. Information downloaded directly from the EHRs; 2. Information entered by consumers; 3. Prompts and reminders for medications and upcoming appointments, and self-management; and 4. Communication with the care team.

Figure 2: Mobile PHR structure



To address limitations in computer literacy and cognitive deficits in some of the population, information will be presented using a simple user interface and graphics, suitable for a 6th grade reading level. A "traffic light" system[38] will be used to represent laboratory and anthropomorphic findings, indicating whether values are normal (green), borderline (yellow) or abnormal (red).

i.Information directly downloaded from the EHR: A PHR can help improve patient activation by helping provide patients with the health information they need to better manage their own illnesses.[39] Providing this information in a single, patient-controlled record may also help providers to better coordinate the care they deliver and make it more patient-centered.[40] Using the patient portal feature on the two EHRs, the mPHR will download to HealthVault and then display in the mPHR:

1. Current medications will be presented, including separate categories for medical and psychotropic medications, along with the indications.
2. Any known allergies.(food, medication, or otherwise) and contraindications will be displayed.
3. The PHR will present lab values including glucose, cholesterol, and hemoglobin A1c, along with a traffic light indicator of whether the values are at target or abnormal.
4. Anthropomorphic measures will be displayed, including blood pressure, weight, BMI and waist circumference, with a traffic light indicating whether values are abnormal, borderline, or normal.
5. Dates and upcoming appointments (medical and psychiatric) will be provided.
6. Name and contact information for all members of the provider team will be included.

ii. Subjects will have the ability to enter data on personal goals either directly into the app or on a PC, via the secured HealthVault website. Fields entered by the patient will include:

1. Current resources and health care needs: This section includes details that the patient identifies as potentially relevant for healthcare professionals, including: disabilities; challenges in transportation; need for a translator, role of spirituality in health care, and living situation.

2. Goals and Action Steps: This is a worksheet developed for the PC-based PHR that asks the respondent to identify longer term health goals, and small, short-term steps and specific actions to be taken in order to pursue those goals. Action plans, which involve setting and tracking short-term health goals, has been shown to be a highly effective strategy for increasing activation and promoting health behavior change.[41]

iii.Electronic Prompts and Reminders: Prompts and reminders will be provided 1. At the time that each medication dosage is due; 2. Two weeks before each medication refill; and 3. One day before each medical and mental health visit.

iv.Communication with providers: The HealthVault Message Center allows patients to send and receive encrypted email to and from healthcare providers including the care coordinator and any other providers who opt-into the subjects' mPHR. All messages are stored in the Microsoft HealthVault record.

IIIB4c. Access controls: Participants can choose to share data with providers, family members, and friends, and will be able to assign an access level to each person listed on the plan to determine the level of access each member has to the specific fields. Access may include the ability to fully edit the plan, view only, or to have no access to the plan.

IIIB4d: Role of the care coordinator: PHRs are most effective if they are used in conjunction with providers who use them as tools to engage patients in their care. [42, 43] The Four Corners clinic employs two full-time care coordinators, bachelor-level care managers who provide education and help coordinate patient care. For the study, we will train the care coordinators to use the mPHR as a tool for patients in the mPHR care condition.

IIIB4e: Training

i.Training the care coordinator in use of the app and ongoing supervision: After the app is developed each of the CMHC care coordinators will receive an interactive, 3-hour training program by the app developer, and by Warren, Zegura and Druss in use of the app and the computer literacy training program. Topics will include: 1. Use of smartphones by persons with SMI. 2. An overview of the computer literacy curriculum 3. A review of each of the each of the components of the app (medications; laboratory values; consumer-derived data on health goals; prompts and reminders for medications and upcoming appointments; communicating with providers. Monthly meetings with the care coordinators will discuss current experiences and troubleshoot problems.

ii.Training clients in use of the app and ongoing support: The training of clients by care coordinators in use of the app will parallel the process of training the care coordinators. The care coordinator will provide a two-session, one-on-one overview of use of smartphones and the mPHR. Topics will include: 1) Overview of smartphones, including basic features from the training curriculum (turning on; charging; using apps), based on the computer literacy curriculum for persons with SMI developed by the study team; 2) An overview of each of the components of the app; and 3) Troubleshooting (what do to if an app is not working; what to do if a phone is lost or stolen). Initial demonstration will be followed by subjects being asked to show that they can use the key smartphone functions and app components. This process will be continued until the subject demonstrates proficiency in using the smartphone and each component of the intervention app. Development and refinement of the training in Aim 1 will guide the standardization of the training we will use in Aim 2 for the RCT.

iii.App maintenance and troubleshooting: The app developer will maintain the app and be available by telephone and email to participants, care managers, and study staff to troubleshoot any problems that arise.

IIIB4f. Refine the intervention using semi-structured consumer interviewers: After the beta version of the app is developed, one-on-one semi-structured interviews will be conducted with 10 participants from the Four Corners Behavioral Health Home. The clinic director will solicit 10 volunteers with SMI who do not have their own smartphone. For this formative work in Aim 1, each participant will be shown a smartphone with the app and asked questions about the usability and content of each of the four components of the app (lab and medication information downloaded from the EHR; personal details and goals entered by the participant; electronic prompts and reminders; and secured communication with the provider). Participants will be asked: How easy is it for you to use this program? What is hardest for you about using it? What changes would make it more useful to you? All interviews will be tape recorded and transcribed. Analysis of these transcripts will include both deductive and inductive analysis, and proceed in three phases:[44, 45] 1) preliminary analysis relying predominantly on a set of deductive codes representing the initial objectives of the interviews (e.g. ascertaining participants' experiences in using each of the three components of the phone application.); 2) in-depth analysis

based on the emergence of key inductive themes, or concepts identified by participants themselves as being important; and 3) interpretation and synthesis of key concepts in the data based on a thorough and systematic exploration of both inductive and deductive themes.

After these interviews are completed and analyzed, the app developer, IT experts (Warren, Zegura), and PI will review the qualitative data. Based on the findings and recommendations from this steering group, the app designer will make further refinements of the intervention prior to the full randomized trial.

IIIB5: Specific Aim 2: Evaluate, using an adaptive, randomized controlled study design, the effects of the mPHR on patient and provider indicators in a sample of 5 sequential cohorts of 60 subjects, half of whom will receive the mPHR.

IIIB5a. Recruitment and Randomization: Subjects will be recruited from a roster of clients from the Four Corners Behavioral Health Home. Characteristics of the clinic are described in IIIB3. The inclusion criteria for participation in the clinic include having a serious mental illness and at least one cardiometabolic risk factor. The only exclusion criterion will be inability to consent based on a 6-item, validated screener. [46] These relatively inclusive criteria were chosen to optimize generalizability to other behavioral health homes; preplanned analyses will assess whether the intervention is effective across putative moderators such as baseline health and computer literacy.

Subjects who meet eligibility criteria and who provide informed consent to participate will be randomly assigned in blocks of 60 (30 case and 30 controls), to either receive the mPHR or continue in usual care in the clinic. Subjects who do not own an Android-based smartphone will be provided with one loaded with the study app for the 6-month duration of the intervention. Those who own an Android-based smartphone will be offered the option of having the Android app loaded onto their own smartphone for the duration of the intervention. All participants will participate in the baseline assessment and those assigned to the mPHR group will receive the two-session, one-on-one app training described above in IIIB4e. Randomization will be stratified by whether subjects own and will use their own Android-based smartphone for the study. A computer-generated algorithm and concealment of allocation techniques will be used to minimize assignment bias.

IIIB5b. Adaptive randomized design: The landscape of public sector mental health service delivery is evolving in the context of health reform and grassroots development of new models of care in communities.[19] Simultaneously, new health technologies, particularly in the mobile space, are rapidly developing. [47] More flexible study designs are need to ensure that study findings are relevant.[48]

To address these issues, the study will use an adaptive randomized design. An adaptive design uses the cumulative knowledge of current treatment successes and failures to change qualities of the ongoing trial.[9] A total of 5 cohorts of 60 subjects each will be sequentially enrolled in the trial for 6 months each, with half randomized to receive the mPHR, after which 2 months will be spent updating and modifying the intervention prior to the next cohort, while recruiting the new cohort of subjects. Modifications to the app will be made based on 1. Feasibility and acceptability of the app within the current cohort 2. New developments in health and PHR apps 3. Changes in usual care both in the clinic and other behavioral health homes. Analyses will examine both overall effects of the intervention, and whether there is a change in its benefits over time.

i. Assessing feasibility and acceptability: At the end the 6-month intervention, participants will return for a follow up assessment of feasibility and acceptability, assessment of quality of care and health outcomes. Feasibility will be assessed by asking clients to demonstrate their ability to access and use the features of the app. A 1-5 Likert scale will be used to rate degree of mastery of each of the components of the application, with a score of 3 in each category representing a “passing grade.” Acceptability will be tested by direct tracking of app use. With informed consent, information from the app will be downloaded to the study server automatically on a weekly basis; information will include the number of times each component of the app is accessed and the particular component that is used.

ii. Reviewing technological advances in mobile health technology: Using methodology used in other systematic app review studies,[49] Elaine Warren, M.C.S. will conduct searches every 6 months in the official application stores for five major smartphones: iPhone (App Store), Android (Android Market), Blackberry (App World), Nokia/Symbian (Ovi) and Windows Mobile (Marketplace), within the health/lifestyle and medical categories, for products related to personal health records or health management. Any new products will be downloaded to examine new developments or features that could be incorporated into the mPHR.

iii. Reviewing changes in usual care: Changes in the usual care condition at both the clinic and patient level will be reviewed every six months. Deborah Strotz, MSW, is the director of the Four Corners clinic. Each year, she will present updates on any changes in staffing or structure of the clinic. At the subject level, questions will

review whether subjects in each group own smartphones, and whether and how they have used any health apps in the past 6 months.

iv. Reviewing national changes in care delivery in community mental health. Behavioral health homes are a relatively recent innovation, and their structure is continuing to evolve. More generally, models of service delivery in the public specialty mental health sector are changing at a rapid pace. In his role as Vice President of Health Information Technology for the National Council for Community Behavioral Healthcare, Michael Lardiere conducts an annual survey of all community behavioral providers on changes in organizational structure and use of technology. He also provides consultation to providers including all SAMHSA PBHCI grantees on topics including purchasing of EHRs and integration of medical and mental health EHRs in behavioral health homes. For each cycle, he will provide an update on new organizational developments in community mental health and use of health technology.

Every 6 months, the study team will meet to review these developments in health technology and in mental health systems. At the meeting, the team will develop recommendations for updates to the mPHR app which the app developer will implement in the next cohort. This process will seek to balance fidelity the core features of the PHR while allowing flexibility to ensure relevance to real-world settings, paralleling strategies used in mental health dissemination and implementation studies. [50, 51] Analyses will account for potential differences across cohorts due to these modifications (IIIB5c).

IIIB5b: Outcome Measures for Specific Aim 2:

i.Overview: The conceptual model predicts that an mPHR can improve quality of medical care by improving patient activation and coordination of provider care. Quality of cardiometabolic and preventive services will be the main study outcomes, and these will be drawn directly from the West End EHR. Patient activation, provider management of chronic illness, and medication adherence will be studied as intermediate (mediating) outcomes, and cardiometabolic quality of care and health related quality of life will also be studied as key distal outcomes resulting from better quality of care. Data from each of the two EHRs will be used for generating the quality indicators. Outcome assessments will be tracked at 6 months, and then an additional six months after the intervention is complete to assess whether any benefits persist over time.

ii.Qualilty of Care Measures:

1.Quality indicators for the cardiometabolic risk factors will be drawn from the two electronic health records using indicators from the Community Quality Index (CQI) study, the largest and most comprehensive study of quality of care ever conducted in the United States.[52 53, 54] There are 9 indicators for hyperlipidemia, 13 for hypertension, and 13 for diabetes; each covering domains of screening, diagnosis, treatment, and follow-up. [55] A quality score for each condition is generated by dividing all instances in which recommended care is delivered by the number of times a participant is eligible for indicator.

2.Quality of Preventive Medical Services: Quality indicators, as well as the populations eligible for each preventive measure, will be obtained from the U.S. Preventive Services Task Force (USPSTF) guidelines. [56] For the study, we will include items with strong research evidence (evidence grade “A” or “B” to support their use.

iii.Intermediate Outcomes:

These outcomes are postulated to be both important measures of the intervention, and pathways through which the intervention may improve quality of medical care.

1. Patient Activation:. The study will assess patient activation, as measured by the patient by Patient Activation Measure (PAM).[26] This is a 22-item measure of patient knowledge, skills and confidence in self-management behaviors that has been shown to have high validity reliability (infit values of 0.71-1.44) and criterion validity based on concordance with related constructs including self-management behaviors.[26 27] medication adherence, and outcomes including quality of life.[28]

2. Provider Management of Chronic Illness: The Patient Assessment of Chronic Illness Care (PACIC) is a 20-item, patient self-report instrument developed by Glasgow, Wagner et al.that assesses the extent to which patients with chronic illness report receiving care that aligns with the Chronic Care Model. [57, 58 59] It has been found to have good test-retest reliability (r = 0.58 during the course of 3 months) and to be associated with improved health behaviors,[58] global patient ratings of their health care, and quality of life. [60]

iv.Clinical Outcomes:

Better quality of care is a first step to improving cardiometabolic outcomes, and improvement in process measures have been shown to predict better clinical outcomes. [61, 62] We therefore hypothesize that the mPHR will result in improved cardiometabolic and quality of life outcomes. For the purposes of the study, these will be treated as secondary outcomes.

1..The Framingham Cardiovascular Risk Index provides the 10-year risk of developing incident coronary heart disease. It is calculated based on a weighted score based on age, blood pressure (4 levels), smoking status (yes/no), diabetes (yes/no), total cholesterol (3 categories), and HDL cholesterol (3 categories). The index has been used successfully to assess cardiovascular risk in populations with severe mental illnesses. [63-66] Secondary analyses will examine changes in individual cardiometabolic risk.

2. Health Related Quality of Life: The SF-36 is a measure of Health Related Quality of Life constructed for use in the Medical Outcomes Study. [67, 68] A summary Physical Component Summary (PCS) and Mental Component Summary (MCS) scores can be constructed from the survey, scored between 0 (poor health) to 100 (perfect health). [69] For patients with severe mental disorders, these measures have been found to demonstrate good internal consistency, test-retest reliability, and concurrent and discriminative validity.[70, 71]

v.Potential Confounding/Moderating Variables: It is essential to assess balance across key variables that could confound results. It is also important to examine key moderators such as baseline health and computer literacy; groups with higher levels of literacy at baseline might be expected to have better study outcomes.

1.Sociodemographic characteristics: Demographic factors such as age, ethnicity, health insurance status, and income will be assessed at baseline, and included in all multivariate models.

2.Health Literacy and computer literacy may be moderators of the intervention effect –that is, individuals with higher levels of literacy may be more able to fully engage with the mPHR and derive maximal benefit from the intervention. Health literacy will be assessed using the STOFHLA, a brief instrument that ranks respondants' reading and numeracy health literacy on a scale of 1-100.[72] Computer literacy will be assessed using a 27-item measure developed by Hargitti et al.[73] Each of these surveys has been conducted in nationally representative samples, allowing for benchmarking findings derived from the current study.

IIIB5c:Data Analytic Strategy for Specific Aim 2:

i.Overall data analytic strategy: All analyses will be conducted as intent-to-treat. The primary analytic technique for assessing differences between the study groups will be random regression.[74] This method makes it possible to compare the difference in change between groups over time, and to conduct intention-to-treat analyses that include subjects with missing data at one or more follow-up periods. These will be conducted using the SAS MIXED procedure for continuous variables and PROC NLMIXED, which is the preferred procedure for binary and ordinal variables when there are relatively few observations per subject.[75] Each equation will model the process or outcome measure of interest as a function of 1) randomization group 2) time since randomization 3) group*time interaction. The group*time interaction will be the primary parameter estimate of interest, since it represents the difference in change between the two randomization arms over time. All models will also include any parameters that vary at baseline at the p=0.05 level.

ii. Analytic issues for the adaptive design: Because the intervention will be updated every 6 months, results will be initially be examined stratified by each of the cohorts. In the final model, cohort will be included as a fixed effect, and group*time*cohort will also be studied to assess whether the effects of the intervention change as it is updated. Because the core features of the intervention will not change over time, we hypothesize that these differences will not be statistically significant.

iii. Sample Size Calculation: The study sample size was calculated to produce a statistical power of 0.8 for detecting a significant change in RAND composite CQI measure for cardiometabolic quality of care. The sample size calculations for random regression models for the primary study outcomes follow the method outlined by Diggle et al.[76] We are conservatively estimating 10-20% attrition. Using this approach, we estimate that an initial sample size of 300 will provide adequate power to detect a 10% difference in the composite quality index with an intraclass correlation of 0.3, which would be considered a clinically significant improvement.[52]

iv: Mediation analysis for intermediate outcomes: In addition to examining patient activation and provider chronic care as intermediate endpoints in the study, we will also conduct analyses to see whether they partly mediate the association between the intervention group and quality of care. Mediation analyses will use adaptations of structural mean models developed for use in mediation analysis in complex randomized trials developed by Ten Have. [77, 78] Using the M Plus package, [79] separate models will be constructed to examine the relationship between the independent variable (study arm), the outcome (quality of care) and each mediating variable. Models will determine whether 1. Intervention status is associated with improved quality of care at 12 months. 2. Intervention status is associated with the patient activation and provider effectiveness in managing chronic illness at 6 months. 3. The 6-month measure of patient activation or provider effectiveness in managing chronic illness is associated with 12-month quality score and 4. Adding the mediator to a multivariate model significantly reduces the magnitude of the association between intervention status and 12-month quality score, using the Sobel test. [80] will be used to test the statistical significance of the separate impact of each

mediator on the direct effect of the baseline intervention by comparing adjusted and unadjusted effects of the baseline intervention relative to their standard errors.

v. Moderator analysis for health and computer literacy: Moderator analyses make it possible to identify what types of clients benefit most from a given intervention. The approach will follow Kenny et al's method for analyzing moderator effects in randomized trials using random regression. [81] For each analyses assessing heath and computer literacy as potential moderators, we will add a group*time*moderator interaction term, the statistical significance of which will allow us to assess the presence of moderation. All appropriate lower-order interactions will also be included in the model.

IIIB6: Specific Aim 3: Evaluate the impact of the mPHR on service use and costs of care. Handheld devices can help improve adherence to medically-indicated treatments by providing prompts and reminders; [82, 83] better adherence may improve efficiency and quality of care. We hypothesize that the prompts and reminders for the mPHR will help improve efficiency of service use, including improving adherence to medications and appointments, and that better adherence to indicated treatments will reduce unnecessary ED visits and improve quality of preventive services**.** Coupled with the relatively low cost of deploying the app once it is developed, we anticipate a favorable cost profile for the intervention from both a societal and managerial perspective.

IIIB6a. Outcome measures for Specific Aim 3.

i. Medical and mental health service use: Health service use will be assessed via chart review for all services provided by each of the two partner organizations, supplemented by a validated self-report instrument developed for the CATIE trial [84] to capture any service use outside of the two organizations. The following categories of service use will be calculated: 1. Primary care medical visits 2. Specialty medical visits 3. Medical Emergency Department (ED) visits 4. Medical Inpatient days 5. Mental Health outpatient visits 6. Mental health ED visits 7. Mental health inpatient days.

ii. Missed appointments: A separate field is available in each of the EHRs for missed appointments. This will be modeled as a two-part model (any missed visit, number of missed visits among those with a missed visit).

iii. Medication Adherence: Adherence will be assessed using chart records, by assessing a medication possession ratio (MPR), defined as the number of days of treatment dispensed divided by the number of days between prescription refills (excluding the last prescription) [85, 86] for those patients with each of the target study conditions (diabetes, hypertension, and hyperlipidemia). Separate indicators will be calculated for each class of medications used to treat diabetes, hyperlipidemia, and hypertension, with an average value across the three cardiometabolic conditions used as an aggregate measure of adherence.

iv. mPHR use: The study will capture mPHR use 1. To assess feasibility of the intervention by study participants; 2. To assess fidelity to the study intervention and 3. To conduct exploratory mediation analyses to assess whether greater app use is associated with better study outcomes. Each instance of mPHR use will be logged along with time and date information indicating the specific fields of the mPHR used, and amount of time spent with the PHR. Event auditing will categorize whether 1. Users view fields without changing data or 2, Users change fields in the mPHR.

IIIB6b: Data Analytic Strategy for Specific Aim 3:

After conducting bivariate analyses, random regression will be used to assess service use outcomes at follow up, using the group*time interactions as the primary variable of interest. See IIIB5c for more detail on the analytic models. The study team has extensive experience in conducting these service use analyses.[87]

i. Service Use analyses: Separate models will be developed for each service use category as a dependent variable. These analyses will focus on the intervention's impact on medication adherence, no shows, and ED use. Additionally, a series of mediation analyses will test the conceptual model postulating that changes in service use will moderate clinical and cost outcomes. In particular, we will test whether improved medication adherence , reduced ED service use, and reduction in missed appointments predicts improved quality of cardiometabolic care, increased use of preventive services, and reduced costs. A second set of mediation analyses will examine whether there is a dose-response association between use of the mPHR and quality of care. These will be exploratory, recognizing that regular mPHR users may be more engaged in their care at baseline than other enrollees. Mediation analysis will follow the methods described in IIIB5c.

ii. Costs from the Health System Perspective: Unit costs for all services will be assigned to each service type based on median national expenditures for each type of service from the Medical Expenditure Panel Survey.[88] This survey is well suited for assessing unit costs from a health system perspective because it uses direct payments, not charges, and captures costs across all insurance groups.

Costs of the intervention will be estimated using micro-costing approaches that calculate direct measures of resources consumed in establishing and maintaining it.[89] [90] [91]. Technology costs will include costs

of the smartphone and monthly data plan, including total data use associated with the mPHR, which could be borne by the patient or a provider organizaiton. Care coordinators will keep logs of all mPHR visits to use for assessing the portion of their total hours per week spent on working with the mobile PHR in intervention clients. Analysis methods: Cost analyses will follow standard approaches from the cost-effectiveness literature. [92-94] For the health system perspective, all expenditures will be counted as positive costs. Analyses will compare change across total costs between the mPHR and control groups, using the group*time variable as the parameter of interest.

iii. Costs from the Managerial Perspective (CMHC, FQHC): Conditions under which a program can be financially viable is among the most pressing and salient questions underlying managers' decisions to adopt and maintain those programs.[95] The methods proposed for the budget impact analysis in the current application follow the approach put forth by the ISPOR Task Force on Good Research Practices.[96] In contrast to the health system perspective, reimbursements will be treated as negative costs.

Billing rates will be obtained for Medicaid, Medicare, private insurance, and for uninsured clients (state or federal block grant rates) for each type of visit. Returns will be assessed varying key parameters that could exist in implementing the program under real-world conditions: 1. Insurance case mix (Medicaid versus uninsured); 2. Provider type working with the mPHR (bachelor's level, MSW, RN); and 3. Patient flow (number of patients using the mPHR). Financial sustainability, defined as conditions in which reimbursement payments break even, or exceed intervention costs,[97] will be assessed at 6 and 12 months after implementing the intervention, examining whether, or at what point, potential reimbursement for services would exceed staff costs for administering the intervention.

Table: Summary of Study Measures

	Baseline	6 months	12 months	Source
Quality Measures				
Medical quality measures (RAND)	X	X	X	Chart Review (EHRs)
Quality of preventive services (USPTF)	X	X	X	Chart Review (EHRs)
Clinical Outcome Measures				
Framingham cardiovascular risk score	X	X	X	Chart Review (EHRs)
Individual measures of cardiometabolic risk	X	X	X	Chart Review (EHRs)
Physical and Mental Health Related Quality of Life	X	X	X	Interview
Intermediate Outcome /Mediator Variables				
Patient activation (PAM)	X	X	X	Interview
Provider management of chronic illness (PACIC)	X	X	X	Interview
Potential Confounders/Moderator Variable				
Sociodemographics	X	X	X	Chart review (EHRs)
Health and computer literacy	X	X	X	Interview
Service Use and Cost				
Use of medical and MH services	X	X	X	Chart review (EHRs), interview
Missed appointments	X	X	X	Chart Review (EHRs)
Medication adherence (MPR)	X	X	X	Chart review (EHRs)
Use of PHR	X	X	X	Chart review (mPHR)
Costs/payments	X	X	X	Chart review

IV. DISSEMNATION PLAN

Passive diffusion of findings through the research literature is a slow and unreliable means of achieving uptake of scientific innovations.[98] To optimize dissemination of the app, we will include a formal dissemination plan for the app in partnership with the National Council for Community Behavioral Healthcare, led by Michael Lardiere. The app will be disseminated to behavioral health homes funded through SAMHSA's PBHCI program (96 sites anticipated by the end of FY 2012) through the Center for Integrated Health Solutions, funded by SAMHSA and HRSA through the National Council for Community Behavioral Healthcare. That site offers a range of technical assistance to PBHCI grantees, including regional meetings, webinars, and online tools. In his role as a consultant to that Technical Center, Dr. Druss regularly conducts webinars and provides technical assistance to sites in developing and evaluating their programs. The mPHR app will be made freely available and Dr. Druss and Michael Lardiere will present at the annual PBHCI grantee meeting explaining how to use it in behavioral health homes. Beyond its role for PBHCI grantees, the National Council for Community Behavioral Healthcare also provides a broad range technical assistance to its 1,900 member organizations. To expand the reach of the mPHR to this broader national platform, Dr. Druss and Michael Lardiere will present annual workshops at the National Council for Community Behavioral Healthcare's annual meeting, and will present a webinar to reach community providers who are unable to attend that meeting.

V. ADDRESSING POTENTIAL LIMITATIONS

We believe the proposed study has a number of strengths, including addressing an issue of high public health importance to a vulnerable population, the use of a novel health information technology innovation, an innovative study design, high potential for generalizability, and rich opportunities for dissemination. Nonetheless, we also recognize several potential issues.

A.Challenges in using technology inter entions in public sector populations: We recognize that rates of smartphone use in persons in poor populations is likely to be lower than usage in the general population. However, extrapolating from the history of cell phone diffusion, competition is likely to drive prices down and encourage widespread use in coming years, with particularly extensive uptake in poor and minority communities. [99-101] Thus while we will provide smartphones to the study participants, we anticipate that by the time the study is completed, most persons treated in the public mental health sectors will own their own smartphones, adding to ease of dissemination.

B.Challenges specific to persons with SMI: We recognize based on our existing work that about a third of persons with SMI may have gaps in health and computer literacy and cognitive symptoms associated with poverty, lower educational attainment, and underlying symptomatology. We are addressing these challenges by 1.ensuring that it is designed to fit the cognitive and literacy needs of the population, 2. using a mobile platform to ensure internet connectivity, and 3. providing all participants in the intervention group with a modified computer literacy training program developed as part of the pilot work. While all members of the behavioral health home will be eligible to enroll in the study, analyses will examine whether persons with lower rates of health or computer literacy at baseline derive the same benefit as higher literacy participants.

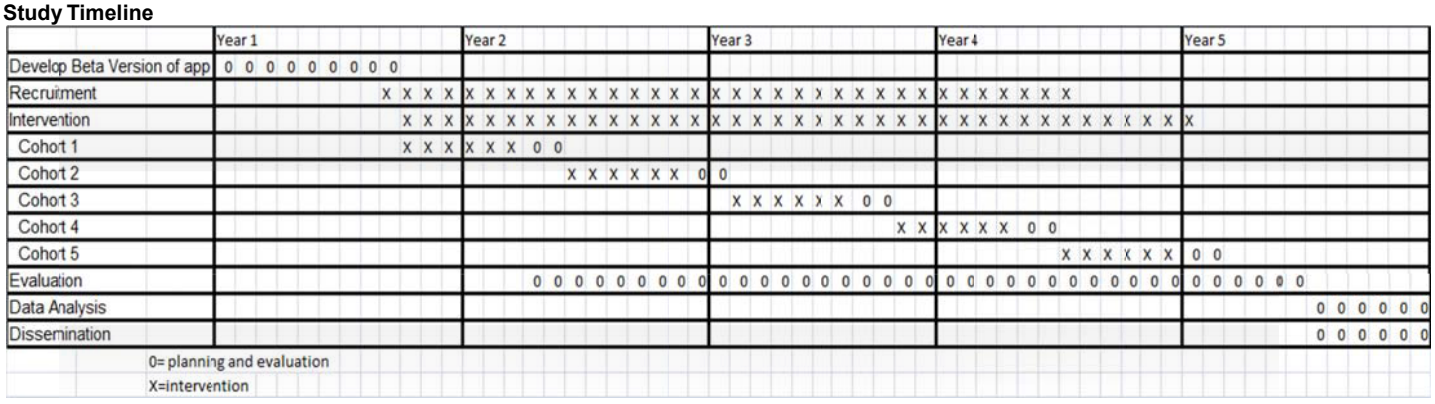
C.Challenges in ensuring privacy: Several steps will be taken to ensure that these data are protected and deleted if a pho e is lost or stolen. All smartphones will be password protected, with only the client and study administrator informed about the password. All patient data will be stored on the secured HealthVault server, none will be stored on the smartphone. If a phone is lost or stolen, Emory's IT Department will remotely disabl the smartphone, and wipe all data including the study app.

C. Challenges in addressing potential contamination: Because the program will be conducted in a single behavioral health home, there is the potential for contamination if providers' practices are changed by use of the mPHR. Such contamin tion would end to reduce the effect size of the intervention, increasing the possibility of type II error.[102] To investigate this possibility, we will examine pre-post changes in process of care measures for the usual care group to assess for potential effects on control subjects.

VI. TIMELINE:

During the first 9 months, we will we will develop a beta version of the app and refine it using qualitative techniques. Next, 5 cohorts of 60 subjects each will be sequentially enrolled in the trial for 6 months each; after each cohort, 2 months will be spent updating and modifying the intervention prior to the next cohort. The intervention will be conducted from year 2 through the first part of year 5. The cohorts will be completed by the final 6 months of year 4, with 12-month follow-ups completed by the 6 months mark at year 5. Data analyses and dissemination will occur during the final 6 months of the study.

Study Timeline



VIII. HUMAN SUBJECTS

The study proposes to develop and test a smartphone-based, mobile personal health record (mPHR) for persons with serious mental disorders treated in behavioral health homes. In the first phase of the study, the study team will develop and refine the app based on qualitative interviews. In the second phase, 5 cohorts of 60 subjects will be randomized to receive either the mPHR or usual care. During the final phase, the program will be disseminated through a national technical assistance center to behavioral health homes nationwide.

VIIA: Protection of Human Subjects

VIIA1: Sources of research material: Sources of research material will include interviews with subjects and administrative data from the Four Corners Behavioral Health Home in Cobb County, GA. Interviews will be audiotaped and transcribed. Audiotapes will be destroyed once interviews have been transcribed.

VIIA2: Plans for Recruitment of Subjects:

Subjects will be recruited from a roster of clients from the Four Corners Behavioral Health Home. All of these patients have a diagnosis of a serious mental illness and one or more cardiometabolic risk factor. The only exclusion criterion will be inability to consent based on a 6-item, validated screener. [46]

VIIB: Informed Consent:

VIIB1. Qualitative interviews: All eligible participants in interviews will be offered written informed consent. The informed consent process will describe the risks and benefits of participating in the interviews, focusing on the potential for breach of confidentiality.

VIIB2. Randomized Trial: All participants will be offered written informed consent. The procedures of the study and the informed consent document will be thoroughly reviewed with the subject in both verbal and written form by a trained research assistant. Only those subjects demonstrating adequate comprehension will be consented and enrolled in the study. Study personnel will also obtain permission to recontact the subjects and ask them to complete follow-up assessments.

The informed consent process will include the following: notification that participants will be interviewed three times (baseline, six-month, and 1-year follow-up); that half of participants (selected at random) will complete and maintain a smartphone-based, mobile personal health record; that agreement to participate in the study does not obligate participants to accept any particular treatments; and that participants are free to withdraw from any part of the study (either the intervention program or the follow-up assessments) at any time.

VIIC: Potential Risks

VIIC1. Breach of confidentiality: It is essential to monitor and minimize the possibility of a breach in confidentiality either via the mobile personal health record, care coordinator, research staff (interviewer), or through inappropriate access to the smartphone-based mobile PHR. These issues are particularly salient in the use of information technology, whose goal is to consolidate and improve access to health information. Section VIID1 describes the mechanisms for addressing these potential privacy concerns.

VIIC2: Acute medical or mental health crisis: It is possible that patients will be found to be in a medical or mental health crisis at the time of screening or that a new problem will emerge sometime during the study. Section VIID2 describes mechanisms for safely addressing these potential problems.

VIIC3.Subject Burden: Study assessments will always result in an expenditure of time and inconvenience for subjects, as well as the potential for discomfort or embarrassment related to the content of the interview.

VIID Adequacy of Protection against Risks:

VIID1. Protecting against breach of confidentiality:

VIID1a: Privacy Protections for the mPHR:

1.Patient's role in selecting who has access to health information: Patients assign an Access Level to each person listed on the plan to determine the level of access each member has to the specific health record. Access may include the ability to fully edit the plan, view only, or to have no access to the plan.

2.Password features: Upon registration, all mPHR users (patients, providers, and other care team members) obtain a unique identification and an encrypted password. Passwords are a minimum of eight characters and are required to use mixed case letters, numbers, and punctuation.

3.Data storage: Data will be stored on HealthVault servers, which are password protected and HIPAA compliant. No patient data will be stored locally on the smartphones. All data transfers to and from the server use 128 mb encryption. If a smartphone is lost or stolen, Emory IT will remotely wipe all apps and data off of the smartphone.
4. Auditing Capabilities: Full-content auditing makes it possible to give users as much access to the application as needed to easily perform their tasks, but with the understanding that a full report of their activities is always available. Participants will be encouraged to review their own audit trails to see who has accessed their mPHR.

There are two different types of auditing that occur within the mPHR. Event auditing occurs when information is logged when users take certain actions (but do not change data). Data auditing occurs when the results of data operations (inserts, updates, and deletes) are logged. Each table in the mPHR schema that holds dynamic user-generated content has an associated audit table. Separate logs are kept for logins, searching for a mPHR, viewing the mPHR, viewing particular screens, and viewing a user's registration information.

The project manager will print weekly logs of auditing activities for all patients in the study. If there is any evidence of a breach (e.g. inappropriate attempts to view or change the record by unauthorized personnel), the principal investigator and data safety monitoring board will be notified, and appropriate action will be taken.

VIID1b: Protecting privacy for the study and study data:
1. For the qualitative interviews, no identifying information will be included in the transcripts of the interviews or in any publications or reports that emerge from those reports.
2. For the randomized trial, all interviews will be held in a private area away from the clinical care area.
3. For study data, unique identifiers will be generated for all study subjects; these will be the only identifiers used in files used for data entry and analysis. The file linking these identifiers to patient names and addresses will be stored in a separate locked file that will be available only to the principal investigator and project manager. All research files will be stored in password-protected computer files or locked file cabinets. Identifying information such as name, address, and telephone number will be available only to those study personnel responsible for contacting study participants.

VIID2: Protocol for addressing acute medical or mental health crisis:
If patients will have a medical or mental health crisis either at the time of an interview by the research assistant, the research assistant will immediately contact the principal investigator. Based on the clinical situation, acuity, and patient preferences, a decision will be made whether to a. Contact the patient's primary care provider or mental health clinician or b. Escort the patient to the Emergency Room for a full evaluation.

VIID3. Minimizing subject burden: To minimize the interview burden for the randomized trial, interviews will be scheduled at a time and location that is as convenient as possible for patients –when possible, prior to or directly after a Four Corners Clinic appointment. Interviews will be conducted in a private, comfortable setting. If a subject appears tired or anxious, the subject will be asked if he or she wishes to rest, take a break, or terminate the interview. Monetary reimbursement for each interview and focus group meeting will help compensate subjects for the time and effort expended. Monetary reimbursement for attendance at each training session will help defray any needed transportation or childcare expenses.

VIIE Potential Benefits of the Proposed Research Project to the Subjects and Others:
VIIE1. For subjects in the usual care group of the trial: For those in the usual care arm of the randomized trial, patients will not receive any direct health benefits from participation.

VIIE2. For subjects in the intervention group: Subjects participating in the intervention group are expected to directly benefit from the mPHR. As described in the body of the proposal, hypothesized benefits include improved quality of care and better clinical outcomes.

VIIE3. For other persons treated in public safety settings: The study's results are hoped to inform the development of other programs to improve care for clients with serious mental Illness.

VIIE4 Risk Benefit Ratio: Given the protections to ensure confidentiality, ensure high quality of the intervention, and minimize subject burden, and the potential benefits of improved care for patients in the active treatment group of the randomized trial, we anticipate a favorable risk-benefit ratio for the projects.

VIIF. Data Safety and Monitoring Plan

VIIF1. Responsibility, Frequency, and Content of Data Safety Monitoring: The PI will be involved in all aspects of the research and will be responsible for monitoring all data. The PI will review safety data on a monthly basis during the course of the study. A three-member DSMB committee will be assembled who will review study recruitment and any potential adverse events twice each year. A semi-annual report by the PI to the Emory IRB will include a brief description of the randomized trial; baseline demographic characteristics, and retention and disposition of study participants.

VIIF2: Adverse Event Reporting: Serious adverse events are expected to be unlikely. If one occurs, the PI will immediately report the event to the Emory IRB. The PI, in consultation with co-investigators and others as needed, will review the adverse event report and determine the need for subsequent action. Any subsequent action will also be documented and reported to the Emory IRB.

VIIF3: Confidentiality and Integrity of Data:

VIIF3a. Qualitative interviews: No identifying information will be included in the transcripts of interviews or in any publications or reports that emerge from those reports. All audiotapes will be destroyed after transcripts have been made, and the transcripts will be kept in a locked file.

VIIF3b. Randomized trial: PHR data will be stored on HIPAA compliant HealthVault servers; no patient data will be stored on study smartphones. Unique identifiers will be generated for all study subjects; these will be the only identifiers used in files used for data entry and analysis. The file linking these identifiers to patient names and addresses will be stored in a separate locked file that will be available only to the principal investigator and project manager. All research files will be stored in password-protected computer files or locked file cabinets. Identifying information such as name, address, and telephone number will be available only to those study personnel responsible for contacting study participants.

VIIF3c HIPAA: The Emory University Institutional Review Board has developed a series of guidelines and amendments to their review process to ensure that all research protocols are compliant with the privacy provisions of the Health Insurance Portability and Accountability Act. We will work closely with that office to ensure that any final IRB protocol is in full compliance with this act.

VIIG1. Inclusion of Women Women will be included in the enrollment process and we expect them to be well-represented based on the characteristics of the CMHCs from which they are recruited.

VIIG2. Inclusion of Minorities Minority groups are well-represented in the mental health centers, and will be included based on their representation in that population.

TARGETED/PLANNED ENROLLMENT: Number of Subjects*			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	8	4	12
Not Hispanic or Latino	187	101	288
Ethnic Category Total of all Subjects	195	105	**300**
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	4	2	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	43	23	66
Hispanic or Latino	8	4	12
White	140	76	216
Other	0	0	0
Racial Categories: Total of All Subjects	195	105	**300**

VIIG3. Inclusion of Children

Because children under age 18 have different health problems and needs from adults, they would not easily be integrated into the broader intervention, and hence will not be included in intervention. Approximately 5% of patients in the four corners behavioral health home is between the ages of 18 and 20, and thus are considered children under NIH guidelines. There is no a priori reason to assume that they would derive less benefit from a mobile PHR than adults over age 21. Therefore, individuals age 18-20 will be included in the study, and there is no reason to expect that special accommodations will be needed for the group.

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