A Quality Improvement Process to Support Delivery of Cardiovascular Care in Community Mental Health Organizations

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Protocol

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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

People with serious mental illness (SMI) such as schizophrenia, bipolar disorder and major depressive disorder, experience high burden and poor control of cardiovascular disease (CVD) risk factors, including hypertension, dyslipidemia, and diabetes mellitus.[1-9,10,11-15] Low rates of guideline-concordant care contribute to poor control of CVD risk factors among individuals with SMI.[10,16-18] This group's complex co-morbidities and social challenges, e.g. housing instability and criminal justice involvement,[19-23] and the historic separation between the general medical and specialty mental health systems[24,25] – where people with SMI receive much of their care[24,26,27] – can impede this group's receipt of effective physical health care.[27,28]

Maryland is among 19 states receiving funding under the Affordable Care Act Medicaid Health Home provision. Medicaid health homes programs were designed to improve physical health care and outcomes for persons with SMI through care coordination.[29] In 2013, Maryland implemented health homes in psychiatric rehabilitation programs, which are affiliated with outpatient mental health clinics and provide skills training, case management, and social service coordination for persons with SMI.[30]

A preliminary evaluation by the state of Maryland suggests that the program has not improved CVD risk factor control among participants with SMI. [31] Studies of other health home programs and other programs integrating physical health care into mental settings for persons with SMI have also shown limited or no improvements in CVD risk factor control.[32,33] Our research shows that Maryland and other health home providers perceive lack of standard care coordination systems and processes to ensure delivery of evidence-based care, e.g. standard protocols for coordinating care for poorly controlled dyslipidemia, as a key barrier to achieving CVD risk factor control in health home participants.[34,35]

This is a R34 pilot study funded by NIMH as part of the Johns Hopkins NIMH P50 Center to Accelerate Translation of Interventions to Decrease Premature Mortality in Serious Mental Illness. In this study, we will pilot test an adapted Comprehensive Unit Safety Program (CUSP) implementation strategy to improve mental health providers' delivery of evidence-based CVD risk factor care for individuals with SMI in Maryland health homes. CUSP is a quality improvement strategy developed by the JHU Armstrong Institute for Patient Safety and Quality[36] and used to improve care delivery in other, primarily inpatient, contexts.[37-45] CUSP is more recently being applied to outpatient quality improvement.[42-45] Our study is the first to adapt CUSP for the community mental health setting.

This study will result in an adapted set of CUSP tools and resources for community mental health programs, which other community mental health programs can use in the future. Study results will lay the foundation for development and evaluation of a scalable model for implementation of evidence-based physical health care in community mental health settings.

2. Objectives (include all primary and secondary objectives)

The project will pilot test a comprehensive unit-based safety program (CUSP) to implement evidenced-based practices to guide delivery of care for hypertension, dyslipidemia and diabetes for persons with serious mental illness in Maryland Medicaid health homes. The project will characterize implementation processes, organizational and provider-level factors, and cardiovascular disease risk factor care and control.

The specific aims are:

Aim 1. Characterize implementation barriers, quality improvement culture, providers' self-efficacy, and CVD risk factor care and control in Maryland Medicaid SMI health home programs. Using observation, focus groups, surveys, and database abstraction, we will answer 4 research questions:
1. What are the barriers to delivery of evidence-based CVD risk factor care at health home sites, and what strategies could help to overcome those barriers?
2. How supportive of quality improvement is the current health home culture?
3. How do providers rate their self-efficacy to deliver/coordinate evidence-based CVD risk factor care?
4. At the health home study sites, what are baseline rates of evidence-based care for and control of hypertension, dyslipidemia, and diabetes mellitus?

Aim 2. Pilot test a comprehensive unit-based safety program (CUSP), designed to implement an evidence-based practice bundle, in Maryland Medicaid SMI health home programs. We hypothesize CUSP will:
1. Improve the organizational culture surrounding delivery of evidence-based CVD risk factor care.
2. Improve providers' self-efficacy to deliver evidence-based CVD risk factor care.
3. Yield preliminary data showing increased rates of evidence-based care for and control of hypertension, dyslipidemia, and diabetes among consumers with SMI.
4. Be perceived as acceptable, appropriate, and feasible by health home providers.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Persons with serious mental illness (SMI) experience high prevalence and poor control of cardiovascular disease (CVD) risk factors including hypertension, dyslipidemia, and diabetes mellitus; [1-9] poor control is driven in part by low rates of guideline-concordant CVD risk factor care in this group. [10,16-18] Our team's data from a trial[46] of 269 adults with SMI in Maryland

shows that 84% have hypertension, diabetes mellitus, or dyslipidemia and 45% meet clinical definitions of poor control for at least one of these conditions.

The historic separation of the general medical and mental health systems contributes to deficits in care quality by impeding access, communication, and sharing of data and expertise across systems.[27,47-52] In recent years, programs designed to integrate primary care services, like CVD risk factor management, into specialty mental health settings – where many people with SMI receive the majority of their care[24,26,27] – have been implemented at the federal, state, and local levels.[33,53,54] Maryland's Medicaid health home program, implemented in October 2013, is one such model.[55]

Health homes are currently implemented in 48 Maryland psychiatric rehabilitation programs, which receive a per-member-per-month payment to provide "health home services," including primary care coordination and case management.[55] All health homes have a director, primary care physician or nurse practitioner consultant, and one or more nurse care managers, but each site chooses their own service structure (ranging from co-location to facilitated referral to offsite primary care services).[55] Nurse care managers provide basic services, like blood pressure monitoring, onsite.[34] While 15% of sites have a primary care provider who provides onsite services 1+ days per week, most primary care physical health services are coordinated with offsite providers.[34] Data suggests that health home implementation has not improved CVD risk factor control among health home participants with SMI.[31]

Our research on health home implementation, including interviews and surveys with >80 health home leaders and >650 front-line providers and staff, suggests that lack of standardized systems and processes for tracking and coordinating evidence-based CVD risk factor care is a key barrier to achieving such care in health home programs.[34] Systems for tracking and ensuring receipt of evidence-based guidelines, e.g. hemoglobin A1C (HBA1C) monitoring among consumers with diabetes, are lacking, as are standard protocols for delivering or coordinating appropriate care with primary care providers when consumers' CVD risk factors are poorly controlled.[34] Health homes received no formal guidance on how to set up such systems.

In this pilot study guided by the Translating Evidence into Practice (TRIP) framework,[56] we will partner with 5 health home programs to test an adapted Comprehensive Unit Safety Program (CUSP) implementation strategy designed to improve delivery of the evidence-based care delivery processes, e.g. population health management and care coordination, needed to implement evidence-based CVD risk factor care in SMI health homes. CUSP is a scalable implementation strategy that includes provider training and implementation of a team-based quality improvement process. CUSP is endorsed by AHRQ[57] and leads to significant improvements in inpatient safety;[37-41] CUSP is more recently being applied to outpatient quality improvement.[42-45] Our study is the first to adapt CUSP for the community mental health setting.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).
b. Study duration and number of study visits required of research participants.

Currently this protocol is being submitted as a study where all study procedures are delivered remotely. If and when COVID-19 restrictions are lifted, we may submit a petition to have some of the study activities (e.g., training) in-person as appropriate.

Overview: We will work with 5 behavioral health home programs in Maryland. Health homes are responsible for coordinating physical health care for persons with serious mental illness and are based in community mental health programs. The project will pilot test a comprehensive unit-based safety program (CUSP) to implement evidenced-based practices to guide delivery of care for hypertension, dyslipidemia and diabetes for persons with serious mental illness in the behavioral health homes. The project will also characterize implementation processes, organizational and provider-level factors, and cardiovascular disease risk factor care and control. The health home programs are already providing care in these domains for these individuals with serious mental illness. They will not be expanding their scope of practice with this project. The evidenced-based practices ("evidence bundle") the study team is providing training for as part of the CUSP model are based on current practice guidelines.[58-63] CUSP is a quality improvement implementation strategy.

Study sites and participants: We plan for five community psychiatric rehabilitation programs that have health home programs to participate in the study. Participants will be health home team staff including a nurse care manager, a primary care consultant (primary care physician or nurse practitioner), and psychiatric rehabilitation program staff who work with the health home program. Other study participants will include the broader psychiatric rehabilitation program staff and primary care physicians outside the community mental health organization with whom the health home coordinates care. Persons with serious mental illness enrolled in the health home are also study participants as their data will be analyzed.

Study implementation intervention: CUSP

CUSP is a scalable quality improvement strategy developed by the JHU Armstrong Institute for Patient Safety and Quality used to improve collaboration and improve patient safety and quality of care. A foundation of CUSP is the CUSP "team" that implements the patient safety and quality processes, in order to increase delivery of care as defined in the evidence-bundle. Each health home program will form a CUSP team that will participate in advanced CUSP training and implement the CUSP process over the course of the project. The CUSP team will have approximately five to ten members including health home program staff and an organizational leader. The CUSP process and trainings will follow standard formats used and evaluated in prior CUSPs. [37-45,64]

Timeline for CUSP

Before CUSP: 1 month. The CUSP team will participate in trainings outlined below (Table 1) as part of the pre-implementation period.

CUSP Implementation: 12-months, monthly meetings. During the implementation period the CUSP team will meet monthly for one hour for a meeting guided by study team expert CUSP facilitators focused on problem-solving through a team-based quality improvement process. At these meetings the CUSP team will review issues, problems or events regarding the

cardiovascular care of health home clients/patients. Health homes already measure CVD risk factor care but without using standard processes. As part of implementing the evidence-bundle on management of CVD risk factors, care coordination and population health, CUSP team members will use a standard population health spreadsheet template that the study team provides to track CVD risk factors and care processes during regular health home program care. Using the spreadsheet, CUSP team members can aggregate patient-level data and identify trends in CVD risk factor prevalence and quality of care metrics for persons enrolled in the health home. Team members will identify problems in the care delivery process and use worksheets and guides to brainstorm processes and procedures as a team to improve care. They will then implement and develop how the process or procedure will be evaluated.

CUSP Sustainment: 3-months. CUSP implementation will be followed by a 3-month sustainment period in which the CUSP team will continue to use evidence-based care practices and follow the CUSP process without our team's expert facilitators.

CUSP Training Overview

Study team members will conduct trainings (Table 1) by Zoom while the study is remote.

All psychiatric rehabilitation program and health home leaders/providers/staff participate in a brief CUSP Process Training that introduces the principles of CUSP, and at the end of the 12-month implementation phase, in a training about sustaining CUSP.[64]

The CUSP team participates in advanced CUSP training including training in the evidence-bundle. The evidence-bundle focuses on evidence-based CVD risk factor guidelines and care coordination/ population health management for CVD risk factors in persons with SMI. The evidence-bundle training also includes content in motivational interviewing as a key-component of helping clients with SMI make healthy behavioral change.

The real-time motivational interviewing training will be supplemented with an online avatar practice module.[65,66] The avatar practice module includes a 15-minute didactic component where providers learn about motivational interviewing and techniques that can be used to guide patients with SMI toward health changes, and 15-minute practice conversations where providers take on the role of virtual provider avatar and practice the use of motivational interviewing techniques in simulated conversations about managing cholesterol in persons with serious mental illness using patient avatars on the Kognito platform. We will recommend CUSP team members practice weekly for the first three months. An online dashboard will give CUSP team members an individualized report on their performance each time they practice.

Table 1. CUSP Training		
Topic	**Who receives training**	**Estimated Length**
CUSP Process Training - Introductory Introduces the Principles of CUSP	CUSP team and all psychiatric rehabilitation program staff	60 minutes
CUSP Process Training- Advanced 1. Introduction to CUSP and Science of Quality 2. Creating Engagement and Ownership of CUSP 3. Identifying and Learning from Challenges 4. Kicking off CUSP	CUSP team	Four one-hour sessions
Evidence Bundle (evidenced-based practices) for CVD risk factors and care coordination/population health management	CUSP team	Two two-hour sessions
Evidence Bundle Motivational Interviewing for CVD risk factor management	CUSP team	Two two-hour sessions
Motivational Interviewing for CVD risk factor management – using Avatar	CUSP team	Recommended weekly 15-minute practice sessions for three months and then as needed/desired
Sustaining a CUSP Team	CUSP team and all psychiatric rehabilitation program staff	60 minutes

Data Collection:

Study data collection is outlined in Table 2 and in more detail below. Study team involvement in data collection is all virtual/remote.

Table 2. Study Data Collection			
Qualitative Data Collection	**Who**	**Estimated time**	**When**
CUSP Team Focus Groups	Selected CUSP team members (~5 per site)	60 minutes	Baseline, 15 months
Primary Care Provider Interviews	Primary care providers caring for health home program patients but who are not health home team members (~5 per site)	30 minutes	Baseline
Survey Measures			
Demographic Characteristics: age, sex, race, ethnicity, length of time at program, role in program, previous Motivational Interviewing training, comfort with technology	Health home team and psychiatric rehabilitation program staff (~30 per site)	~5 minutes	Baseline
Implementation Climate: This is a measure of the degree to which an organization supports evidence-based practice implementation	Health home team and psychiatric rehabilitation program staff (~30 per site)	~3 minutes	Baseline
Quality Improvement Culture: Measured using a modified version of the validated 42-item Survey on Patient safety used in inpatient CUSPs	Health home team and psychiatric rehabilitation program staff (~30 per site)	~5 minutes	Baseline, 12 months

Pre-Implementation Health Homes Survey: The nurse care manager will assess the behavioral health home's database and what is currently tracked.	CUSP team member (health home nurse/nurse care manager) (1 per site)	~10 minutes	Baseline
Self-Efficacy: Self-efficacy to deliver evidence-based CVD risk factor	CUSP team (~10 per site)	~5 minutes	Baseline, 12 months
Acceptability, Appropriateness, and Feasibility of the Intervention Implementation Strategies: Measured with a brief 4-item practice instrument (AIM, IAM, FIM)[67]	CUSP team (~10 per site)	~5 minutes	Baseline, 12 months
Acceptability, Appropriateness, and Feasibility of the Evidence-Based Practice Bundle: Measured with a brief 4-item practice instrument (AIM, IAM, FIM)[67]	CUSP team (~10 per site)	~5 minutes	Baseline, 12 months
Motivation: Degree to which providers and staff agree or disagree with statements that deal with aspects of the health homes intervention to improve cardiovascular risk factor care	CUSP team (~10 per site)	~3 minutes	Baseline, 12 months
Beliefs about Motivational Interviewing Questionnaire	CUSP team (~10 per site)	~2 minutes	Baseline, 3, 6, 12 months
Importance and Confidence of Using Motivational Interviewing	CUSP team (~10 per site)	~2 minutes	Baseline, 3, 6, 12 months
Perceived Usefulness	CUSP team (~10 per site)	~2 minutes	12 months
Fidelity Measures			
Avatar Motivational Interviewing Performance Measurements: from use of motivational interviewing techniques in simulated online conversations	CUSP team (~10 per site)	15 minutes	Baseline to 3 months (weekly requested), 6, 12 months
Fidelity to Motivational Interviewing: Standardized Actor Interviews will be conducted to assess fidelity to motivational interviewing.	CUSP team (~10 per site)	30 minutes	Baseline, 3, 6, 12 months
Health Home Enrollee Measures			
Sociodemographic and Mental Health: age, gender, race, ethnicity, living arrangement, disability status, any issues with transportation, scheduling or obtaining medications, primary diagnosis, categories of psychotropic medications used	All health home enrollees (patients) (~200 per site) Collected by CUSP team/ health home staff during regular health home program care		Baseline, 6, 12 months
CVD risk factors: weight, BMI, tobacco smoking status, blood pressure, diabetes, HgbA1c, lipids, diagnoses of hypertension, diabetes, dyslipidemia, CVD risk scores			
Evidence-Based CVD Risk Factor Care: % of consumers eligible to receive each care process in the evidence bundle who receive that process (e.g., statin prescription, diabetes foot exam, follow-up visits)			
CVD Risk Factor Control: % of consumers meeting clinical criteria for having controlled hypertension (eg BP< 130/80) dyslipidemia, and diabetes (HgbAc1<7.0)			

Qualitative Data Collection

CUSP Team Focus Groups: ~ 5 selected CUSP team members per site will be asked to participate in focus group interviews by Zoom. These focus groups will be 60-minutes and conducted by our research team using a semi-structured guide. Focus groups will be audio or video-recorded, and recordings will be transcribed using Production Transcripts, Inc.

Primary Care Provider Interviews: ~5 primary care providers per site who provide care for health home enrollees and coordinate care with but are not formally part of the health home team will participate in a ~30-minute interview by phone or Zoom. Interviews will be audio or video-recorded, and recordings will be transcribed using Production Transcripts, Inc.

Surveys

Surveys will be administered via email with instructions and a link to the surveys in REDCap. Surveys may also be delivered in hard copy if needed and mailed back to the study team.

Demographic Characteristics: Health home team and psychiatric rehabilitation program staff (~30 per site) will provide demographic characteristics such as age, sex, race, ethnicity. We will also ask about their current role in the program and length of time at program. We will ask about any prior Motivational Interviewing training and comfort with using technology for online trainings. This survey is 13 questions.

Implementation Climate: Health home team and psychiatric rehabilitation program staff (~30 per site) will take this survey. Ehrhart's implementation climate scale;[68] overall score of 4 = excellent implementation climate. This is a measure of the degree to which an organization supports evidence-based practice implementation.

Quality Improvement Culture: Health home team and psychiatric rehabilitation program staff (~30 per site). Measured using a modified version of the validated 42-item Survey on Patient safety used in inpatient CUSPs. Score ≥4 indicates good quality improvement culture.

Pre-Implementation Health Homes Survey: The nurse care manager who is part of the CUSP team (~1 per site) will assess the behavioral health home's current methods of collecting and tracking information on cardiovascular risk factors.

Self-Efficacy: The CUSP team (~10 per site) will take this survey. Measures self-efficacy to deliver evidence-based CVD risk factor measured as a numeric score created by averaging 10 items adapted from Compeau & Higgins' task-focused self-efficacy scale[69]

Acceptability, Appropriateness, and Feasibility of the Intervention Implementation Strategies: The CUSP team (~10 per site) will take this survey. Acceptability, feasibility and appropriateness of the implementation strategies (cardiovascular risk factor reduction intervention and CUSP quality of care process) will be measured with validated 4-item measures[67]

Acceptability, Appropriateness, and Feasibility of the Evidence-Based Practice Bundle: The CUSP team (~10 per site) will take this survey. Acceptability, feasibility and appropriateness of the evidence-based bundle will be measured with validated 4-item measures[67]

Motivation: The CUSP team (~10 per site) will take this survey. Measured by assessing the degree to which providers and staff agree or disagree with statements that deal with aspects of the health homes intervention to improve cardiovascular risk factor care. Categories include expectancy, instrumentality, and valence regarding the evidence-based CVD risk factor care bundle and the CUSP quality of care process.

Beliefs about Motivational Interviewing Questionnaire: The CUSP team (~10 per site) will take this survey. A 7-question survey assessing the extent to which each person agrees with statements about motivational interviewing.

Importance and Confidence of Using Motivational Interviewing: The CUSP team (~10 per site) will take this survey. A 6-question survey assessing the importance and confidence each person has with motivational interviewing.

Perceived Usefulness: The CUSP team (~10 per site) will take this survey. A 6-question survey assessing the perceived usefulness of the motivational interviewing avatar platform during the course of the project.

Fidelity Measures

Avatar Motivational Interviewing Performance Measurements: Members of the CUSP team (~10 per site) will use the avatar platform and have 15-minute practice "conversations" where they practice use of motivational interviewing techniques in simulated conversations about managing cholesterol with patient avatars. An online dashboard will give CUSP team members an individualized report on their performance each time they practice.

Fidelity to Motivational Interviewing: Standardized Actor Interviews: Members of the CUSP team (~10 per site) will participate in 30-minute audio-recorded phone interviews with standardized patient actors. These standardized patient actors are trained actors playing roles of patients with SMI and CVD risk factors.

Health Home Enrollee Measures

As part of implementing the evidence-bundle on management of CVD risk factors, care coordination and population health, CUSP team members will be using a standard population health spreadsheet template that the study team provides to track CVD risk factors and care processes during regular health home program care. Using the spreadsheet, CUSP team members can aggregate patient-level data and identify trends in CVD risk factor prevalence and quality of care metrics for persons enrolled in the health home. This data (in a limited dataset) will also be used for study evaluation purposes. Health home enrollee data will include sociodemographic and basic mental health diagnosis/medication categories, CVD risk factors, evidence-based CVD risk factor care processes and CVD risk factor control.

Data Management:

Qualitative data. Interview and focus group data will be audio or video-recorded and

recordings will be transcribed using Production Transcripts, Inc or another approved Johns Hopkins vendor. Names will be removed from transcripts. Recordings will be stored in a Johns Hopkins secure network drive and will be destroyed when analyses are complete. Standardized actor interview recordings will be reviewed by experts in motivational interviewing for fidelity to motivational interviewing practices and stored in a Johns Hopkins secure network drive or OneDrive.

Quantitative data. Each participant will be assigned a unique study ID number for data collection. We will store data in a Johns Hopkins REDCap database. Study team members are trained to protect integrity and confidentiality of the data. Kognito, a health simulation company, developed the avatar simulations for this project and hosts the avatar training platform and dashboard. Avatar performance measurement data for motivational interviewing practice conversations is accessible only by the individual study participant (CUSP team member) and the study team, not shared outside Kognito. Kognito stores data securely behind two firewalls. For health home enrollee measures, the CUSP team will use participant initials and a study ID number in the Excel population health tracking spreadsheet. Participant names, used for implementing the evidence-bundle, will be removed by the CUSP team. They will use Johns Hopkins OneDrive, available to non-Johns Hopkins collaborators, to deposit the spreadsheet at baseline, 6 and 12 months. The data will contain no names or birthdates but will have dates of process measures (e.g., lab values) thus it will be a limited dataset. Each study site will only be able to access a folder specific to their site, and spreadsheets will have password protection.

c. Blinding, including justification for blinding or not blinding the trial, if applicable. N/A
d. Justification of why participants will not receive routine care or will have current therapy stopped. N/A
e. Justification for inclusion of a placebo or non-treatment group N/A
f. Definition of treatment failure or participant removal criteria. N/A
g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely. N/A

5. Inclusion/Exclusion Criteria

Psychiatric rehabilitation program and health home team staff, including providers and leadership are those employed by the psychiatric rehabilitation program or health home program. All are adults and English-speaking.

Primary care providers are those who provide primary care to health home enrollees.

Health home enrollees are by definition persons with serious mental illness who are members of a behavioral health home. All are 18 years and older.

6. Drugs/ Substances/ Devices-N/A

a. The rationale for choosing the drug and dose or for choosing the device to be used.
b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.

c. Justification and safety information if non-FDA approved drugs without an IND will be administered.

7. Study Statistics

a. Primary outcome variable and analytic plans

We will conduct three main analyses. First, we will compare pre/post (baseline, 12 mo.) quality improvement culture and provider self-efficacy, the mechanisms through which CUSP is designed to improve delivery of evidence-based care, using a generalized linear mixed effects modeling approach. We will evaluate the effects of CUSP (baseline, 6 mo, 12 mo) on consumer-level evidence-based care and CVD risk factor control outcomes using a multi-level modeling approach. We will assess mediator and moderator by testing whether sites' quality improvement culture and provider self-efficacy mediate CUSP's effects on health home enrollee outcomes by adding these variables to the multi-level models of health home enrollee outcomes. We will also assess potential moderating effects of implementation climate by adding appropriate interaction terms to the main models. We will use descriptive statistics to analyze survey measures of staff perceptions of the acceptability, feasibility and appropriateness of CUSP and the evidence-bundle. Interview and focus group transcripts will be analyzed in NVivo V.11, using inductive coding to identify key themes. Survey analysis will be done using Stata 14 or SAS software.

8. Risks

We expect any risk to be minimal in this study.

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

For the CUSP implementation of the evidence-based bundle for CVD risk factor care, coordination and population health, the health home programs are already providing care in these domains for their enrollees with serious mental illness. Health home staff will be working within their current scope of practice with this project. The evidenced-based practices the study team is providing training for as part of the CUSP model are based on current practice guidelines. CUSP is a quality improvement implementation strategy. Thus, we do not expect there to be increased risk for health home enrollees.

Psychiatric rehabilitation program and health home team staff and primary care providers may be come tired or bored during surveys, interviews or focus groups.

b. Steps taken to minimize the risks.

Psychiatric rehabilitation program and health home team staff, and primary care providers will be appropriately recruited and informed of the study by the study team with waiver of documentation of informed consent. The study team will inform them that they do not have to answer any questions they do not want to, and that their employment or evaluations will not be affected by their responses.

c. Plan for reporting unanticipated problems or study deviations

Dr. Daumit, internist with experience in working with persons with SMI and staff in community mental health settings, will be responsible for data safety and monitoring. If new guidelines for treatment of hypertension, dyslipidemia, or diabetes mellitus were to be released during the study period, we will make any appropriate modifications in the evidence bundle/protocol and communicate with the study sites. If safety issues about management of cardiovascular risk factors in individual health home enrollees care are raised, Dr. Daumit will communicate with the health home nurse director as appropriate. Any unanticipated problems will also be reported to the IRB. We expect any issues to be rare.

d. Legal risks such as the risks that would be associated with breach of confidentiality

Risk of loss of confidentiality is the main risk. We expect this risk to be extremely low, as we will be taking multiple safeguards to protect the data. To protect against breach of confidentiality, all information will be considered confidential. This confidentiality will be assured through several mechanisms.

As per above, psychiatric rehabilitation program and health home team staff, and primary care providers will be appropriately recruited and informed of the study by the study team with waiver of documentation of informed consent. The study team will inform them that they do not have to answer any questions they do not want to, and that their employment or evaluations will not be affected by their responses.

For qualitative data, no focus group participants will be individually identified; a site identifier will be used. The link to the site ID will be held in a locked file. Focus group transcripts will have names (if mentioned during the group) removed, and no participants will be identified by name in any publications. Furthermore, data will not be presented in such a way that their identity can be inferred. Similar procedures will be used for interviews. Psychiatric rehabilitation program/health home directors will give assurance to providers/staff that their participation and information shared will not affect their employment or their evaluation. Data will not be presented in such a way that identity can be inferred. As described in Data Management, data will be stored in Johns Hopkins secure drives.

For quantitative data, as in Data Management above, each staff participant will be assigned a unique study ID number for data collection and data will be stored in REDCap. For health home enrollee measures from the population health spreadsheet, we will request a waiver of informed consent. The study team will receive limited datasets from health home program sites in Johns Hopkins OneDrive with study IDs. The data will have dates of process measures (e.g., lab values) but no names or birthdates. Folders and spreadsheets will have password protection.

9. Benefits

a. Description of the probable benefits for the participant and for society.

There is no benefit to individual participants. This research will help stakeholders have a greater understanding of the organizational and staff-level barriers to delivery of evidence-based cardiovascular risk factor care in community mental health settings.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Primary care providers will be paid $50 for completing an interview. CUSP team members will be paid $50 for participating in a focus group and will be paid $25 for each standardized actor interview. CUSP team members will be compensated $25 for completion of surveys administered at baseline and 12-month data collection and $10 for completion of surveys at all other time points. Psychiatric rehabilitation program staff, who are not part of the CUSP team will receive $10 for completion of surveys at baseline and 12 months.

11. Costs – N/A

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

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