IMPROVING HEALTH OUTCOMES AND EQUITY BY TARGETING POSTPARTUM MOTHERS AT RISK: A PILOT RANDOMIZED CONTROL TRIAL

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Study Summary

Title	**Improving Health OutcoMes and Equity by targeting postpartum mothers at risk: a pilot randomized control trial**
Short Title	**HOME RCT**
IRB Number	850584
Methodology	Randomized controlled trial
Study Duration	18 months
Study Center(s)	Single-center
Objectives	To assess feasibility, acceptability, and target effect size and potential efficacy of the intervention to reduce ED visits and postpartum readmissions at 30-days postpartum.
Number of Subjects	214 subjects
Main Inclusion and Exclusion Criteria	Black women planning on delivering a baby at the Hospital of University of Pennsylvania and are 18 or above years old.
Intervention	Education Intervention
Statistical Methodology	Our primary analysis will focus on a categorical outcome: postpartum ED visit or readmission within 30 days after discharge. A chi square test will be used to determine the difference in the proportion of patients who experience ED visits or readmissions between the two study groups. Poisson regression will be used to estimate and compare the ED and readmission rates between the two groups.

Background and Study Rationale

This study will be conducted in full accordance with all applicable University of Pennsylvania Research Policies and Procedures and all applicable Federal and state laws and regulations.

This study is the third phase/aim of a four-phase mixed method study to better identify Black and Latina women most at risk for poor outcomes following delivery, the problems they experience, and to adapt an evidence-based intervention that aims to improve quality of postpartum care for high-risk women. The aims of our research study, "Improving Health Outcomes and Equity by Targeting Postpartum Mothers at Highest Risk" are to: 1) Develop a risk prediction model using sociodemographic, clinical, behavioral, and neighborhood factors to identify high-risk mothers using ED visits and postpartum readmissions as a marker of severe maternal morbidity. 2) Use qualitative methods to adapt and intensify an evidence-based behavioral educational intervention aimed at improving quality of care to reduce severe maternal morbidity as measured by postpartum ED use and hospital readmission, 3) Conduct a pilot RCT utilizing the cohort identified by the risk prediction model in Aim 1 to assess feasibility, acceptability, and target effect size and potential efficacy of the refined intervention to reduce ED visits and postpartum readmissions, and 4) Evaluate the pilot study results and procedures to inform the refinement of the intervention and to prepare for a larger implementation trial of this intervention. This study is the third phase, a pilot randomized controlled trial to assess the postpartum intervention.

1.1 Background and Relevant Literature

Significant racial and ethnic disparities in maternal mortality persist in the US. Black women and birthing people are three to four times more likely to die a pregnancy-related death as compared with white women, and in some regions Latinas are also at increased risk.[1,2] This disparity is rooted in the fact that Black and Latina women experience elevated maternal health risks throughout the pregnancy-postpartum continuum. Women of color are more likely to begin pregnancy with a chronic health condition such as hypertension or diabetes, experience a complication while pregnant, and to suffer a life-threatening morbidity during delivery.[3-5] Less recognized is that heightened maternal health risks extend into the postpartum period. Black women are more likely to have an emergency department (ED) visit after delivery,[6] and Black and Latina women have a two-fold increased risk of postpartum hospital readmission relative to white women.[7,8] Black women are also more likely to experience severe morbidity and suffer life-threatening complications such as pulmonary edema and heart failure during the readmission.[9] The majority of pregnancy-related deaths across the pregnancy-postpartum continuum and a significant proportion of severe maternal complications are preventable, suggesting that evidence-based interventions addressing maternal health disparities have great potential to be impactful.[10]

Many Black and Latina women with chronic illness such as hypertension and diabetes fail to get appropriate medical follow-up postpartum, putting their short and long-term health at risk. These chronic health conditions not only contribute to the significant excess maternal morbidity and mortality burden among women of color in the short term but lead to elevated risk of cardiometabolic disease in later life.[11] In prior research, we implemented an evidence-based postpartum intervention to improve receipt of postpartum care for high risk women (e.g., women with hypertension, gestational diabetes, positive depression screens).[12] Our primary outcome was to increase the timely postpartum visit rate. The behavioral educational intervention successfully increased postpartum visit rates.[12] However, high rates of ED use and readmissions for mothers within the first month postpartum occurred even among this cohort with supplemental care. Our results suggest a dire need to look beyond individual clinical risk factors to incorporate social context to identify high-risk mothers, and to develop a more comprehensive intervention to improve the postpartum health of Black and Latina women.

Our mixed methods study aims to do exactly that - design and test an effective postpartum intervention to improve postpartum health. In Phases 1 and 2 we are developing a risk-prediction model to identify women at high risk for postpartum ED visits or readmission and we are conducting qualitative interviews to inform the adaptation of the behavioral educational intervention discussed above. The goal of the

current phase, Phase 3, is to conduct a pilot RCT in 214 postpartum women to test whether the adapted behavioral educational intervention reduces postpartum ED visits or readmissions within 30 days from discharge.

2 Study Objectives

2.1 Primary Objective

- To obtain data on feasibility, acceptability, and target effect size and potential efficacy of the intervention for the primary outcome of postpartum morbidity and mortality as measured by Emergency Department (ED) visits and hospital readmissions in the 30-day post discharge period.

2.2 Secondary Objectives (if applicable)

- To detect the intermediate outcome: ability of participants to "obtain needed services" and ability for patients to see their provider when they need to, in the 30-day post discharge period as one of the main pathways of unnecessary ED visits.
- Depressive symptoms

3 Investigational Plan

3.1 General Design

This will be a pilot randomized control trial with an intervention arm consisting of a 1. patient-navigator postpartum education and resources component and 2. a control arm which consists of usual postpartum care.

3.2 Allocation to Interventional Group

After successful screening, each participant will be assigned a screening number and a randomization number that determines the treatment group according to a predetermined randomization scheme. The randomization scheme will be a blocked scheme (e.g., random block
of size 4 and 6). The treatment assignment will be obtained electronically through a web-based interface, REDCap.

3.3 Study Measures

Participants in both arms of this RCT will be surveyed at three time points by a research staff member Visit 1 or baseline will occur during the delivery hospitalization, after consent but prior to randomization. Visit 2 will occur 3-6 weeks postpartum, and Visit 3 will occur approximately six-months postpartum The surveys will assess symptoms of depression and anxiety, experiences of discrimination, social support, emotional/physical symptoms, and self-efficacy (see survey). The baseline survey conducted in-person at discharge will last 10 minutes, and surveys for visits 2 and 3 will last 25 minutes and will be conducted by telephone or other electronic modality. Computerized survey instruments will be administered by trained staff.

We will utilize the surveys we developed, piloted, and used for the RWJF (a previous) intervention, with minor revisions. The surveys include validated scales where possible. Maternal depressive symptoms are assessed using the Edinburgh Postnatal Depression Scale (EPDS).[13,14] Social support domains important during the postpartum period (e.g., help with infant, household, emotional support) will be assessed.[15,16-18] Questions also assess physical symptoms, emotional symptoms (depression and anxiety)[19, 146] infant-related role function,[16] and self-efficacy,[22].

We will utilize the EMR and phone review with patient during surveys to ascertain whether patients have an ED visit or are readmitted within 30 days post discharge.

3.4 Study Arms

Study Intervention Arm

The study intervention consists of a patient education pamphlet and partner sheet (physically and virtually accessible) that will educate and prepare post-partum participants about health conditions (hypertension, diabetes, and depression), important health behaviors, physical and emotional postpartum symptoms, teach self-management skills, enhance social support, and connect post-partum participants with community resources. The education materials will provide simple actions that participants can utilize to address symptoms, realistic time frames for healing, danger signs to look out for and contact their physicians, and a list of resources for specific issues. The patient navigator will spend approximately 20 minutes with participants after enrollment, in the hospital. Following discharge, the patient navigator will contact each patient between 4 and 20 times, by phone and/or text with a research phone, to address questions and link participants to medical and community resources (see patient navigator communication schedule).

To assess understanding, participants will also be asked a short set of true-false questions about the session material and to summarize its objectives after the in-hospital education session (see assessment of understanding document). Participants will receive a text and email reminding them to review the booklet. Participants who have misplaced their booklets will be encouraged to email or call research staff and new booklets will be sent to them or shared electronically through text or MyPennMedicine. At the one-month survey, participants will be asked a set of questions about their use of the booklet, how helpful it was, review specific content areas and ask whether certain sections were more helpful than others, and how many times they reviewed the booklet.

For the purposes of training the patient navigator, and to ensure the consistency of the intervention over time for each patient randomized to the intervention, we will use detailed scripts and training sessions (including face-to-face didactics by the PI, interactive role-play, and supervised patient contact). These will be led mainly by the project manager and will continue for the first full month of recruitment.

Control Arm

The control arm will consist of usual postpartum care. Usual care participants will receive the hospital's standard postpartum education and discharge materials that include nurse discussions and written materials on breastfeeding, infant care, wound care, and other routine peripartum care issues.

Patients in both arms of the study will complete the surveys as described above in section 3.3.

3.5 Study Endpoints

3.5.1 Primary Study Endpoint

The primary endpoint will be number of ED visits and re-hospitalizations in the 30-day post discharge period.

3.5.2 Secondary Study Endpoints

- Assessment of ability to obtain needed services at 30-days post discharge, including patient access to providers when they needed them.
- Depressive Symptoms

4 Study Population and Duration of Participation

4.1 Duration of Study Participation

Each subject's participation in the study will be for approximately 6 months.

4.2 Total Number of Subjects and Sites

214 subjects will be enrolled in the study.

4.3 Inclusion Criteria

- Postpartum patients who have delivered a baby at the Hospital of University of Pennsylvania
- Ages 18 or older
- Self-identify as Black (listed on chart)
- Speak English
- Able to read
- Other characteristics defined by our risk prediction model (algorithm)
- PI discretion for enrollment safety

4.4 Exclusion Criteria

- Unable to provide informed consent
- Speaks a language other than English

4.5 Subject Recruitment

For the pilot RCT, patients will be approached during their postpartum hospital stay. Potential patients will be identified using the Hospital of the University of Pennsylvania EPIC system. . Research staff will have access to the schedules of all patients who become pregnant. The data analytic centers as well as electronic medical records (EMR) recruitment tools such as SlicerDicer, patient reports, and best practice announcements (BPA), may be utilized to provide a list of potential subjects based on clinical practice information. Patients will be approached for recruitment (either in-person, via direct messaging through the electronic medical record platform (MPM), phone, text, or email). The subset of covariates identified by predictive modeling as the most predictive of ED visit/readmission will be used to create a screening checklist to enroll patients into the study. We will use coefficients from the logistic model equation for the predictors determined to be the best fit across models. We programmed coefficients into a free online custom calculator (https://app.calconic.com/public/calculator/6591cebbe36573001e25f34f?layouts=true) which is fast and convenient for the research coordinator. Patient responses to the checklist will be input into the equation to determine a risk score and categorized as eligible based on previously determined risk threshold. We will take the subset of neighborhood attributes which were in the final predictive model and calculate average values for each census tract. Census tracts in the riskiest quartile of each predictive attribute will be flagged as “high risk”, and living in one of those census tracts will be an eligibility item on the checklist.

Once identified as eligible, the patient navigator/coordinator will introduce the study to the patient and assess interest in participating and will give out IRB-approved information postcards. If the patient meets all initial criteria for inclusion and is willing to participate in the study, a more detailed discussion will occur. All questions will be answered, and appropriate informed consent will be obtained from the patient. Patients interested in the study and who meet eligibility criteria will be given consent forms for them to read. Information provided at the time of informed consent will clearly state that participation is voluntary, the person can withdraw from the study at any time, the fact that the project will protect the confidentiality of patient information, and who to contact for questions regarding the research. The study team member will obtain consent electronically and will co-sign the consent form on REDCap using a study specific iPad., and a copy of the consent form will be emailed to the subject. IRB approval for the informed consent and waiver of authorization will be obtained before recruitment.

4.6 Vulnerable Populations:

Children, pregnant women, fetuses, neonates, or prisoners are not included in this research study.

5 Study Procedures

5.1 Screening

Informed consent will be obtained from subjects as noted in section 4.5. The Baseline Visit will be conducted after the participant is consented and has delivered.

5.2 Study Intervention Phase

5.2.1 Baseline Visit

After informed consent is obtained, the 10 minute survey will be administered via REDCap to participants using computerized survey instruments on an iPad in the hospital during the postpartum visit, which ask about social support domains, experiences of racism, health factors such as sleep and physical well-being as well as the PHQ-9. If needed the surveys can be completed with hardcopies or via entry by a study team member.

Once the surveys are completed participants will be randomized to the intervention or control arm of the trial. For subjects randomized to the control arm, the visit will then end.

For subjects randomized to the intervention, the patient navigator will introduce the intervention, and review the patient education pamphlet and partner sheet with the participant and her partner. The patient navigator will spend approximately 20 minutes with the participants. The patient will then be given the assessment of understanding the materials (True/False questions).

Following this introductory meeting, the patient navigator will be in contact with the subject for the remainder of the study. This contact will last up until the 3rd study visit (as described below). The subject may be contacted anywhere from about 4 to 20 times, depending on the patient's needs during the postpartum time (see attached patient navigator message schedule).

5.2.2 Visit 2

Visit 2 occurs around the one-month postpartum mark, and patients will be contacted over the phone, text, patient portal, or by email. The visit window for Visit 2 is 3 to 6 weeks post discharge. This window allows our team to capture as many patients as possible. The patients will be asked to complete a survey like the one administered at the Baseline Visit (with the addition of some postpartum-specific related questions). All surveys will be sent via REDCap as an email, patient portal message, or text, whichever the patient prefers. These surveys can be completed over the phone with a study team member, if needed.

Data from the EMR will be collected from this time period between the Baseline Visit and Visit 2 to ascertain whether participants have an ED visit or are readmitted within 30 days post discharge. We will also abstract from the EMR data on past medical illness, comorbidities, medications, complications during pregnancy, delivery, and the postpartum hospital stay.

5.2.3 Visit 3

Visit 3 occurs around the six-month postpartum mark. The visit window for this visit is 5 to 8 months post discharge to maximize participation. Patients will be sent the Visit 3 surveys via email, patient portal, or text, whichever the patient prefers. If a patient does not complete the surveys electronically, study team members may reach out to the participant over the phone to complete the survey. The same survey instruments will be administered as in the previous two time points via REDCap.

5.3 Subject Withdrawal

Subjects may withdraw from the study at any time without impact to their care. It will be documented whether each subject completes the study.

6 Statistical Plan

6.1 Sample Size and Power Determination

We base the sample size of our pilot RCT by first calculating the needed sample size for a definitive RCT with the primary outcome of ED Visit/Readmission, then following Cocks et al calculate our pilot sample size as 9% of the sample size needed for the main trial.[149] To detect a decrease in ED

Visits/Readmissions from 12% to 7% at 90% power, we will need a sample size of n=721 per arm. We therefore calculated the sample sized needed for the pilot RCT as n=65 per arm. However, we sought to additionally power the study to detect the intermediate outcome “able to obtain needed services”, as one of the main pathways to ED visits. We estimate that 82% in the treatment group and 65% in the control group will be able to obtain services, indicating a sample size of 90 per arm is needed. We assume an attrition rate of 16% (based on our previous intervention), increasing the needed recruitment sample size to 107 participants per arm. Based on our prior research,[96] our limited sample size will allow us to the precision as detailed in this table for feasibility, acceptability, and intermediate outcomes.

Sample Size Calculations			
Primary & Intermediate Outcomes	Control %	Treatment %	Power (alpha=0.05)
	n=90	n=90	
30-day Readmission/ED Visit	21%	6%	81%
Felt unprepared for postpartum experience	26%	10%	80%
Able to obtain needed services	65%	82%	80%

6.2 Statistical Methods

The aim of this phase of the study is to conduct a pilot randomized controlled trial and evaluate those results to inform a definitive RCT. The primary outcome will be the prevention of postpartum ED visits and readmissions within 30 days following discharge for delivery. Our primary analysis will focus on a categorical outcome: postpartum ED visit or readmission within 30 days after discharge. A chi square test will be used to determine the difference in the proportion of patients who experience ED visits or readmissions between the two study groups. Poisson regression will be used to estimate and compare the ED and readmission rates between the two groups. We will conduct exploratory analyses to determine if the intervention was successful for patients with the most common conditions predicting readmission, e.g. hypertension. We will also conduct exploratory analyses to assess the impact of the intervention at six-months. Since the intent of this analysis is to obtain estimates of the effect sizes, we will not use a correction to account for the multiplicity of the tests. All analyses will be conducted according to an intention-to-treat principle. All statistical tests will be two-sided at of 0.05 significance level.

6.2.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive statistics (including mean and standard deviation for continuous variables such as age and standard percentages for categorical variables such as gender). To determine comparability of the two groups at randomization, we will compare baseline characteristics between the two trial arms, using the t test for continuous variables and the chi square or Fisher’s exact test as appropriate for dichotomous/categorical variables. We will also examine differences in dropout rates between the two arms.

6.2.2 Analysis of Primary Outcome of Interest

Our primary analysis will focus on a categorical outcome: postpartum ED visit or readmission within 30 days after discharge. A chi square test will be used to determine the difference in the proportion of patients who experience ED visits or readmissions between the two study groups. Poisson regression will be used to estimate and compare the ED and readmission rates between the two groups.

7 Safety and Adverse Events

We have developed a referral plan for all women (in both trial arms) with severe depressive symptoms as defined by an EPDS score ≥13 or a PHQ-9 score ≥20. For all patients who meet these criteria, we will follow the safety protocol that was used for our previous intervention studies. All patients at HUP receive an EPDS prior to discharge so this safety pathway and assurance of evaluation is already set up and in place for postpartum patients, even outside of this study. All patients will be given the phone numbers, for the psychiatric clinic, and community sites that provide mental health services. The patient navigator conducting the intervention will be trained by Drs. Howell and Levine on the safety protocol and will be monitored by the program manager. Staff will automatically get notified by email if a participant score is ≥11 or the patient endorses suicidal ideation on the EPDS. Within 24 hours of the research team receiving the alert, at least 2 initial contacts will be attempted (by phone and email). The research staff will provide the patient with any resources they have not yet received/they request and staff will offer to facilitate a conversation with their provider. Concurrently, study staff will send a message through PennChart (electronic medical record) to the patients' provider or social work team documenting the steps taken thus far. Staff will ask the clinician to follow up with the patient as necessary. The PI and all study team members will be cc'ed on every message to the clinical team. This is a survey based minimal risk study, so not all events that would traditionally be defined as AEs will be collected for this trial.

7.1.1 Data and Safety Monitoring Plan

Our proposed pilot RCT poses minimal risk to enrollees. The project leader, Co-investigator, and program manager will monitor the scientific integrity and patient safety for the full duration of this study. The project leader (Dr. Howell), the study program manager, patient navigator, coordinator, and Co-Investigator (Dr. Levine (Maternal-Fetal Medicine Specialist) will meet bi-weekly to discuss trial accrual, intervention progress, study patient safety, and adverse events. The referral to appropriate care for subjects who have severe depressive symptoms will be monitored at this meeting. In addition, we will systematically collect, evaluate, and report all adverse events (including suicidal ideation and or suicidal intent) to the University of Pennsylvania Institutional Review Board via HRP-224 form, Reportable New Information. This form reports the description of the incident, the description of action steps the investigator has put in place to handle this incident and to prevent such occurrence in the future and if there is no action steps were required, we will explain the reasons (i.e. no action steps required, safety protocol followed). We will check "written reports of study monitors, internal audit reports, data safety monitoring reports, etc." and submit the form in real time as the University of Pennsylvania IRB currently requires the reporting of this information within five business days. A PICA form will be submitted annually at the time of Continuing Review to ensure quality assurance.

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8 Study Administration, Data Handling and Record Keeping

8.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

8.2 Data Collection and Management

Data will be collected prospectively by designated research personnel. Original source documents will be kept in the study subject folder. Well-designed data collection forms will be developed to minimize data collection and recording errors. Administrative forms, such as visit procedure checklists, will be designed to assist the research staff in complying with protocol procedures. Data will be collected solely for the purpose of research, and these will not become part of the participant's medical record.

Study data will be managed using REDCap (Research Electronic Data Capture), a secure web application designed to support data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation, audit trails, and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). Database access for REDCap is granted on a study-by-study basis. At the start of the trial when the database is created, all research personnel will be given defined user roles and assigned a unique username and password. There is a 90-day password update policy for all REDCap users. The REDCap database sits behind an application firewall and the data are stored on a virtual machine at the University of Pennsylvania that is backed up daily.

Subjects will be assigned a study ID number. Any PHI data will be collected and recorded into password-protected files. Furthermore, a separate spreadsheet containing the link that identifies the patient by their study ID number will be kept securely in a password-protected computer file. Only study personnel who will need access to the identifying data - either to schedule the follow-up research visits or to collect pregnancy outcomes from the medical record, will have access to the link. Identifiable data will not be shared with any other study personnel or included on any data shared with other investigators or future collaborators.

8.3 Records Retention

Research data will be collected by research staff and stored in study-specific files kept in a locked area in one of the research locations during the active phase of the study. Any electronic data will be kept in a secured database on REDCap. Only the PI and study staff listed will have access to these data. There should not be a need to transmit data files containing personal health information for this study. At the conclusion of the study, data will be retained on site in the same secured manner for a minimum of two years and may be transferred to a long-term storage facility (Iron Mountain) thereafter.

To comply with Good Clinical Practice (GCP) requirements, investigators must maintain the master log that identifies all patients entered into the study for a period of two years after the study ends so that the subjects can be identified by audit. The PI must maintain adequate records pertaining to subjects' files and other source data for a minimum of 5 years after completion of the study.

9 Study Monitoring, Auditing, and Inspecting

9.1 Study Monitoring Plan

The study PI will be responsible for ensuring the ongoing quality and integrity of the research study.

10 Ethical Considerations

No study procedures will take place until the protocol and consent form have been approved by the Penn IRB.

10.1 Risks

Participation in this study should not subject patient to any new risks beyond those inherent in having a baby including pregnancy complications, or chronic illnesses (i.e. hypertension and diabetes). The intervention elements are educational, and we do not anticipate any significant physical, psychological, or

social risk to the patients in the intervention arm. Patients could face risks from breach of confidentiality in data collection and analyses procedures. We are instituting rigorous data confidentiality and privacy protections to minimize the chance that this will occur. Please see Procedures to minimize RCT risk below, #1-6.

Procedures to Minimize Risk
We will be conducting the pilot RCT among Black patients. We plan to enroll 214 Black patients. All patients will be consented for medical chart review. All data at the Hospital of the University of Pennsylvania (HUP) are stored on secure password protected HIPAA compliant server systems.

To protect patients' confidentiality, we will observe the standard institutional and departmental operating procedures to secure PHI, including the following:
1) All staff with access to project data must obtain HIPAA training certification and completion of all University of Pennsylvania IRB (Program for the Protection of Human Subjects (PPHS)) CITI Research Education Requirements.
2) Study data will be entered and stored in REDCap database. REDCap is a secure web platform for building and managing online databases and surveys. The REDCap server to be used to capture survey data for this project resides on a separate DMZ network in the hospital data center. Data at rest is stored on fully AEA-encrypted disks and all network interactions are over TLS-encryption sessions that require logins.
3) Sensitive hardcopies of consents will be processed in a centralized location with controlled physical access, and it will be secured in locked file cabinets when not in use. All research information containing patient identifiers will be kept in locked files in research offices.
4) Patients will be assigned a unique, numeric identifier and the link for this identifier will be stored on a password protected encrypted computer drive. Patients will be identified by a study ID in REDCap. During a trial the site study coordinator will maintain a separate list of participating patients, their contact information, and their study identifiers in a secure location. This list will be used by study coordinators to maintain patient contact for follow-up This separate list containing patient contact information will be destroyed at the end of the trial as part of the closeout procedure.
5) The research team will remove names, addresses and other direct identifiers from hardcopy and computer readable data after they are no longer necessary for patient tracking and then using encrypted notes for subsequent identification of patients.
6) Destroy all identifiable linkages to data after data accuracy has been verified and final analyses have been completed.

Questionnaires

Some questions may make a subject feel embarrassed or uncomfortable while answering. They do not have to answer any questions which make them uneasy (missed answers or surveys will not be considered protocol deviations).

Safety standard of procedures for EPDS The clinical team will handle any concerns with EPDS results at the first visit (postpartum stay) due to the survey being routinely collected as part of standard of care. The study team will implement a specific safety protocol for Visit 2 and 3 EPDS results. Staff will automatically get notified by email if a participant score is >11 or the patient endorses suicidal ideation on the EPDS. Within 24 hours of the research team receiving the alert, at least 2 initial contacts will be attempted (by phone and email). The research staff will provide the patient with any resources they have not yet received/they request, and staff will offer to facilitate a conversation with their provider. Concurrently, study staff will send a message through PennChart (electronic medical record) to the patients' provider or social work team documenting the steps taken thus far. Staff will ask the clinician to follow up with the patient as necessary. The PI and all study team members will be cc'ed on every message to the clinical team.

10.2 Benefits

Potential Benefits of the Proposed Research to Research Participants and Others: Our survey tools will be equipped to monitor certain behaviors or combinations of behaviors that will identify women with

postpartum depressive symptoms, specifically patients with severe depressive symptoms and chronic illnesses (i.e. hypertension and diabetes). Patients may benefit by receiving additional follow up from the research team and in addition, opportunities to receive the intervention may translate into improved quality of postpartum care, management of chronic conditions and or other relevant clinical outcomes (reduce ED/readmission utilization rates and increase in continuity of care) Without this trial, those needs may have gone untreated or untreated longer than necessary.

Importance of the Knowledge to be Gained: The knowledge acquired from this project may offer guidance on how to improve care for postpartum women, reduce ED utilization, and reduce postpartum hospital readmissions that can be sustained beyond the grant-funded cycle. These potential benefits far outweigh the minimal risks of the study.

10.3 Risk Benefit Assessment

This study confers no more than minimal risk to the study subjects. While the subjects themselves have no real potential for direct benefit from participating in the study, there is a possibility that this research will be useful in advancing pregnancy and postpartum care which would be beneficial to society. Identifying the information obtained from this study is critical for the overall health of this study population. Therefore, the potential benefits for this study outweigh any of the risks stated above.

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10.4 Informed Consent Process / HIPAA Authorization

Potential participants will be approached to participate by the research coordinator or non-care providing physician through the EMR patient portal, email, telephone, or in person. Informed consent may be completed in person, by telephone call or via telehealth. At this time, study details will be explained. Risks and benefits will be thoroughly discussed, and the IRB-approved consent given to the patient to review. The study team will obtain the participant's consent prior to any study procedures being performed. During the consenting process, study staff will discuss alternatives to participation, and privacy and confidentiality. Participants will be informed that their participation in the study is voluntary, and that they may change their mind at any time if they wish to discontinue. In addition, the consent form will be written in simple English that will ensure adequate understanding by the subject. Subjects will be provided ample time to review the consent form and ask questions. The participant should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. We have included the elements of HIPAA authorization within the consent form and will be using a combined informed consent and HIPAA authorization form. Both the subject and the study personnel who is obtaining the consent will sign the consent form and the subject will be provided with a copy.

11 Study Finances

11.1 Funding Source

This study is supported by an R01 grant from the NIMHD/NIH

11.2 Conflict of Interest

All University of Pennsylvania Investigators will follow the University of Pennsylvania Policy on Conflicts of Interest Related to Research.

11.3 Subject Stipends or Payments

Subjects will be given up to $125

- $40 to compensate for patient time and effort for initial participation and completion of baseline surveys.
- $45 compensation will be given after completing the second visit.
- $40 will be given after completing the final visit.
  Subject compensation will be distributed via Greenphire ClinCard at University of Pennsylvania.

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