Study Title: Randomized Evaluation of hypertensive Moms: Interventional Nudge to Drive transitions of care

NCT number: NCT04660032

Protocol Date: 7/21/2021

Modification

Basic Info

Confirmation Number:	**decfejje**
Protocol Number:	**844269**
Created By:	**TRIEBWASSER, JOURDAN E**
Principal Investigator:	**TRIEBWASSER, JOURDAN E**
Protocol Title:	**Randomized Evaluation of hypertensive Moms: Interventional Nudge to Drive transitions of care**
Short Title:	**REMIND Trial**
Protocol Description:	**Hypertensive disorders of pregnancy are stress tests which identify women at high risk of future cardiovascular disease, However, most women do not receive adequate counseling nor do they seek preventative care in the months following delivery. We will perform a randomized, controlled trial of electronic prompts to obstetric care providers to initiate transitions of care to continuity care providers. This will be a hospital-wide initiative using a pre-existing postpartum monitoring system.**
Submission Type:	**Biomedical Research**
Application Type:	**FULL**

PennERA Protocol Status

Approved (No CR)

Resubmission*
No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Closed to subject enrollment (remains active)

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

0

Actual enrollment at participating centers

0

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

222

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
Adding study staff. Clarice Zhou's CITI training certificates are attached to protocol resubmission.

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
No

If YES, please choose from the options below regarding re-consenting

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site? Yes

Active Hospital Sites

Pennsylvania Hospital (PAH) ***Primary***

Study Personnel

Principal Investigator

Name:	**TRIEBWASSER, JOURDAN E**
Dept / School / Div:	**4333 - OB-Obstetrics and Gynecology**
Campus Address Mail Code	
Address:	
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HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

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HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**WALHEIM, LAUREN**
Dept / School / Div:	**2100 - Health System**
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Phone:	
Fax:	
Pager:	
Email:	**Lauren.Walheim@Pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Responsible Org (Department/School/Division):

4333 - OB-Obstetrics and Gynecology

Key Study Personnel

Name:	**ZHOU, CLARICE**
Department/School/Division:	**Health System**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**RIIS, VALERIE**
Department/School/Division:	**WM-Ctr for Res on Reprod and Women's Health**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**MORLEY, ANDREA M**
Department/School/Division:	**WM-Ctr for Res on Reprod and Women's Health**

HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**
Name:	**SEHDEV, HARISH M**
Department/School/Division:	**OB-Obstetrics and Gynecology**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**? No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Clinical Trial*
Is this a clinical trial?
Yes

If Yes, please be aware that for each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

Investigator Initiated Trial*
Is this an investigator initiated trial?
No

Drugs or Devices*
Does this research study involve Drugs or Devices?
No

IND Exemption

For studies that fall under an IND exemption, please provide the number below

For studies including IND or IDE's, please provide the number(s) below

IDE Review*
NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory. Consult the Penn Manual for Clinical Research: https://www.med.upenn.edu/pennmanual/secure/investigational-product-management-at-sites-not-usinginvestigational-drug-services-(ids).html Please check the box Yes if you have reviewed the guidance.
No

Research Device Management*
Please indicate how research device(s) will be managed.
Not Applicable (no investigational devices)

Drug, Herbal Product or Other Chemical Element Management *
Please indicate how drugs, herbal products or other chemical entities will be managed. Not Applicable (no drugs, herbal products or other chemical entities)

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Gene Transfer*
Does this research involve gene transfer (including all vectors) to human subjects?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Investigational Agent or Device within the Operating Room*
Does the research project involve the use of an investigational agent or device within the Operating Room?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Processing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

In-House Manufacturing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes? Yes

If the answer is YES, indicate which items is is provided with this submission:

Request for HIPAA Waiver of Authorization

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Clinical Trial (prospectively assigning subjects to health-related interventions to evaluate outcomes)

Protocol Interventions

Sociobehavioral (i.e. cognitive or behavioral therapy)	
Drug	
Device - therapeutic	
Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)	
Surgical	
Diagnostic test/procedure (research-related diagnostic test or procedure)	
Obtaining human tissue for basic research or biospecimen bank	x
Survey instrument	
None of the above	

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**HELFRICK, MEGAN**
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Department budget code

400 - 400 - 2 - 014001 - xxxx - 2813 - 0940

Funding Sponsors

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.
N/A

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND Sponsor

none

400 - 400 - 2 - 014001 - xxxx - 2813 - 0940

Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
No

Sponsor Funding
Is this study funded by an industry sponsor?

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Multi-Center Research

Penn as lead

1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?

No

Management of Information for Multi-Center Research

Penn irb of record

2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?

No

Other Sites

No other sites

Protocol

Abstract

Hypertensive disorders of pregnancy (HDP) are stress tests which may identify women at high risk of future cardiovascular disease (CVD), the leading cause of death among women. Given the public health impact of HDP and CVD, there is a compelling need to identify scalable interventions to improve preventative care among women who have risk identified during pregnancy. We will examine the effects of delivering electronic prompts to obstetric care providers (nudge) on transitions of care in the postpartum period. We will conduct a pilot randomized trial to evaluate whether this nudge intervention will improve postpartum counseling and lead to greater follow-up with preventative care providers among women with HDP. ***Objectives***

Overall objectives

The objective of the study is to evaluate the effect of a hospital-wide initiative using electronic prompts to encourage physicians to transition care for women with HDP to continuity care providers in accordance with national society guidelines.

Primary outcome variable(s)

The primary outcome measure is documentation of counseling about transitioning care to a continuity care provider (primary care or cardiology) at the postpartum visit.

Secondary outcome variable(s)

Secondary outcomes include 1. Electronic prompts opened by obstetric care providers within 1 week of receipt. 2. Documentation of CVD risk at the postpartum visit. 3. Use of scripted dot phrases (available in Epic) for counseling on transitions of care and CVD risk in the postpartum note. 4. Attendance at a primary care or cardiology visit for preventative care within 6 months of delivery.

Background

Women with HDP need ongoing care in the postpartum and inter-pregnancy period. HDP, including PEC and gestational hypertension (GHTN), complicate up to 10% of all pregnancies and are associated with immediate and long-term cardiovascular morbidity and mortality.1 HDP increase lifelong risk for chronic hypertension, diabetes, ischemic heart disease, stroke, and heart failure.2-5 Black women have a higher incidence of HDP and have a disproportionately higher morbidity and mortality compared to non-black women.6,7 ACOG and the American Heart Association (AHA) emphasize the postpartum period as an important opportunity to identify and intervene upon women at high-risk for future cardiovascular disease (CVD).8,9 However, current postpartum practices inadequately address transitions of care for women with

HDP. A significant proportion of women with HDP do not see a preventative care provider (primary care, cardiology) in the months after delivery.10-12 Black women are particularly vulnerable to being lost to follow-up after complicated pregnancy.10,11 The HSM program is an innovative, patient-centered program that monitors postpartum blood pressure remotely using a text-based interface. It is supported by the Way to Health platform. HSM improves blood pressure management in the two weeks after delivery and eliminates racial disparities in blood pressure ascertainment during that time.13,14 However, enrollment in HSM did not improve follow-up in the year after delivery, with less than 1/3 of women having a preventative care visit.15 Poor follow-up is likely multifactorial, but may be driven by inadequate patient counseling in the postpartum period. Among women enrolled in HSM, only 21% of women were counseled on follow-up with primary care and only 4% were counseled on CVD risk at their postpartum visits based on chart review.16 Nudges are effective for changing medical decision-making and improving clinical outcomes. Nudges utilize concepts from behavioral economics to subtly change the decision-making environment to facilitate evidence-based care and can be delivered to patients, providers, or both.17 Examples of nudges include electronic prompts to order cancer screening and electronic defaults that guide ordering practices.18 Nudges are low cost, scalable using Electronic Medical Record (EMR) systems, and improve rates of preventative services including influenza vaccination, referral to mammography, and statin prescription for CVD prevention.19-22 References: 1. American College of Obstetricians and Gynecologists; Task Force on Hypertension in Pregnancy. Executive summary: hypertension in pregnancy. Obstet Gynecol 2013;122:1122-31. 2. Timpka S, Stuart JJ, Tanz LJ, Rimm EB, Franks PW, Rich-Edwards JW. Lifestyle in progression from hypertensive disorders of pregnancy to chronic hypertension in Nurses Health Study II: observational cohort study. BMJ 2017 Jul 12;358:j3024. 3. Cirillo PM, Cohn BA. Pregnancy complications and cardiovascular disease death: 50-year follow-up of the Child Health and Development Studies Pregnancy Cohort. Circulation 2015;132:123442. 4. Theilen LH, Fraser A, Hollingshaus MS, Shliep KC, et al. All-cause and cause specific mortality after hypertensive disease of pregnancy. Obstet Gynecol 2016;128:238-44. 5. Wu P, Haththotuwa R, Kwok CS, et al. Preeclampsia and future cardiovascular health: a systematic review and meta-analysis. Circ Cardiovasc Qual Outcomes 2017;10:e003497. 6. Gyamfi-Bannerman C, Pandita A, Miller EC, Boehme AK, Wright JD, Siddiq Z, et al. Preeclampsia outcomes at delivery and race. J Matern Fetal Neonatal Med 2019:18. 7. Miranda ML, Swamy GK, Edwards S, Maxson P, Gelfand A, James S. Disparities in maternal hypertension and pregnancy outcomes: evidence from North Carolina, 1994-2003. Public Health Rep 2010;125:57987 8. American College of Obstetricians and Gyenecologists. Optimizing postpartum care. ACOG Committee Opinion No. 736. Obstet Gynecol 2018;131:e140-50. 9. Brown HL, Warner JJ, Gianos E, et al. Promoting risk identification and reduction of cardiovascular disease in women through collaboration with obstetricians and gynecologists: a presidential advisory from the American Heart Association and the American College of Obstetricians and Gynecologists. Circulation 2018;137:e843-52. 10. Bennett WL, Chang H-Y, Levine DM, Wang L, Neale D, Werner EF, et al. Utilization of primary and obstetric care after medically complicated pregnancies: an analysis of medical claims data. J Gen Intern Med 2014;29:63645. 11. Levine LD, Nkonde-Price C, Limaye M, Srinivas SK. Factors associated with postpartum follow-up and persistent hypertension among women with severe preeclampsia. J Perinatol 2016;36:1079. 12. Lewey J, Levine L, Yang L, Groeneveld P. Abstract 21105: The Impact of Gestational Hypertension and Preeclampsia on Postpartum Rates of Follow-Up With Continuity Providers. Circulation 2017. 13. Hirshberg A, Downes K, Srinivas S. Comparing standard office-based follow-up with text-based remote monitoring in the management of postpartum hypertension: a randomised clinical trial. BMJ Qual Saf 2018;27:8717. 14. Hirshberg A, Sammel MD, Srinivas SK. Text message remote monitoring reduced racial disparities in postpartum blood pressure ascertainment. Am J Obstet Gynecol 2019;221:2835. 15. Triebwasser JE, Srinivas SK. 1077: Effect of a text-based blood pressure monitoring program on continuity care after hypertensive pregnancy. Am J Obstet Gynecol 2020;222:S664-5. 16. Janssen MK, Sehdev HM, Triebwasser JE. 779: Measuring quality: counseling after hypertensive disorders of pregnancy. Am J Obstet Gynecol 2020;222:S494. 17. Patel MS. Nudges for influenza vaccination. Nat Hum Behav 2018;2:720-1. 18. Patel MS, Navathe AS, Liao JM. Using Nudges to Improve Value by Increasing Imaging-Based Cancer
Screening. J Am Coll Radiol 2020;17:3841. 19. Patel MS, Volpp KG, Small DS, Wynne C, Zhu J, Yang L, et al. Using active choice within the electronic health record to increase influenza vaccination rates. J Gen Intern Med 2017:32;790-5 20. Yokum D, Lauffenburger JC, Ghazinouri R, Choudhry NK. Letters designed with behavioural science increase influenza vaccination in Medicare beneficiaries. Nat Hum Behav. 2018 Oct;2(10) 743-749. doi:10.1038/s41562-018-0432-2. PMID: 31406294. 21. Hsiang EY,
Mehta SJ, Small DS, Rareshide CAL, Snider CK, Day SC, et al. Association of an Active Choice Intervention in the Electronic Health Record Directed to Medical Assistants With Clinician Ordering and

Patient Completion of Breast and Colorectal Cancer Screening Tests. JAMA Netw Open 2019;2:e1915619.
22. Patel MS, Kurtzman GW, Kannan S, Small DS, Morris A, Honeywell S Jr, et al. Effect of an Automated Patient Dashboard Using Active Choice and Peer Comparison Performance Feedback to Physicians on Statin Prescribing: The PRESCRIBE Cluster Randomized Clinical Trial. JAMA Netw Open 2018;1:e180818.

Study Design

Phase*
Not applicable

Design
This study will be a randomized, controlled superiority trial to evaluate a hospital-wide initiative to improve counseling for postpartum women who experienced HDP during their pregnancy or in the immediate postpartum period. Hypotheses: 1. We hypothesize that the prompt will increase the proportion of women counseled on transitioning care to a primary care provider or cardiologist after pregnancy (primary outcome). 2. We hypothesize that the provider nudge will increase the proportion of women attending a preventative care visit within 6 months of delivery as assessed by chart review and patient surveys. The HSM daily log generated through the Way to Health platform will be used to generate lists of patients who eligible for the study. For each eligible woman, the date of and obstetric care provider for her postpartum visit will be recorded within 3 weeks of delivery. Patients will then be randomly assigned to a control group with no intervention (usual care through HSM) or the intervention group (physician nudge) using simple 1:1 randomization through the Way to Health Platform. If a woman is randomized to the intervention arm, her obstetric care provider for her postpartum visit will receive a staff message in Epic (Penn Chart) that his/her patient has an upcoming postpartum visit. The message will be sent 1 week before the scheduled visit. The message will have patient-specific information including hypertensive diagnosis, blood pressure medication(s), gestational diabetes diagnosis, and primary care provider as listed in the Epic banner. The message will also have dot phrases for recommended counseling and contact information for UPHS primary care and cardiology providers. There will be a dot phrase recommending follow-up with primary care or cardiology; counseling on risk of future CVD; and recommending aspirin in a future pregnancy. A web-based survey will be distributed to all women in the study 6 months after delivery through the Way to Health platform. The survey will assess attendance at a preventative care visit, social determinants of health, health status, and insurance status after delivery. Demographic characteristics, medical and obstetric history, hypertensive disorder, laboratory test results (platelet count, creatinine, liver function tests, urine protein, total cholesterol, triglycerides, LDL-C, HDL-C, glucose, hemoglobin A1c), blood pressure measurements, height, weight, and office visits within 6 months of delivery will be abstracted from the EMR. We will perform detailed abstraction of counseling at the postpartum visit and additional office visits within 6 months of delivery focusing on 1) health maintenance 2) hypertension, or 3) cardiovascular risk reduction. Two reviewers will assess counseling at each visit. We will obtain data on obstetric care providers including level (resident physician, attending physician, nurse practitioner, physician assistant, or certified nurse midwife), gender, and years in practice from publicly available databases or websites online.

Study duration
Estimated length of time is 12 months. We believe it will take no more than 4 months to enroll all patients with follow-up survey at 6 months, and allow two months for data analysis. This is based on number of women clinically enrolled over the 1st year of Heart Safe Motherhood at Pennsylvania Hospital. We hope to initiate the proposed study on November 1, 2020.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
The research staff will include Maternal Fetal Medicine attendings, residents in obstetrics & gynecology, and the Maternal and Child Health Research (MCHRC) clinical research team. The MCHRC provides an established infrastructure for clinical and translational research. The Way To Health platform has multiple features to implement this trial and capture data including two-way texting, integrated survey options, integration with the EMR, and automated schedules for patient messages. Patients will be clinically

enrolled into the WaytoHealth Texting Platform per usual clinical care. Data collection will be performed by Drs. Triebwasser and Walheim, and by a study coordinator through the MCHRC. Patient logs for Heart Safe Motherhood (Way to Health) will be reviewed daily. Randomization will take place through Way to Health after ensuring all eligibility criteria is met. Electronic prompts will be sent to obstetric care providers by Dr. Triebwasser or the study coordinator. Survey invitations will be sent through the Heart Safe Moterhood interface in Way to Health. All research staff will receive education regarding the protocol and their duties prior to the start of the study.

Characteristics of the Study Population

Target population
Postpartum women followed by obstetric care providers at the University of Pennsylvania Health System (UPHS) who are diagnosed with HDP and are clinically enrolled in Heart Safe Motherhood (HSM) are eligible.

Subjects enrolled by Penn Researchers 222

Subjects enrolled by Collaborating Researchers
0

Accrual
Sample size calculations were based on the assumption that 21% of patients in usual care and 40% of patients receiving a provider nudge would have documentation about transitioning care. A sample size of 222 patients (randomized 1:1) would provide 80% power to detect this difference assuming 20% of patients will not attend their postpartum visit. Approximately 100 women are enrolled in HSM each month at Pennsylvania Hospital. We anticipate that over 90% of those women receive prenatal care at a UPHS practice (n=90 per month), and at least 80% will attend a postpartum visit (n=72). We thus anticipate that 222 women could be enrolled in 3-4 months, allowing for 6-month follow-up during the grant period.

Key inclusion criteria
1. At least 18 years old. 2. Have a diagnosis of HDP during delivery admission or have a diagnosis made at time of evaluation in the Perinatal Evaluation and Treatment Unit after discharge from the delivery admission. HDP diagnoses are based on criteria from the American College of Obstetricians and Gynecologists (ACOG). 3. Enrolled in HSM at Pennsylvania Hospital. 4. Have a postpartum visit with a UPHS provider scheduled 4-12 weeks after delivery.

Key exclusion criteria
1. Women diagnosed with chronic hypertension (CHTN) without superimposed pre-eclampsia (PEC).

Vulnerable Populations

Children Form

Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form

Fetuses and/or Neonates Form

Prisoners Form

Other x **None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
This is a hospital-wide initiative which will equally include all postpartum women in HSM who do not meet exclusion criteria.

Subject recruitment
The HSM daily log generated through the Way to Health platform will be used to generate lists of patients who eligible for the study. For each eligible woman, the date of and obstetric care provider for her postpartum visit will be recorded within 3 weeks of delivery.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Subjects who complete a web-based survey 6 months postpartum will be compensated with a $5 giftcard.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
A flowsheet of patient participation is attached. Subjects will be identified through the HSM daily log. A waiver of informed consent is requested for the intervention portion of this study. At 30 days after discharge, all participants, regardless of study arm will receive the following message "Hello from Heart Safe Motherhood! We hope you are doing well. Dont forget to follow-up with your primary or heart doctor in the next 2-4 weeks. If you were given an appointment, make sure to keep it. If you want to make an appointment with a heart doctor focused on women's health, call 215-662-7700. Have a great day!" At 6 months postpartum, women will receive a secure text message through the Way To Health platform. "We are trying to understand how women with high blood pressure or preeclampsia stay healthy after delivery. Respond yes if you are willing to complete a survey. You will receive $5 for participating." If she responds yes, she will receive a survey link integrated with Way To Health. Patient information will be obtained from the electronic medical record including demographic characteristics, medical and obstetric history, hypertensive disorder, laboratory test results (platelet count, creatinine, liver function tests, urine protein, total cholesterol, triglycerides, LDL-C, HDL-C, glucose, hemoglobin A1c), blood pressure measurements, height, weight, and office visits within 6 months of delivery. We will perform detailed abstraction of counseling at the postpartum visit and additional office visits within 6 months of delivery focusing on 1) health maintenance 2) hypertension, or 3) cardiovascular risk reduction. Two reviewers will assess counseling at each visit (from the discharge summary and after visit summary). We will obtain data on obstetric care providers including level (resident physician, attending physician, nurse practitioner, physician assistant, or certified nurse midwife), gender, and years in practice from publicly available databases or websites online.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
We hypothesize that a provider nudge will increase the proportion of women who are counseled about 1) transitioning care and 2) CVD risk after pregnancy complicated by HDP. This is designed as a superiority trial. We hypothesize that the provider nudge will lead to improved follow-up with continuity care providers. Primary efficacy endpoint: 1. Documentation of counseling about transitioning care to a continuity care provider (primary care or cardiology) at the postpartum visit. Secondary efficacy endpoints: 1. Documentation of CVD risk at the postpartum visit. 2. Attendance at a primary care or cardiology visit for preventative care within 6 months of delivery. Chi square or Fishers exact test will be used to compare categorical data. T-test will be used to compare parametric data. Mann-Whitney U test will be used to compare non-parametric data. Univariate comparisons will be made between exposure (intervention) and outcome. Proportion and relative risk (95% CI) will be presented for primary and secondary outcomes. Multivariable logistic regression models will be created to control for potential confounders. Outcomes will be analyzed by the intention to treat principle. Our threshold for statistical significance will be two-side with alpha 0.05. Exploratory analyses: Primary and secondary outcomes will be analyzed by race (Black vs. Non-Black) based on data that HSM reduced racial disparities in blood pressure ascertainment outcomes. We will explore whether there is an interaction of race with regards to counseling and follow-up. We will also assess time trends in counseling over the study period.

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**

x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

x **Wherever feasible, identifiers will be removed from study-related information.**

A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

x **A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)**

x **Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.**

Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related

information. Precautions are already in place to ensure the data are secure by using passwords and HIPAA-compliant encryption. Data on patients will be obtained from Epic and patient-completed surveys. Any information that is obtained will be used for research purposes only. Information on patients will only be disclosed within the study team and to the patients obstetric care provider. All study staff will be reminded of the confidential nature of the data collected and contained in these databases. All members that access data must complete HIPAA training including secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. Only trained study staff will have access to the code that links the unique identifier to the subjects identity. Electronic data will be stored on secure, password-protected firewalled servers at the University of Pennsylvania. Data collected for this study will be stored in REDCap and the WayToHealth platform. Linkage to PHI will be stored until study analysis and publication completion, and then will be destroyed.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
All efforts will be made by study staff to ensure subject privacy. Data will be evaluated in a deidentified manner whenever possible.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
No

*Data Protection**

x **Name**

x **Street address, city, county, precinct, zip code, and equivalent geocodes**

x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**

x **Telephone and fax number** x **Electronic mail addresses**

Social security numbers

x **Medical record numbers**

Health plan ID numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers/serial numbers

Web addresses (URLs)

Internet IP addresses

Biometric identifiers, incl. finger and voice prints

Full face photographic images and any comparable images

Any other unique identifying number, characteristic, or code

None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research* Are
Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded* Would
specimens otherwise be discarded?
No

Tissue Specimens - publicly available* Will
tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol* Will
tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use* Does
research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable." Not applicable.

Consent

1. Consent Process

Overview
A waiver of informed consent is requested for the intervention portion of this study. This is a hospitalwide initiative that will be implemented. The study is to evaluate that initiative. Therefore, physicians and their patients will not be consented as this will be the standard practice for women in Heart Safe Motherhood at Pennsylvania Hospital. Without a waiver of the consent, the initiative would still be implemented at Pennsylvania Hospital, but the study would be infeasible. There are several additional reasons why we feel a waiver of consent should be granted. First, it is not feasible to consent every patient and physician. Second, if members of the control group were consented, they would know they were being studied and this could change their behavior. This could potential disrupt the design of the study and making interpretation of the findings challenging. Third, physicians are not being forced to use the information from the prompt or suggested counseling with their patients. Instead, they are being reminded of evidence-based practice and offered an opportunity to review pertinent information prior to the postpartum visit. This is no different than standard of care in which a physician would review the same information and decide on postpartum counseling. The initiative is simply a reminder for the physician and makes their standard of care process easier to conduct.

Children and Adolescents

Children and adolescents will not be enrolled.

Adult Subjects Not Competent to Give Consent
All adult subjects with be competent to give informed consent.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
Yes

If no written statement will be provided, please provide justificiation

The subjects will receive a written statement of research for the web-based survey, but will not receive a statement on research for the intervention as knowledge of the intervention may change behavior and make interpretation of the study difficult.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
The potential risks associated with this study are minimal. Breach of data is a potential risk that will be mitigated by using HIPAA compliant and secure data platforms for patient identification, randomization, and web-based surveys (Way to Health) and data storage (REDCap).

Potential Study Benefits
An intervention that prompts obstetric care providers to actively think about postpartum care guidelines could contribute positively to patient care and outcomes. However, it is possible that patients will receive no benefit from this study.

Alternatives to Participation (optional)
Women will be receive postpartum counseling per the usual practice of their obstetric care provider.

Data and Safety Monitoring
Principal investigator.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
There is minimal risk to participation in this study with potential for improved counseling and transitions of care.

General Attachments

The following documents are currently attached to this item:

Additional forms (citi-clarice.pdf) Additional forms (citi2-clarice.pdf) Additional forms (citi3-clarice.pdf)