COMMUNITY IMPLEMENTATION OF THE SEVERE HYPERTENSION DURING PREGNANCY AND POSTPARTUM SAFETY BUNDLE

PROJECT PLAN

A. Understanding/Need

The United States (US) is the only developed nation with rising rates of maternal morbidity and mortality (3M). These unacceptably high rates of 3M in the US are also wrought with racial and ethnic disparities. From 2014-2017 Non-Hispanic Black (NHB) women delivering in the US had a 3.1-fold increased risk of death compared to their Non-Hispanic White (NHW) counterparts (1). Additionally, the risk of severe maternal morbidity (SMM) among NHB women was 2.1 times higher than NHW women (2). Both the overall rates of 3M and the racial and ethnic disparities in 3M have become a critical public health focus for the US. It is not entirely understood why US 3M rates are rising nor why the stark racial and ethnic disparities exist, but it is likely that increasing rates of comorbidities such as hypertension, diabetes and obesity, as well as structural barriers to care and systemic racism, are major contributors (3,4). A Center for Disease Control and Prevention (CDC) report described that the pregnancy-related mortality (PMR) ratio is higher in rural counties and it increases with increasing rurality. Within each urban-rural category, PMRs were higher among NHB women compared to NHW women. The authors suggested that "geographic location might reflect the intersection of historical structural disadvantage, chronic health conditions, and access to care, including risk appropriate care." (5). There are evidence-based prevention interventions that can improve outcomes, but many have not been implemented at scale (6,7).

Hypertensive disorders of pregnancy, a major contributor to 3M, affect 2-8% of pregnancies globally, with 16% of maternal deaths attributable to hypertensive disorders (8). In the US, the rate of preeclampsia increased by 25% in the last three decades and severe preeclampsia increased 6.7-fold (8). Hypertensive disorders of pregnancy are also related to heart failure and other cardiovascular and cerebrovascular contributors to 3M. Unfortunately, NHB women are more likely to have pre-existing chronic hypertension and to be diagnosed with a hypertensive disorder of pregnancy (9). There are also notable racial differences in onset, presentation, and short- versus long-term complications of hypertensive disorders of pregnancy (10). NHB women diagnosed with hypertensive disorders of pregnancy have an increased risk of intrauterine fetal demise, stroke, pulmonary edema, heart failure and renal failure relative to NHW women, often necessitating iatrogenic preterm delivery (11,12). Compared to NHW women, NHB women are also at a higher risk of in-hospital mortality related to hypertension (11).

Focus on treatment of severe pregnancy-related hypertension was selected by the Alliance for Innovation on Maternal Safety (AIM) for development and implementation of a safety bundle because it is recognized as a leading cause of preventable morbidity and mortality (13). According to the Institute of Healthcare Improvement, patient safety bundles are "a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices…that, when performed collectively and reliably, have been proven to improve patient outcomes" (14). The Severe Hypertension During Pregnancy and Postpartum Safety Bundle (the HTN bundle) intends to improve life-saving care for pregnant women with chronic hypertension, pregnancy-related hypertension and preeclampsia or eclampsia (15). The bundle has largely been implemented in inpatient settings (16,17,18), but barriers and opportunities for implementation in an outpatient, community setting are unknown.

North Carolina (NC) is an ideal setting to study implementation strategies to improve treatment of severe pregnancy-related hypertension with specific attention to health disparities. According to the US Census, NC's population is 63% White, 21% Black or African American, 10% Hispanic or Latino. The 2018 PRAMS survey of women who had given birth in NC found that approximately 14% had experienced high blood pressure during their pregnancy (19). A study of 56,000 NC births had similar findings; 13% of women experienced hypertension while pregnant. Preeclampsia was the most common disorder among these women and was associated with premature delivery (20). A 2017-2018 review of SMM in NC found that non-transfusion related SMM occurred in 68.6 women per 10,000 delivery hospitalizations with a significant racial disparity (rate in NHB women 99.1 per 10,000, NHW women 56.0 per 10,000) (21). Additionally, 37% of NC births are to women living in rural counties, where the rate of SMM exceeds that

of urban counties (22). The NC maternal mortality review committee has recognized hypertension as a major contributor to preventable deaths and recommended identification and treatment of severe preeclampsia as a priority for provider education in NC (23).

Our well-established academic/community partnership is ideally positioned for this work. The NC Department of Public Health and The University of North Carolina's (UNC) Center for Maternal and Infant Health are already collaborating in NC's Maternal Health Innovation Program (24). The program provides a region-based infrastructure to build coalitions to address disparities in maternal health and improve outcomes, inclusive of preventing 3M. The state has six perinatal regions and UNC is situated in Region IV. In a gap analysis carried out by Region IV's Provider Support Network, our community partner, Piedmont Health Services (PHS), noted the need for the HTN bundle in their federally qualified health center (FQHC) settings. While paths for treatment of hypertensive emergency are being addressed in the inpatient settings in Region IV, adaptation and adoption are needed for effective care in the outpatient, community-based context.

PHS is a non-profit, community-governed organization created in 1970 to broadly address barriers to health care access for low-income and other medically vulnerable populations across a multi-county region. PHS operates ten FQHCs located in Alamance, Caswell, Chatham, and Orange counties, serving more than 48,000 individuals of all ages annually with full-scope family medical and dental care, integrated behavioral health care, comprehensive pharmacy, and nutrition counseling. Additional care support services include care management, interpretation, eligibility assistance and outreach. In 2020, PHS served a population comprised of 45% Hispanic/Latino (of any race), 25% White/Caucasian, 21% Black/African American, 4% unreported, 3% Asian, and 2% more than one race. The population was 52% uninsured, 23% Medicaid, 17% privately insured, and 8% Medicare. Nearly all who applied for sliding fee care had documented household incomes below 200% of the federal poverty level, and 38% preferred care in a language other than English. Hypertension control is one of four quality measures of focus for PHS in 2021, so this project is well-timed for the agency. This project also aligns well with a national focus on hypertension control in community health centers.

Researchers from UNC will convene a regional coalition to carry out Community Implementation of the Severe Hypertension During Pregnancy and Postpartum Safety Bundle, or outpatient bundle (the O-HTN bundle). This community-based coalition includes UNC, PHS, and the community coalition Equity for Moms and Babies Realized Across Chatham (EMBRACe), with representation from key state/regional program efforts on an Advisory Group. The coalition will carry out Phase I of this project to identify adaptations needed to the bundle in PHS clinic settings. Importantly, given the need to address social determinants of health, this project will incorporate elements from the Reduction of Peripartum Racial and Ethnic Disparities complementary bundle into the O-HTN bundle as the 5th "R" – Respectful Care.

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C. Technical Approach/Scientific Design

Overview and Goals

This effectiveness-implementation hybrid early phase/pilot study will test the potential effect of implementation strategies in the adaptation, adoption, integration, and implementation of a safety bundle on recognition and treatment of severe hypertension during pregnancy and postpartum (the HTN bundle) (1) into community outpatient settings. The O-HTN bundle, to be adapted from the HTN bundle, will add a crucial new component to be developed in collaboration with our RC partners and is expected to markedly improve heart, lung, blood, and sleep (HLBS) health outcomes for women before and during pregnancy, and postpartum. The study aims to: 1) conduct a community-based needs assessment and effectively engage stakeholders in the study; 2) test the adaptation and integration of the evidence- based inpatient severe hypertension bundle in outpatient/community settings; 3) inform the prioritization and development of related equity-informed implementation strategies; and (4) assess the potential effects of the selected implementation strategies.

Healthcare inequities research and implementation science focus on improving the quality and outcomes of health services and increasing access to treatments and services in communities. Both fields emphasize the importance of contextual factors in contributing to inequities and consider multi-level approaches when addressing the determinants linked to healthcare inequities (2). Patient outcomes will improve when they benefit from evidence-based interventions, such as use of the HTN bundle. However, achieving such outcomes in outpatient, community-based care settings, will require that this evidence-based intervention is effectively adapted, adopted, integrated and implemented in these settings. The field of implementation science can help to address inequities not only by studying the factors and strategies that influence the uptake of this effective intervention, but also by supporting, through systematic approaches, the use, scaling up and, ultimately, the sustainability of evidence-based interventions in community settings. This project is responsive, in both its focus and its proposed methodologies, to an urgent recent call to emphasize health equity in implementation science approaches (3).

The goal of implementation research is to integrate evidence-based medical and public health interventions into practice (4). Provider level, organizational level, and community level implementation strategies are essential for achieving this goal when interventions are being implemented in community settings. Provider level implementation strategies (e.g., training, coaching, and performance feedback) and organizational level implementation strategies (e.g., integration) are needed to ensure the full and effective use of these evidence-based interventions, as well as their sustainability (5). Community level implementation strategies require meaningful engagement and partnership with the community that selects the strategies, co-designs their components, determines their goals, and ultimately uses the strategies to achieve the adoption and implementation of the intervention. While provider and organizational level implementation strategies can be tested in a controlled environment which, in turn, enhances internal validity, testing of community level strategies will require a study approach that takes into account community needs and contexts which, in turn, will enhance external validity (6,7).

As referenced earlier, the HTN bundle is a multifaceted intervention with four major areas of focus:

1) **Readiness** to ensure that clinics have protocols, processes and needed resources in place to diagnose, monitor and treat severe preeclampsia; 2) **Recognition and Prevention** to ensure that clinical staff, women and families have the information they need to recognize early warning signs; 3) **Response** to ensure that clinics apply timely and appropriate treatment with escalation to a higher level of care when needed; and 4) **Reporting/Systems Learning** to establish a culture of improvement. We will use a systematic approach that assures successful adaptation of the content and structure of the HTN bundle to community settings to create the O-HTN, while preserving core components to ensure effectiveness. Moreover, to bring focus to the imperative of acknowledging and addressing inequities in care, we intend to engage stakeholders from our Regional Consortium to create and test **Respectful Care** as the "5th R", drawing heavily on the

"Reduction of Peripartum Racial/Ethnic Disparities" bundle (8). Elements to consider will be determined in the course of our proposed needs assessment and engagement strategies, but might include items such as: 1) staff training in implicit bias related to hypertension; 2) establishing a mechanism for patients, families and staff to report occurrence of inequitable care, miscommunications, or disrespect; 3) elevating the practice of shared decision making; 4) ensuring that patient education materials meet health literacy, language, and cultural needs; and 5) a data dashboard that is stratified by race/ethnicity. In every step of the adaptation process, we intend to use an equity lens to ensure that our methods, approaches, intervention, and implementation strategies incorporate the perspectives of both implementers and those the intervention is designed to benefit and address the determinants of healthcare inequities and implementation barriers.

The **Respectful Care** component of the O-HTN bundle, i.e. the "5th R" that addresses health equity, will be designed by patients and community advocates to ensure that it genuinely captures the community's needs and perspectives. We will leverage an existing mechanism –Charrettes – a tested and highly effective Community-based Participatory Research (CBPR) and community engagement methodology (9,10). Charrettes was launched at UNC and is designed to bring diverse community and academic partners together to strengthen collaborative approaches, build capacity of partnerships, and brainstorm innovative solutions to challenges. Using Charrettes will enable us to engage community-based partners in a meaningful, equity-focused and resource-effective way throughout Phase I.

Elements from the "5th R" identified by the community will be assessed for determining what is appropriate to test in Phase I. We expect that elements which have implications for provider training and clinic operations will be included in the bundle to further adapt it to community needs and test it. Other elements that may require elaborate and complex implementation strategies will be further developed and tested in Phase II. Our main focus in Phase I is to test the performance of the bundle in community settings, as well as the provider- and clinic-based implementation strategies that ensure its successful and sustainable implementation. Additionally, we will include an iterative process to determine the refinements needed to the bundle to optimize its impact. This early phase/pilot study is designed with an eye toward the full-scale study in Phase II and its findings will inform its conduct and improve its quality (11,12).

Theoretical and Conceptual Model

Our approach to conducting the project will be guided by evidence- and community-based methods and grounded in implementation and equity theories.

The Consolidated Framework for Implementation Research (CFIR) (13) provides a comprehensive framework to systematically assess potential barriers and facilitators in implementing the bundle. The CFIR is well suited to be used in a feasibility study as it helps to identify the adjustments and refinements to the bundle from the start. The five domains of the CFIR will be considered as implementation barriers are assessed. These domains, as described by Keith et al. (14) and, as they relate to the study, are:

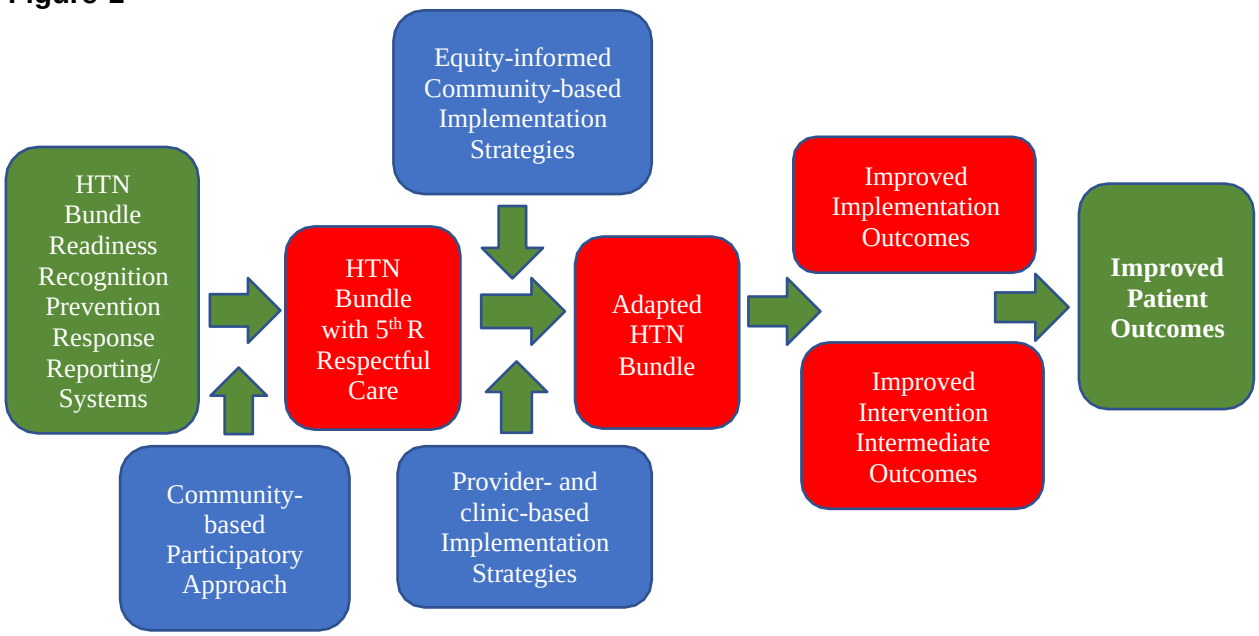
1. The bundle characteristics—features, such as complexity of the bundle, that might influence implementation. For this domain, there are eight constructs to consider, including stakeholders' perceptions about the relative advantage of implementing the bundle;
2. The inner setting—clinical features that might influence implementation. For this domain, there are twelve constructs to consider, including implementation climate and leadership engagement;
3. The outer setting—there are four constructs to consider, including external policy and incentives;
4. Characteristics of individuals involved in implementation--there are five constructs to consider, including knowledge and beliefs about the intervention; and
5. Implementation process—there are eight constructs to be considered, including use and evaluation of the intervention.

Powell et al. have highlighted the lack of systematic approaches for designing implementation strategies, leading to their lack of effectiveness in addressing key contextual determinants (i.e. barriers at the intervention, settings, provider, and community levels) affecting the implementation of the intervention

(15,16). Intensive and systematic approaches, including UNC's Charrette model (details below) will be used to engage key stakeholders at these different levels to select and design implementation strategies that match the contextual implementation determinants to enhance the likelihood that they facilitate the implementation process. In addition to applying the CFIR and collecting data through focus groups and key informant interviews, we will use *Intervention Mapping* (17), an evidence-based framework for program planning, to not only systematically use the data we are collecting to help develop the "5th R", but also to identify the desired behavior change (provider, organizational, and community levels) methods and the relevant implementation strategies to support the change. While fully developing and testing the "5th R" is beyond the scope of Phase I, we will, in this phase, use the Charrette model to select, with our community partners, the components that will be created and assessed. We will further develop and test 5th R components in Phase II.

Figure-1 depicts the multi-pronged approach we will take in conducting this project.

Figure-1



Context— North Carolina (NC) Perinatal Region IV clinics and community partnerships

NC's Perinatal Region IV includes a total of 24 FQHCs, Community Health Centers (CHCs), and county health department clinics across six health systems that provide care for women during and after pregnancy. The Perinatal Region IV Provider Support Network has built connections among providers across the region, and the perinatal clinical champions provide clinical support to disseminate best practices and meet the needs identified by providers to improve maternal health outcomes and advance equity in maternal care. PHS is a network of CHCs that serves many counties across the region, and providers at PHS are among many regional providers across multiple disciplines engaged in the Provider Support Network. In addition to providing prenatal and postpartum care services, PHS provides comprehensive primary care across the lifespan. Three PHS community health centers – Moncure Community Health Center (Chatham County), Siler City Community Health Center (Chatham County) and Prospect Hill Community Health Center (Caswell County) will be the community clinical sites for implementation of the O-HTN bundle. These sites represent two of the rural counties in Perinatal Region IV.

In Chatham County, community engagement infrastructure exists to improve perinatal care and advance health equity. EMBRACe seeks to ensure successful and equitable birth outcomes for women and children

through system and service alignment across multiple community partners and agencies, including PHS (and the Moncure and Siler City Community Health Centers) and UNC Department of Family Medicine. EMBRACe has conducted an organizational equity assessment, as well as an assessment on identifying and addressing social determinants of health. In partnership with Chatham Organizing for Racial Equity (CORE), EMBRACe is engaging in community listening sessions with mothers, with a focus on storytelling to center the voices of mothers in the organization's work. Recently, EMBRACe partnered with the UNC Family Medicine Department to support the planning and successful opening of a new Level 1 Maternity Care Center at Chatham Hospital, a rural critical access hospital. Additionally, the Chatham Health Alliance, a collaborative of local professionals and community members working together to improve health and well-being in Chatham County, conducted its state-mandated Community Health Assessment (CHA) in 2019 (18) that examined the social determinants of health in the county and identified top health priorities, including health equity.

In Caswell County, PHS Prospect Hill Community Health Center has a longstanding partnership with UNC Family Medicine and Obstetrics and Gynecology Departments and became NC's first teaching health center with the goal of enhancing the quality of care across the lifespan and training UNC health professional students and medical residents in the rural community setting. Through this effort, this community health center has expanded prenatal care and reproductive health services. Caswell County also conducted its CHA in 2019 (19), leveraging the involvement of diverse partners, including the Caswell County Public Health Department and the Caswell Chapter of the Health Collaborative, to identify community strengths and assets, as well as needs, determinants of health, and health priorities. Caswell's CHA identified improved race relations as one of its priorities. Our Phase I project will benefit from the robust community engagement infrastructure in place in these two counties, UNC's longstanding partnerships with PHS Community Health Centers, the involvement of new partners (such as EMBRACe and CORE) with missions that are well-aligned with the proposed work, and the commitment to addressing racial disparities in maternal mortality with an equity lens among project partners.

Approach/Framework

Three critical undertakings are considered for this Phase I study with community participation underpinning their stages. The results of the efforts will position us well for a full-scale study in Phase II.

I. Understanding Community Needs, Engaging Community Stakeholders and Strengthening the Planned Regional Coalition

We will use multiple qualitative approaches in Phase I: 1) focus groups to elicit community needs related to Respectful Care and perceptions of facilitators and barriers that may affect implementation; and 2) CBPR Charrettes to: a) engage community stakeholders in reviewing the focus group findings and determining potential implementation strategies; and b) strengthen and sustain the RC.

We are fortunate to have comprehensive Community Health Assessment data from each county collected via community-engaged participatory processes that provide key indicators, insights into county-level social determinants of health, demographics and racial/ethnic disparities in health outcomes as a contextual foundation for our proposed work. To augment the CHA data from our partner counties, Chatham and Caswell, we will conduct a community-informed needs assessment to elicit the perspectives of patients and providers and inform the development of the "5th R". We will conduct focus groups (n=6) with diverse cohorts of patients (10 each) from racial/ethnic groups who are disproportionately affected by racial disparities in maternal mortality (i.e., African American and Latinx women). We will leverage a focus group process (20) successfully implemented in a prior study that used a racial equity framework and CBPR approach to address racial disparities in cancer treatment outcomes. The process engaged patients in identifying the facilitators and barriers they experienced during their cancer care journey (21) to inform an intervention component, Healthcare Equity Education and Training for cancer center providers and staff, intended to address those barriers (22). The CFIR will be used to develop the needs assessment questions

with a focus on respectful care and the identification of barriers and facilitators (determinants) for successful implementation of the bundle. Additionally, we will further the development of the assessment with an equity lens to help to identify community needs and current knowledge/attitudes/practices towards maternal health issues (hypertension in particular) and the bundle. Finally, we will include questions to elicit perceptions of, and insights into, how to incorporate the Respectful Care (the "5th R") component in the bundle as a critical step in achieving equitable care for women with hypertension. We will also conduct semi-structured interviews with PHS providers to understand their perspectives on respectful care and identify training content, skills, and support that they need to care for their patients with respect, as it is defined by the community.

Our community partners in each county, including EMBRACe in Chatham, and PHS, will select the geographical areas and cohort for the focus group discussions (FGDs) based on their longstanding community support, as well as collaboration with the University. The FGDs will be co-facilitated by Community Experts (from the Charrette process described below) who are racially and linguistically congruent with each focus group cohort to minimize power differentials between the community and research project team (22,23). Research team members and community representatives will carry out conversations with Spanish speaking focus group members.

Assuming participant's consent, and given the need to implement them quickly over the summer when not all may be vaccinated, the FGDs will be initially conducted on Zoom, digitally recorded, transcribed and prepared for analysis. Each transcript will be summarized in a template of FGD topics and summaries will be consolidated into matrices using a qualitative analysis approach that facilitates the rapid application of preliminary findings to implementation strategy development(24). We anticipate conducting the interviews with providers in person since it is likely that all involved will have been vaccinated. A similar analysis process will be undertaken to analyze provider interviews.

Once we have the preliminary findings from this rapid analysis process, we will organize one CBPR Charrette with consortium stakeholders to examine facilitators and barriers, inform development of the "5th R" and determine relevant implementation strategies to integrate the Respectful Care component into the bundle. A second CBPR Charrette will be conducted to help to select components of the 5th R that we will develop and test in this Phase I. Both Charrettes will be conducted in the first three months. CBPR Charrettes, as adapted by UNC from design science and community development, offer a tested, action-oriented means of harnessing the expertise within communities to spur priorities, action and solutions responsive to, and shaped by, community needs as well as strengthen partnership approaches to research (9,10). We will use the Charrette process to facilitate conversations among RC stakeholders to align perspectives around respectful care, as well as ensure fit with local context based on structure, content, provider, and delivery methods while preserving the bundle core components. We anticipate the Charrette process will be a useful mechanism to ensure systematic and comprehensive input from key stakeholders, generate collaborative solutions, and align perspectives of patients, community and providers on quality and respectful care. One of our team members (Lightfoot) who leads Charrettes around the state and the country with Community Experts, racially/ethnically diverse community partners with extensive lived and research expertise (22,23), will co-facilitate the process to engage relevant stakeholders, identify facilitators and barriers, and elicit community-driven equity-focused ideas to accelerate solution development.

A readiness assessment of the planned RC will be conducted using the Intervention and Research Readiness Engagement and Assessment of Community Health Care (I-RREACH) tool to identify existing strengths and areas requiring further development for effective implementation (25). The aforementioned CBPR Charrettes will enhance the historical partnership between the University and the community in NC Perinatal Region IV. In turn, this will help to enhance community-based research capacity and lay the groundwork for ongoing engagement with the community around improving equitable care in general, and hypertension treatment and sustainable and impactful outcomes, in particular. This will ensure that the partnership will not only be ready for Phase I of the project but will also be fully prepared for Phase II.

II. Adapting the Bundle and Selecting the Implementation Strategies

Pregnancy induced hypertension, preeclampsia with severe features, or chronic hypertension with superimposed preeclampsia can manifest signs and symptoms during pregnancy or in the weeks postpartum. Severe hypertension can be present without symptoms and thus only identified through blood pressure monitoring. Timely and appropriate identification and treatment of severe hypertension can prevent stroke other maternal and neonatal morbidities and can be lifesaving. While the hospital setting is inherently prepared to respond with continuous monitoring, intravenous medications and a full team of nurses, obstetricians and anesthesiologists, the outpatient setting is quite different. Women may be presenting for a "routine" prenatal visit when a blood pressure elevation in need of immediate treatment is recognized. She may be calling in from home to her local community health center with complaints consistent with preeclampsia, which is a need that must be triaged appropriately. Most clinics do not have the capacity to treat with intravenous medications and need a readily available mechanism for treatment with oral medication. Clinics may not have the capacity to dedicate nursing staff to provide continuous monitoring and need a mechanism for escalating care and transfer to the hospital.

The CFIR-ERIC Implementation Strategy Matching Tool (26) will be used to help tailor the adaptation of the bundle and implementation strategies to the outpatient settings. Additionally, the adaptation will be initiated using key steps from the framework for program adaptation created by Escoffery, et al. (27). The adaptation process will build on the input provided by experts on what elements of the bundle are considered core and what can be adapted in a community setting. With the exception of the addition of the "Respectful Care" domain, the changes to the bundle are expected to be minimal. The implementation processes to be addressed, such as training and coaching, will be at the "Does it Work" phase since a strong interest in adapting the bundle to the outpatient setting has already been expressed by the community. Additionally, the adaptation process will address the local clinic context and include factors such as the number of staff involved in providing the bundle services and how patients pay for these services. The scope for the adaptation process as well as the methods and strategies will be documented to create adaptation guidance for the anticipated full-scale study in Phase II.

As we are building on current related efforts and other initiatives/projects in the region, we expect that the developmental stage of the selected strategies will vary. For example, the planned community-based needs assessment will simultaneously be developed with an equity lens, focused on the perceived implementation barriers by the community and on the gap analysis performed by the Region IV Provider Support Network. In this gap analysis, community providers were asked to identify priorities in their clinic setting that could decrease maternal morbidity and mortality. The need for focus in outpatient treatment of severe hypertension was thus identified. Moreover, given that the HTN bundle is proven effective in inpatient settings and, thus, no major adaptation to its contents is expected, the adaptation process will focus on the structure, provider, and target population elements. In this regard, because the HTN bundle must be adapted for a population that has either not received the inpatient bundle before or has limited access to it, the bundle will be at the "Can it Work" phase (10).

Strategies for successful and sustainable implementation, including **engaging leadership** to ensure organizational fit and support, and **integration** of the bundle into clinic day-to-day routine and data systems will be considered. Challenges in adapting and sustaining the bundle at the clinic level will be addressed and solutions will be developed with the community. These challenges may include: the complexity of the bundle and the amount and level of changes required to put it in place in outpatient settings; the structure of the intervention and cost of the related strategies for its uptake—facilitation, training and other supportive strategies; the context of the clinic—inner context (for example, leadership support and priority for the intervention), and outer context (for example, financial system and policy). Additionally, strategies for provider uptake of the adapted bundle with fidelity will include **adoption, selection, training and coaching** staff, and **developing fidelity measures** to ensure quality implementation. Challenges at this level may include staff availability for training. Modules for training and tools to support knowledge and skill building will be developed with providers and staff. We will develop pre-post assessments to test providers' level of

adoption, and the effectiveness of training and coaching. We will use a platform approved by the three clinics to administer these assessments.

III. Conducting a multiple baseline study to test the bundle and the implementation strategies

Multiple Baseline Design:

We will use a multiple baseline design to simultaneously test the potential effectiveness of the adapted bundle and the selected implementation strategies. The implementation strategies will be developed as they would be tested in a full-scale study, however, the assessment of these strategies in Phase I will be based on intermediary outcomes and limited to *potential* impact. While we will use the multiple baseline approach for Phase I, we plan to use a stepped wedge design using GLMMs or GEEs as the method of statistical analysis for the anticipated full study in Phase II. As an alternative, we also will consider use of a factorial design to assess the relative impact of the implementation strategies in Phase II.

For Phase I, the multiple baseline design will enable us to determine: (1) whether a change in providers' behavior has taken place as assessed by visual analysis and statistical testing as appropriate, including a comparison of the means of measured indicators pre- and post-intervention across the three clinics; and

(2) whether the implementation strategies (i.e., training and coaching) have resulted in a change and, if so, the extent of change, in providers' behaviors as reflected by fidelity measures, obtained repeatedly and tested for trend within and across clinics, using statistical techniques that take into account autocorrelation (28).

Potential Algorithm for the Multiple Baseline Design to Enhance Internal and External Validity, Adapted from Hawkins et al. (28)

Steps	
Identify the target population units	Community-based clinical teams, including providers, nurses, and others who provide support for prenatal care in the three selected FQHCs
Match the population units by potential confounders (e.g., demographics, behavior)	Will consider matching for confounders as identified with community partners.
Randomly select the desired number of matched units for analysis	There will be no randomization in Phase I; will consider randomization for Phase II.
Determine the appropriate time and number of measures needed to collect baseline data	Baseline data will be collected in Phase I for a minimum of three months prior to intervention. A minimum of 3 indicators will be selected for each of the five Rs in the bundle
Select outcome measure(s) suitable for repeated data collection	Examples of measures: adherence to recommendations for blood pressure measurement; escalation policies and maternal transport plans in are place; escalation and maternal transport plans followed.
Determine the optimal time interval between intervention implementation in each unit	One month
Randomly assign each unit to an order of intervention implementation	The three clinics will be randomized to determine sequence of clinics receiving the intervention/implementation strategies.
Implement interventions according to the predetermined schedule	As above
Examine outcomes using statistical methods suitable for time-series data	To account for autocorrelated data, will consider use of "Auto-Regressive Integrated Moving Average" or "Independent Time Series Analysis of Autocorrelated Data" modeling

Implementation Research and Intervention Logic Model

Research activities	**Intervention activities**	**Implementation strategies and activities**	**Implementation outcomes**	**Intervention intermediary outcomes**	**Impact**
-Community based needs assessment -Determinants assessments (implementation barriers and facilitators) -Focus groups with patients -Key informant interviews with providers -Adaptation of the hypertension bundle to outpatient settings -Charrettes to facilitate co-design on Respectful Care -Assessment of capacity of Regional Consortium -Multiple baseline research testing bundle and implementation strategy effectiveness	**Readiness**: improve capacity for diagnosis, monitoring, and treatment of severe preeclampsia **Recognition and Prevention**: improve capacity of families to detect early warning signs of potential birth complications hypertension and know how to seek help (expected in Phase II) **Response**: improve capacity of clinics to escalate the management of treatment **Reporting/Systems Learning**: create culture of improvement within clinic **Respectful Care**: ensure equitable care as determined by community (expected in Phase II)	**Provider level** -Training/ capacity building -Coaching -Performance feedback **Organizational level** -Integration of intervention -Leadership engagement **Intervention level** -Adaptation **Community level** -Identify the components of the "5th R" (Charrettes) -Co-design strategies with community (based on assessments) (expected in Phase II)	**Provider level** -Acceptability -Adoption -Fidelity -Integrated bundle -Supportive leadership **Community level** -Community input included -Community level barriers identified and addressed	-Providers are using the bundle with fidelity -Bundle is adapted and operational-ized -Respectful Care included in bundle	Improved heart, lung, blood, and sleep (HLBS) health outcomes for women during pregnancy and post-partum

Illustrative Implementation Outcomes, Strategies, Research Questions and Methods

1. **Acceptability** is mainly focused on the reaction of the community. It considers the extent to which the bundle is suitable, satisfying, or attractive to providers, patients, and communities.

   - Possible implementation strategies: Engagement in the development and conduct of community-based needs assessment; Engagement in the adaptation process.
   - Research questions 1 & 2: To what extent is the bundle attractive to providers, and patients and communities? To what extent is the bundle suitable for delivery in outpatient settings?
   - Measures: satisfaction of providers, satisfaction of patients, intent to continue to use, perceived appropriateness, and fit within organizational culture and settings.

2. **Implementation** explores the extent to which the intervention can be fully implemented as planned and proposed.

- Possible implementation strategies: Providers' capacity building, patients' education, development and integration of data support systems, leadership engagement.
- Research question 3: To what extent can the bundle be successfully delivered to the participants in the targeted population?
- Measures: degree of execution, success or failure of execution, resources needed to implement

3. **Adaptation** focuses on changes in the bundle content or procedures to be appropriate in an outpatient setting. The process for and actual modifications to accommodate the context will be documented.

- Possible implementation strategies: Expert advisory input, adaptation plan, PDSA cycles
- Research Question 4: To what extent does the bundle perform in the outpatient context?
- Measures:
    - *Readiness:*
        - 1) Standards in place for early warning signs, diagnostic criteria, monitoring and treatment of severe preeclampsia; 2) % of staff educated on proper blood pressure measurement; 3) Plan in place for rapid access to oral nifedipine; Escalation and maternal transport plan in place; 4) Standards in place for education of prenatal and postpartum patients/families on early warning signs and how to get help.
    - *Recognition:*
        - 1) % of calls to office with signs and symptoms of preeclampsia that are triaged appropriately; 2) % of pregnant and post-partum patients in office who have proper measurement of BP; 3) % of clinical staff who can describe early warning signs and treatment thresholds; 4) % of patients who can describe early warning signs and how to get help.
    - *Response:*
        - 1) Standard and appropriate protocol escalation policies in place for management and treatment of severe hypertension and postpartum presentation of severe hypertension/preeclampsia; 2) Adherence to protocol in simulated conditions (time to treatment of severe hypertension); 3) Adherence to protocol in real-life situations.
    - *Reporting/Systems Learning:*
        - 1) Data available regarding bundle implementation (e.g., phone call management); 2) Occurrence of post-transfer debrief with your team to identify successes and opportunities; 3) Multidisciplinary review of all severe hypertension/preeclampsia
    - *Respectful Care:* To be determined after elements are determined in partnership with community.

4. **Integration** assesses the level of system change needed to integrate a new program or process into an existing infrastructure (4,9). The organizational and social/physical environment changes that occurred as a result of the integration process will be documented to help to determine if the new bundle is feasible.

- Possible implementation strategy: cost-effectiveness analysis
- Research Question 5: To what extent can the bundle be integrated within selected clinics?
- Measures: Extent to which bundle is integrated in day-to-day clinic operation.

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