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Community-engaged implementation of a safety bundle for pregnancy-related severe hypertension in the outpatient setting: protocol for a type 3 hybrid study with a multiple baseline design

Jennifer Leeman[1*], Catherine L. Rohweder[2], Feng-Chang Lin[3], Alexandra F. Lightfoot[4], Jennifer Medearis Costello[5], Narges Farahi[6], Kimberly Harper[7], Johanna Quist-Nelson[8], E. Nicole Teal[9], Maihan B. Vu[10], Sarahn Wheeler[11] and M. Kathryn Menard[8]

Abstract

Background Hypertensive disorders of pregnancy are among the leading causes of maternal mortality and morbidity in the U.S., with rates highest among birthing people who are Black, rural residents, and/or have low-income. Severe hypertension, in particular, increases risk of stroke and other serious pregnancy complications. To promote early detection and treatment of severe hypertension, the Alliance for Innovation on Maternal Health developed the Severe Hypertension During Pregnancy and Postpartum Period Safety Bundle (HTN Bundle). Multiple studies have demonstrated the HTN Bundle's effectiveness in the inpatient setting. With funding from the National Heart, Lung, and Blood Institute, we engaged community partners to adapt the HTN Bundle for the outpatient setting (i.e., O-HTN Bundle) and planned for its implementation. In this paper, we describe the protocol for a study evaluating O-HTN Bundle implementation in 20 outpatient clinics serving Black, rural, and/or low-income populations.

Methods This study is a hybrid type 3 effectiveness-implementation trial with a multiple baseline design. We will implement the O-HTN Bundle in three successive cohorts of clinics using a multicomponent implementation strategy to engage community partners (coalition, patient workgroup) and support clinics (training, facilitation, education materials, and simulations of severe hypertension events). To test the strategy, we will compare clinic fidelity to evidence-based guidelines for (a) patient education on hypertension and (b) blood pressure measurement technique, with repeated measures occurring before and after strategy receipt. We will also observe strategy effects on community- and clinic-level intermediate outcomes (community engagement, organizational readiness), implementation outcomes (reach, adoption, fidelity, maintenance), and effectiveness outcomes (receipt of guideline concordant care). Analyses will address whether outcomes are equitable across Black, rural, and/or low-income

*Correspondence:
Jennifer Leeman
jleeman@email.unc.edu

Full list of author information is available at the end of the article

subgroups. Guided by the Consolidated Framework for Implementation Research 2.0, we will use mixed methods to identify adaptations and other determinants of implementation success.

Discussion This study integrates community engagement and implementation science to promote equitable and timely response to severe HTN in the outpatient setting during pregnancy and postpartum. This is one of the first studies to implement an outpatient HTN Bundle and to use simulation as a strategy to reinforce team-based delivery of guideline concordant care.

Trial registration This study was registered with ClinicalTrials.gov as "Testing Implementation Strategies to Support Clinic Fidelity to an Outpatient Hypertension Bundle (AC^{3}HIEVE)." Registration number NCT06002165, August 21, 2023: https://clinicaltrials.gov/study/NCT06002165.

Keywords Maternal health, Maternal Mortality, Maternal Morbidity, Preeclampsia, Pregnancy-related Hypertension, Implementation Science, Community Engagement, Health Equity, Pragmatic Clinical Trial, Simulation

Background

Hypertensive disorders of pregnancy affect 5–7% of pregnancies globally and are among the leading causes of maternal mortality, severe maternal morbidity, and prematurity in the United States [1–5]. Additionally, hypertensive disorders of pregnancy are associated with increased lifetime risk of cardiovascular and cerebrovascular diseases [6, 7]. Birthing people who are Black, rural residents, and/or have low-income are at greatest risk of hypertensive disorders of pregnancy and may have more severe presentations with worse outcomes [8–11]. Severe hypertension (i.e., blood pressure [BP] reaching or exceeding 160 mmHg systolic and/or 110 diastolic), in particular, increases the risk of stroke and other serious medical complications including maternal death [9, 10]. For this reason, early identification and treatment of severe hypertension (ideally within 30–60 min) is essential to preventing maternal mortality and morbidity [11]. To promote early detection and treatment, the Alliance for Innovation on Maternal Health (AIM) developed the Severe Hypertension During Pregnancy and Postpartum Period Safety Bundle (HTN Bundle), initially released in 2015 and revised in 2022 [12, 13]. The AIM HTN Bundle provides hospitals with a set of processes they can use to implement evidence-based guidelines for recognition and response to severe HTN in pregnancy. Multiple studies have demonstrated the HTN Bundle's effectiveness at improving time to treatment and reducing maternal morbidity and mortality in the inpatient setting [14–17]. However, birthing persons with severe hypertension often initially present in the outpatient setting, during the prenatal and postpartum periods. The purpose of this study is to test an HTN Bundle that is adapted for the outpatient setting, particularly settings that reach birthing people who are Black, rural residents, and/or have low-income, with the goal of providing equitable and timely treatment for severe hypertension.

Conceptual framework: integrating engagement, equity, and implementation science

Foundational to this research is a commitment to promoting health equity and respectful care for all birthing persons. We define health equity as being achieved when everyone attains their full health potential [18]. Respectful care is care that is provided to all birthing persons "in a manner that maintains their dignity, privacy and confidentiality, ensures freedom from harm and mistreatment, and enables informed choice" [19]. To promote equity and respectful care, we engage the expertise of birthing people who have experienced inequitable health outcomes, their families, and representatives from community-based clinics and organizations. Our approach to community engagement is guided by principles of community-based participatory research and the recently released Assessing Meaningful Community Engagement conceptual model with the goal of fostering trust, co-learning, and collaboration among community partners [20, 21]. We are engaging partners in operationalizing respectful care and identifying the multilevel determinants of timely, respectful, and equitable recognition and response to severe hypertension during pregnancy and postpartum. We are also working with partners to iteratively tailor and test implementation strategies to address the identified determinants.

With funding from the National Heart, Lung, and Blood Institute (NHLBI) through the Maternal Health Community Program (MH-CIP) we are conducting a two-phase study: "Advancing Community and Clinical care for Childbirth-related Hypertension: Implementation, Engagement and Valuing Equity (AC^{3}HIEVE)". In Phase I of AC^{3}HIEVE we adapted the AIM HTN Bundle for the outpatient setting and created the Outpatient-HTN (O-HTN) Bundle. We also tailored a multicomponent implementation strategy, and piloted implementation of the O-HTN bundle in three clinics. In this paper, we describe the protocol for Phase II of AC^{3}HIEVE, which aims to establish the impact of implementing the O-HTN Bundle on timely recognition and

response to severe hypertension in 20 outpatient clinics serving birthing patients who are Black, rural residents, and/or have low-income.

Aims

Study aims are as follows:

Aim 1. Implement the O-HTN Bundle in 20 outpatient clinics serving Black, rural, and/or low-income populations.

Aim 2. Compare effects of the AC^{3}HIEVE implementation strategy versus usual care on fidelity to selected elements of the O-HTN Bundle.

Aim 3. Observe effects of the AC^{3}HIEVE implementation strategy on intermediate, implementation, and effectiveness outcomes.

Methods

Design

This study is a hybrid type 3 effectiveness-implementation trial with a multiple baseline design in each of three successive clinic cohorts across four North Carolina (NC) counties (see Additional File 1 for SPIRIT checklist). A hybrid type 3 trail was selected consistent with our focus on testing the effects of O-HTN Bundle implementation processes on clinic fidelity to evidence-based guidelines for recognition and response to severe HTN in pregnancy. After a six-month baseline data collection period, each of the three cohorts will move sequentially into a 12-month implementation phase, beginning 6 months apart. Patients will not be prospectively recruited; patient-level data will be assessed using retrospective chart audits. Figure 1 provides an overview of the design and data collection for Aim 2.

Engagement of the wider community is central to our approach, with community defined geographically at the level of the county. Therefore, we designed our study to phase clinics into the implementation arm in three successive, county-based cohorts. We chose a multiple baseline design to allow us to implement the strategy sequentially across counties while also controlling for temporal effects across cohorts. Prior to implementation, we will collect multiple baseline measures in all 20 clinics to assess the impact of usual care. We then will implement the O-HTN Bundle in each successive cohort over a three-year period.

Study sites and population

We identified a total of 59 clinics in central NC that provide prenatal care in the four counties of focus. Recruitment started in settings where members of the research team had pre-existing relationships. To recruit clinics, a provider lead from the research team reached out to assess clinics' eligibility and interest. Clinics were eligible to participate if they provided prenatal care to a minimum of 50 birthing people annually, had an electronic health record, and served a patient population at risk for disparities in obstetric outcomes, defined as one or more of the following: at least 20% Black, at least 20%

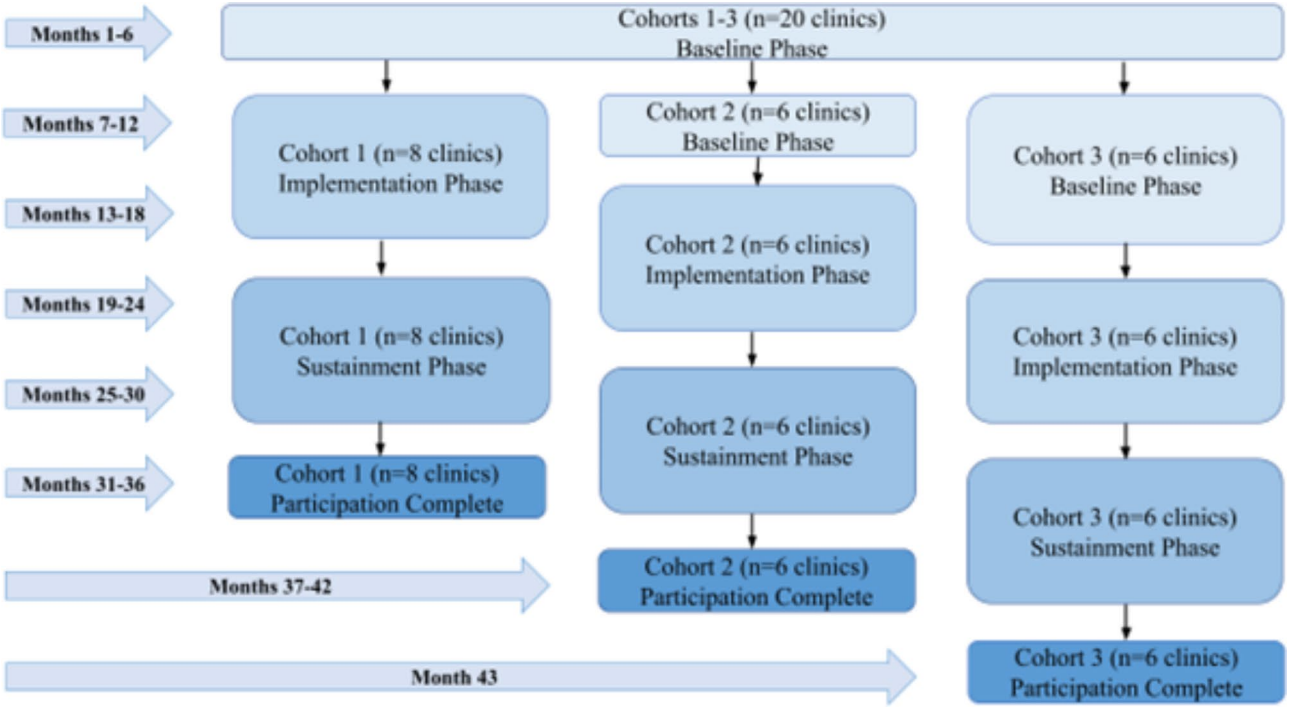

Fig. 1 Multiple baseline design

rural, and/or at least 50% uninsured or insured by Medicaid (as a proxy for low-income). After determining eligibility and inclusion/exclusion criteria, a member of the research team assessed the clinic's willingness to participate in baseline data collection, establish an implementation team, and commit to participating in the AC^{3}HIEVE implementation strategy (described below). Participating clinics are provided a financial incentive for their participation, based on the estimated amount of time required for providers and staff to engage in all study activities. Funds are distributed incrementally as milestones are completed during the study.

Participant recruitment, consent, and study oversight

The research team's nurse facilitators will recruit and consent all staff responsible for taking BP measurements on pregnant patients (medical support personnel), providers and staff who provide care to pregnant patients (care team), and members of each site's implementation team (see Additional File 2 for consent form). To promote continued participation, we will monitor team member attendance at coaching sessions, trainings, and simulations. If average participation drops below 80% over 3 months, we will begin intensive outreach efforts and discuss commitment to the study with clinic leadership. If sub-par attendance occurs over the subsequent 3 months, we will disenroll the clinic. Clinics are free to withdraw from the study at any time but would not be replaced as baseline data would not be available for comparison purposes.

Study protocols were reviewed and approved by The University of North Carolina at Chapel Hill's Office of Human Research Ethics, IRB #23–0968. Based on the low level of risk, the PI (MKM) will provide data monitoring and safety oversight for the study and promptly report any UPIRSO (Unanticipated Problems Involving Risks to Subjects or Others) to the IRB. Modifications to the clinical trial protocol will be discussed with the funder, submitted to UNC's IRB for approval, and updated in clinicaltrials.gov when necessary. Corresponding changes will also be made to the study's regulatory binder.

Table 1 Outpatient hypertension bundle

Domains	Core Elements
Readiness (Processes)	● Implementation Team ● Protocol for BP measurement technique ● Protocol for patient education ● Patient education materials ● Protocol for response to severe HTN
Recognition (Guidelines)	● Accurate BP measurement ● Appropriate identification and assessment of severe range BP ● Education on signs and symptoms of preeclampsia and when to get help
Response (Guidelines)	Timely Response to Severe HTN ● Notification of provider if systolic BP =/> 160 and/or diastolic BP =/> 110 and retaken in 15 min ● After the second severe range BP, treatment with oral Nifedipine IR (10 mg) initiated if available (ASAP, ideally within 30 min of BP verification) ● Escalation and care transition ● Maternal transport
Reporting (Processes)	● Plan for ongoing monitoring of severe HTN Recognition & Response ● Plan for training/educating newly hired staff on severe HTN Recognition & Response ● Plan for sustaining competency in proper BP Measurement Technique and Response to episodes of severe HTN
Respectful Care (Guidelines)	● Open, transparent, and empathetic communication with birthing persons and their support people ● Educational materials designed appropriately for patient's health literacy, cultural needs and language proficiency. ● Patient's concerns acknowledged and assistance provided to overcome barriers

O-HTN bundle

The O-HTN Bundle specifies *evidence-based guidelines* for recognizing and responding to severe hypertension and *processes* clinics might use to integrate those guidelines into routine practice (Table 1). Following the organization of the original AIM HTN Bundle [13], the O-HTN Bundle addresses five domains: (1) Readiness: processes for clinics to establish the protocols, workflows, and resources needed to recognize and respond to severe hypertension; (2) Recognition: evidence-based guidelines for measuring blood pressure and educating birthing people and their families to recognize signs and symptoms of preeclampsia; (3) Response: evidence-based guidelines for timely response and treatment of severe hypertension, with escalation to a higher level of care when needed; (4) Reporting/Systems Learning: processes for clinics to monitor, improve, and sustain evidence-based guidelines; and (5) Respectful Care: evidence-informed guidelines for culturally appropriate, patient-centered communication and practice.

Usual care condition

The usual care condition was designed to replicate the way new guidelines are typically disseminated to clinics via online materials and brief recorded webinars promoted by local clinical experts. At baseline, we will send all clinics a link to the O-HTN guidelines and education materials. These resources are available on the NC Perinatal Region IV Provider Support Network website [22].

Implementation strategy

Consistent with this study's overall conceptual framework, AC^{3}HIEVE integrates two categories of implementation strategies: (1) strategies to engage community partners (coalition and workgroup) and (2) strategies to

support clinic-level integration of the O-HTN Bundle (facilitation, training, simulation, and educational materials). We developed and piloted these strategies in Phase 1 and further refined them based on Phase 1 findings. Below and in Table 2, strategies are named according to terminology provided by the "Expert Recommendations for Implementation Change (ERIC)" compendium [23] and described following Proctor et al. guidelines for reporting implementation strategies [24].

Build a coalition The research team built a coalition to "cultivate relationships with partners in the implementation effort" [23]. Members of the research team with expertise in community engagement (AL, JC) conducted asset mapping to identify and engage partners with relevant experience and expertise within three levels of community: patient, clinic, and the broader community. The coalition meets monthly with a focus on strengthening relationships among coalition members, fostering equity in coalition operations, promoting mutual benefit for both research and the community, and leveraging the expertise of members to guide iterative cycles of implementation strategy tailoring and testing. Coalition members also advise on activities to elicit community input. These include patient workshops to guide development of patient-facing elements of the O-HTN Bundle (e.g., education materials), and Story Circles [25–27] to gain understanding of patients' prenatal, birth, and postpartum experiences and perceptions of respectful care. The overarching objective of the coalition is to learn together, collaborate, and build trust among all communities involved in O-HTN Bundle implementation, while ensuring patient and community perspectives inform all aspects of our research and implementation processes.

Use a workgroup The research team is partnering with a Patient Action Group (PAG) "to provide input and advice on implementation efforts and to elicit recommendations for improvements" [23]. The PAG plays a crucial role in ensuring patient engagement within and across partner counties and providing input into the development and roll out of patient-facing elements of the O-HTN Bundle. The PAG is led by a patient partner and consists of birthing people who have experienced pregnancy-related hypertension or cardiovascular disease. The group meets monthly to share experiences and provide recommendations and feedback on AC^{3}HIEVE study materials and procedures.

Conduct ongoing training A physician on the research team will provide a 45-minute training in-person or virtually to all care teams at each clinic. The training will focus on the Recognition, Response, and Respectful Care elements of the O-HTN Bundle. Nurse facilitators will provide a 20-minute on-site training on guideline-concor-

Table 2 Implementation strategies

Strategy (19)	Actor	Actions	Action Target	Dose	Timing
Build a coalition	Research Team, birthing persons, clinic staff, and members of wider community	Obtain community expertise through coalition meetings, Story Circles, and workshops to operationalize Respectful Care, identify barriers to care, and tailor implementation strategies	Academic-Community partner co-learning, collaboration, and trust	Monthly 60–90-minute coalition meetings; five 90-minute Story Circles; four 90-minute workshops	All phases of the project
Use a workgroup (Patient Action Group)	Research Team and birthing persons who have had pregnancy-related HTN	Incorporate patient insight, guidance and feedback into AC^{3}HIEVE materials and protocols	Patients' experience of barriers and facilitators to respectful, timely, and equitable care	Monthly 60-minute meetings	All phases of the project
Provide ongoing training	Research Team's lead physician and Nurse Facilitator	Training on O-HTN Bundle, Respectful Care and BP measurement	Clinic staff knowledge and skills to recognize and respond to severe HTN	45-minute O-HTN Bundle training (physician led); 20-minute BP trainings (nurse led)	Implementation Phase
Facilitation	Nurse Facilitator	Coach Implementation Team through process elements of O-HTN Bundle	Implementation Team readiness to implement O-HTN Bundle	Monthly 60-minute coaching sessions	Implementation Phase
Simulate change	Nurse Facilitator	Conduct and provide feedback on a simulation of a clinic patient presenting with an episode of severe HTN	Care Team knowledge and skills to recognize and respond to severe HTN	Three 20-minute simulations	Implementation and Sustainment Phase
Distribute education materials	Nurse Facilitator	Provide Implementation Team with O-HTN protocols, patient education and other materials	Implementation Team capacity to integrate O-HTN Bundle into routine practice	Ongoing	Implementation Phase

dant BP measurement technique to medical support personnel. They also will provide brief refresher trainings as needed during debriefing sessions following simulations (described below).

Facilitation One of two nurse facilitators on the research team will meet at least monthly with each clinic-based implementation team over the course of each cohort's one-year implementation period. Both nurses are trained as Institute for Healthcare Improvement (IHI) coaches and will employ IHI methods and tools (e.g., Plan-Do-Study-Act Cycles) [28]. Following a detailed protocol, nurse facilitators will coach teams on the processes involved in components of the O-HTN Bundle related to Readiness and Reporting/Systems Learning. They also will provide implementation teams with data collected on their clinic's fidelity to Recognition and Response guidelines (i.e., BP measurement, patient education, and simulated response to severe HTN).

Simulate change Episodes of severe hypertension may present frequently in high volume obstetrics clinics, particularly those that specifically care for high-risk birthing persons. However, they are relatively rare in low volume primary care settings (<1–2 times per month in the AC^{3}HIEVE Phase 1 pilot clinics). Therefore, providers and staff have limited opportunity to apply what they learn in training. Simulation is a strategy recommended for rare events because it allows providers and staff to practice and become proficient in newly acquired skills [29]. The nurse facilitators will coordinate three simulations per clinic at the beginning, middle, and immediately after O-HTN Bundle implementation. During simulations, a standardized patient (i.e., patient actor) will present with severe hypertension, and the care team will respond accordingly. Afterwards, the nurse facilitator will lead a debrief with the care team on their Recognition of and Response to the episode of severe hypertension as well as their provision of respectful care.

Distribute education materials The nurse facilitator will provide implementation teams with materials to support implementation and educate clinic staff, providers, patients, and patients' family members. Materials include an algorithm to guide care team Response to severe hypertension in the outpatient setting, sample clinic policies and protocols, and patient and family education materials. The research team developed materials in Phase 1 and will continue to engage community partners through the coalition, patient-facing workshops and the PAG, to tailor materials for each new cohort. The nurse facilitator will coach the implementation team on how to customize materials to fit their setting and population.

Measures

As summarized in Fig. 2 and Table 3, data will be collected on implementation, intermediate, and effectiveness outcomes, and on potential determinants of implementation success. For practical purposes, data collectors will not be blinded to clinic assignment to implementation or comparison phase of the trial. For chart audits and observations, inter-rater reliability will be established prior to data collection and validation procedures put into place to promote data quality. Personal

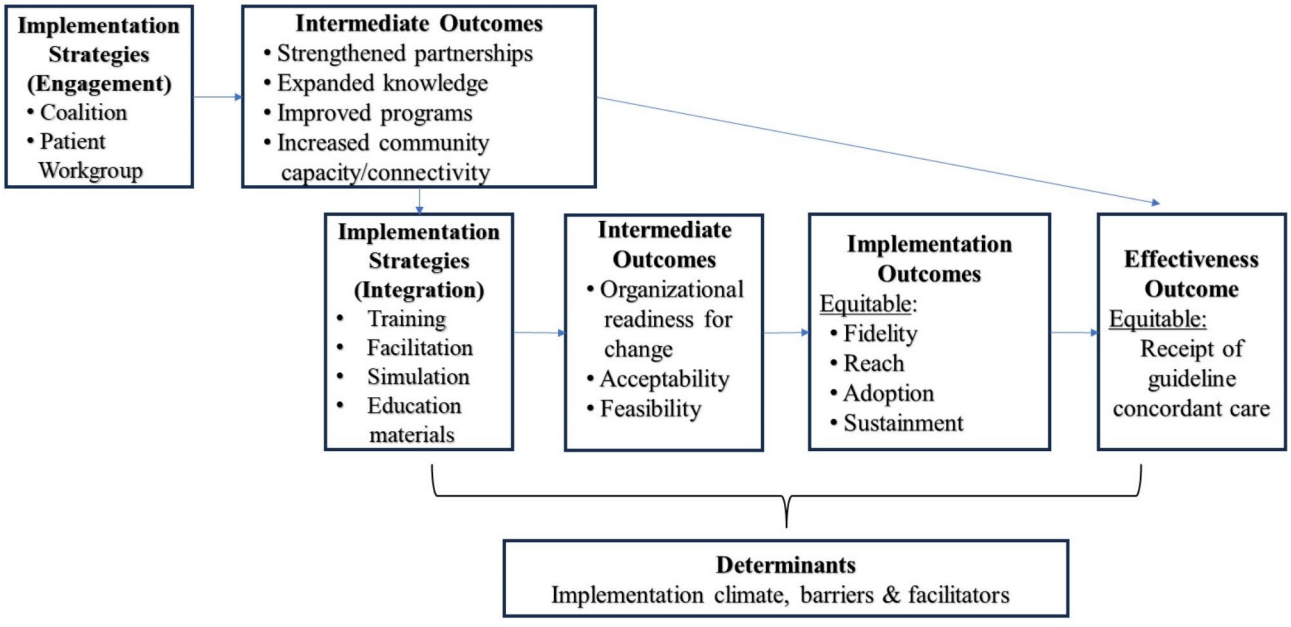

Fig. 2 Evaluation framework

Table 3 Measures of outcomes and determinants

Construct	Measure	Source	Frequency & Timing
A. Implementation Outcomes			
Fidelity and equity* of fidelity to Recognition guidelines (Primary Outcome)	Medical Support Personnel measures BP and patient education is provided per guidelines	Observation of BP measurement technique checklist and chart audit of documented patient education	At least 3 times during Baseline Phase; 3 times during Implementation Phase (at 3- to 6-month intervals); 2 times during Sustainment Phase
Fidelity to Response and Respectful Care guidelines	Clinic care team treats severe HTN per guidelines (simulation)	Simulation checklist and Respectful Care checklist	2 times during Implementation Phase and 1 time at start of Sustainment Phase (at 6-month intervals)
Fidelity to Implementation strategies	Nurse Facilitators delivers strategies per protocols	Fidelity/Adherence checklist	Monthly during Implementation Phase
Fidelity to Implementation processes	Clinic Implementation Team completes recommended implementation processes	Fidelity/Adherence checklist	Monthly during Implementation Phase
Reach and equity* of reach to patients	Number and representativeness of pregnant women with at least two clinic visits during Implementation Phase	Electronic Health Records	Retrospective chart audit at end of Implementation Phase
Reach to providers and staff	Numbers, proportion, and types of clinic staff participating in training/facilitation/ simulation	Nurse Facilitator Log	At every training, facilitation, and simulation
Adoption and equity* of adoption by clinics	Proportion of invited clinics that agree to participate and reasons for declining	Project Coordinator Log	During recruitment
Sustainment and equity* of sustainment	Sustained fidelity to Recognition guidelines (BP measurement technique and patient education)	Observation of BP measurement technique checklist and chart audit of documented patient education	2 times during Sustainment Phase at a 6-month interval
B. Intermediate Outcomes			
Strengthened partnerships	REST Survey, meeting attendance (numbers) [31]	Coalition and PAG	Coalition: Annually starting with the month the Coalition and PAG were formed
Expanded knowledge and improved programs	FRAME-IS [32] guided documentation of how community engagement informed implementation strategies	Minutes from Coalition, PAG, Research Team, Story Circles, & Patient facing workshops	All phases of the project
Increased community capacity/ connectivity	Ripple Effect Mapping [33]	Clinic providers/ staff, Coalition and PAG, Community members	Month 1 of Sustainment Phase
Organizational readiness for change	ORIC Survey (12 items) [35]	Implementation Team	Month 3 of Implementation Phase
Acceptability/ Feasibility	AIM, FIM surveys (8 items) [36]	Implementation Team	Month 3 of Implementation Phase
C. Determinants			
Implementation Climate	Implementation Climate Scale survey (18 items) [37]	Clinic providers/staff	Month 1 of Implementation Phase
Barriers/Facilitators	CFIR-guided focus groups [48]; Clinic Sustainability Assessment Tool (CSAT) [40]; guided reflection [39]	Implementation Team	Focus groups: Once during months 6–9 of Implementation Phase; CSAT and guided reflection: Month 10 of Implementation Phase
Clinic Adaptations to implementation processes	FRAME-guided periodic reflection [38, 39] on how and why clinics adapted processes	Nurse Facilitators and Nurse Facilitator Log Document review	Monthly during Implementation Phase
D. Effectiveness Outcome			
Receipt and equity* of receipt of guideline concordant care for severe HTN	Retrospective chart audit of all pregnant women with systolic BP =/> 160 and/or diastolic BP =/>; distribution by race, insurance status, and Zip Code	Electronic Health Record audit	Annually at Baseline, Implementation and Sustainment Phases

Health Identifiers (PHI) will be protected according to the IRB-approved procedures, and all data will be stored on password protected, HIPAA (Health Insurance Portability and Accountability Act)-compliant servers. Study documents containing PHI will be retained for a minimum of three years up to a maximum of five years after the completion of study procedures to allow adequate time for data analysis, including secondary analyses.

Implementation outcomes To test the AC^{3}HIEVE implementation strategy (Aim 2), we will compare fidelity to two elements of the Recognition guidelines: blood pressure measurement and patient education (primary outcomes). Because severe hypertension is a rare event in most outpatient clinics, our primary outcomes address components of the O-HTN Bundle relevant to all pregnant women (Recognition) in order to provide a sufficient sample to demonstrate statistically significant differences. Using simulation, we will observe fidelity to O-HTN Bundle guidelines for Recognition and Response to severe hypertension and Respectful Care. We also will observe fidelity to implementation strategies and processes, and reach, adoption, and sustainment (Aim 3).

Fidelity to recognition guidelines: blood pressure measurement and patient education (primary outcome) A member of the research team will observe BP measurement technique for at least 80% of medical support personnel at each clinic. To minimize interference with clinic workflow and eliminate the need for patient consent, we will provide a standardized patient and an observer will assess BP measurement technique using a structured checklist. To assess fidelity to guidelines for patient education on hypertensive disorders of pregnancy, a member of the research team will conduct retrospective chart reviews on a random sample of 20 prenatal care recipients per enrolled clinic who gave birth up to six months prior to the data collection timepoint. Clinics with fewer than 20 births in the sample period will have 100% of charts audited. Chart reviewers will extract data on verbal and/or written education provided, gestational week when education was provided, pregnancy-related information (prenatal care visits, parity, delivery date), and patient demographics (race/ethnicity, insurance status, and Zip Code). Consistent with the multiple baseline design, both measures will be collected at least three times for all 20 clinics prior to the implementation phase. Measures also will be collected three times during the one-year implementation phase and two times during the one-year sustainment phase.

Fidelity to response and respectful care guidelines Simulations will be videotaped, and trained observers will review the videos and document care team response using a standardized checklist to capture fidelity to Response and Respectful Care elements of the O-HTN Bundle.

Fidelity to implementation strategies and processes The nurse facilitators will use checklists to document research team completion of implementation strategies (e.g., trainings, simulations) and implementation team completion of the processes involved in the Readiness and Reporting components of the O-HTN Bundle (e.g., clinic-level patient education protocols and materials). Each completed item will be assigned one point, with a total score of 11 for fidelity to implementation strategies and 11 for fidelity to implementation processes. (See Additional File 3 for a complete list of processes and strategies).

Reach We will document reach to birthing people and clinic staff. For birthing people, we will query the EHR to identify the number and demographics (race/ethnicity, insurance status, and Zip Code) of birthing people who were seen at least twice in each clinic during the implementation phase. We also will examine the degree to which the demographics of those reached are representative of the county's population of birthing people. For reach to clinic staff, we will document the number, proportion, and type of clinic staff participating in facilitation, training, and simulation.

Adoption To assess adoption, we will document the proportion of invited clinics that agree to participate and reasons for declining.

Sustainment To assess sustainment, we will document clinic fidelity to Recognition guidelines (blood pressure measurement and patient education) two times at six-month intervals during the one-year sustainment phase.

Intermediate outcomes To assess the impact of community-engagement implementation strategies, we build on the National Academy of Medicine's Model for Assessing Meaningful Community Engagement (ACE) [21]. This model posits that community engagement impacts health equity and systems transformation through four mechanisms: strengthened partnerships, expanded knowledge, improved healthcare programs, and thriving communities [21]. To assess the impact of clinic-level implementation strategies, we will evaluate staff perceptions of organizational readiness for change and O-HTN Bundle acceptability and feasibility. Although many scholars classify acceptability and feasibility as implementation outcomes, we follow the recommendation of Damschroder et al. (2022) and view them as antecedent to actual implementation [30].

Strengthened partnerships We will administer the 9-item Condensed Research Engagement Survey Tool (REST) [31] to assess coalition and PAG member perceptions of engagement (e.g., trust, respect, shared decision making among partners). We also will document attendance at coalition and PAG meetings.

Expanded knowledge/improved programs Guided by the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) [32], we will systematically document how input from community partners was used to tailor implementation strategies. The FRAME-IS provides a tool for documenting when, why, and how implementation strategies are adapted to address context and the needs of implementation partners. Input from coalition meetings and the PAG, as well as findings from patient-facing workshops and Story Circles [25–27], will be presented to the research team during a series of discussions focused on how to tailor strategies (e.g., education materials, clinic trainings) to incorporate community input. During these meetings, we will use a structured template to document why and how strategies are tailored, guided by FRAME-IS [32]. Decisions on tailoring will be presented to the coalition and PAG for member checking.

Thriving communities To gain understanding of the broader community impacts of AC^{3}HIEVE, we will conduct Ripple Effect Mapping (REM) [33, 34] with clinic, patient, and community-based organizational partners at the end of each cohort's implementation phase. REM offers a systematic, participatory process well-suited for assessing the multi-level impacts of complex community-engaged interventions. Using appreciative inquiry and visual mapping to engage participants, REM will help us understand intervention impacts at multiple levels from the perspectives of patients, clinic providers/staff, and members of the broader community. We will conduct 2–3 hour REM sessions with partners from each cohort at month 1 of sustainment. Each session will start by having pairs of participants engage in appreciative inquiry interviews to elicit perceptions of impact. This will be followed by an interactive mapping process designed to visually map collective perspectives on community impact.

Organizational readiness In month three of the implementation phase, we will administer the 12-item Organizational Readiness to Implement Change (ORIC) [35] survey to members of the implementation team. The ORIC assesses perceptions of an organization's commitment and efficacy related to a specific change, in this case implementation of the O-HTN Bundle.

Acceptability and feasibility In month three of the implementation phase, we will administer the validated 4-item Acceptability Implementation Measure (AIM, $\alpha=0.85$) [36] and 4-item Feasibility Implementation Measure (FIM, $\alpha=0.89$) [36] to members of the implementation team.

Effectiveness outcomes

Receipt of guideline concordant care for severe HTN The study team will conduct retrospective chart reviews of all episodes of pregnant or postpartum patients presenting to the clinic with severe HTN in the 12 months prior, during, and after the implementation phase. The purpose of this retrospective chart review is to observe changes over time in Recognition of and timely Response to episodes of severe HTN in concordance with the O-HTN guidelines and across subgroups (Black, rural, and/or low-income).

Determinants

We will collect data on potential determinants of implementation and effectiveness outcomes.

Implementation climate In the first month of the implementation phase, members of the implementation team will complete the 18-item Implementation Climate Scale ($\alpha=0.91$) [37]. The scale captures six dimensions related to respondents' perceptions of how their organization (i.e., clinic) prioritizes and values the implementation of evidence-based interventions generally, without focusing on a specific intervention.

Barriers and facilitators A team member with training in qualitative methods (MV) will conduct focus groups with each clinic's implementation team to elicit their perceptions of barriers and facilitators to O-HTN implementation. Focus group guides will be informed by the updated Consolidated Framework for Implementation Research (CFIR) [48]. Questions will assess determinants of clinic engagement with implementation strategies, completion of implementation processes, and fidelity to O-HTN Bundle guidelines. The focus group facilitator will not be involved in delivering implementation strategies.

Clinic adaptations to implementation processes Guided by the Framework for Reporting Adaptations and Modifications (FRAME) [38], a doctoral student under the supervision of a member of the research team (JL) will engage nurse facilitators in monthly periodic reflections [39] on why and how clinics have adapted implementation processes. This will include review of clinic-generated documents (e.g., policies, education materials) and nurses' documentation of clinic fidelity and adaptations to implementation processes.

Sustainability Each clinic implementation team will complete the Clinical Sustainability Assessment Tool (CSAT) [40] during month 10 of implementation. The tool identifies potential determinants of sustainability and includes 35 items in seven domains (e.g., engaged staff and leadership, workflow integration). The nurse facilitators will provide feedback to each team on results and will facilitate team reflection on factors contributing to domains with low scores and how those factors might be addressed.

Sample size considerations

Sample size was determined based on our primary outcomes, fidelity to Recognition guidelines for blood pressure measurement and patient education. In our Phase I pilot study, clinic-level fidelity to blood pressure measurement protocols was assessed using this study's structured checklist. Fidelity was 45.1% (SD=5.2) at baseline and 76.8% (SD=8.2) following receipt of the AC^{3}HIEVE implementation strategy, a difference of 31.7% (SD=11.4) pre- to post-implementation. Given this effect size, five clinics are needed to achieve 95% power under a one-sample t-test with a 5% type-I error rate. Patient education was not measured in Phase I, but a similar effect size is anticipated. The current study's larger sample will allow sub-analyses of differences by clinic characteristics (e.g., primary care versus obstetric provider, prenatal volume, and demographics of the population served). A larger sample size will also allow for the evaluation of Response to relatively infrequent episodes of severe hypertension.

Analysis plan

Data will be analyzed using mixed methods. Descriptive statistics will be used to examine the distribution of variables, influential data points, and missing data, including means (standard deviations) for continuous variables and frequencies (percentages) for categorical variables. Directed content analysis will be applied to qualitative data [41]. Two members of the research team will read through relevant documents (meeting minutes, ripple effect maps, focus group transcriptions, and/or notes from periodic reflections) to create code books. They will use Dedoose [42], a qualitative software program, to independently code documents and then meet to reconcile coding discrepancies. The two team members will then identify themes within and across codes and present them to the implementation team members for member checking.

Compare effects of the AC^{3}HIEVE implementation strategy versus usual care on fidelity to selected elements of the O-HTN bundle We hypothesize that fidelity to Recognition guidelines (BP Measurement and patient education) will be significantly greater at 6 and 12 months after the AC^{3}HIEVE implementation strategy than before. We anticipate that all participating clinics will be retained in the study. Hence, missing data on clinic-level variables will be minimal. If clinics are lost-to-follow-up, we will include only clinics with some follow-up data for the modified intention-to-treat (ITT) analysis. Data will be collected at multiple points during the baseline, implementation, and sustainment phases. We will use a linear mixed-effects model that includes secular trends, implementation effect, and heterogeneity to model the mean outcome.

In addition to comparing fidelity to O-HTN Bundle Readiness and Response guidelines before and after AC^{3}HIEVE implementation strategies, secondary analyses will include the association between fidelity to those guidelines and (a) clinic readiness [35], (b) clinic fidelity to implementation processes, and (c) implementation team perceptions of acceptability/feasibility [36]. A Pearson or Spearman correlation coefficient for bivariate analysis will be used to describe the correlation when appropriate. We will also explore whether clinic organizational readiness (ORIC measure) [35] may mediate the impact of implementation strategies. A mediation analysis following Baron and Kenney's steps will be used to test the mediation effect [43].

The implementation effect may be confounded by clinic-level covariates. We will explore confounding by adding the covariates into the primary model. If the change of the implementation effect exceeds 10%, we will conclude that confounding is possible and include the covariate in the model. We will also explore possible factors that may moderate the impact of implementation strategies on fidelity, including (1) the overall percentage of implementation team members who turn over during the study period and (2) the implementation climate at baseline [37]. The moderation effect will be tested by adding an interaction with the implementation strategy in the primary model. Wald-type statistics derived from the linear mixed-effects model will be used to summarize the test significance of the moderation effect. We will consider the clinic characteristics (e.g. family medicine versus obstetrician/maternal fetal medicine providers; prenatal volume; urban/rural residence, race/ethnicity, and insurance status of population served) by subgroups and test the difference between subgroups.

Observe effects of the AC^3 HIEVE implementation strategy on other intermediate, implementation, and effectiveness outcomes We will use mixed methods to assess the impact of engagement on strength of partnerships, expanded knowledge/improved programs, and community capacity/connectivity (community-level intermediate outcomes). We will use descriptive statistics to describe the strength of partnerships developed with

coalition and PAG members based on findings from the REST survey [31] and meeting attendance. We will apply qualitative methods to document how community input led to expanded knowledge and improved programs (i.e., tailored implementation strategies) through directed content analysis of meeting minutes, guided by the FRAME-IS [32]. Qualitative methods also will be applied to capture impact on the community through content analysis of visualizations and minutes generated by the Ripple Effect Mapping exercise [33, 34]. Descriptive statistics will be used to document impact on clinic-level intermediate outcomes: clinic organizational readiness (ORIC measure) [35] and implementation team perceptions of the O-HTN Bundle (AIM & FIM measures) [36].

Descriptive statistics will be used to document impact on implementation and effectiveness outcomes: reach to patients and providers; adoption; fidelity to Response guidelines, implementation strategies, and implementation processes; and receipt of guideline concordant care.

Identify determinants We will use convergent mixed methods to identify factors that may explain gaps and variations in fidelity across clinics and for birthing persons who are Black, rural residents, and/or have low-income [44]. Each clinic will be assigned two fidelity scores: (a) a composite of fidelity to Recognition and Response guidelines and (b) fidelity to implementation processes. Matrices will be used to identify patterns between clinic fidelity scores and potential determinants. Potential determinants will include quantitative findings on organizational readiness, organizational climate, acceptability, feasibility, and fidelity to implementation strategies. The matrix will also include qualitative themes from CFIR-guided analyses of focus group data and reflections on sustainability and adaptation. Matrices and narratives will be used to describe barriers and facilitators that may explain variations in fidelity [44, 45].

Dissemination of results

Results will be disseminated through peer-reviewed conference presentations and manuscripts, and findings will be shared with study partners through other products such as newsletters, coalition meetings, and the AC^{3}HIEVE website. AC^{3}HIEVE nurse coordinators will share interim results with clinic participants during coaching sessions.

Discussion

In this study, we engage community partners to tailor and test our implementation strategies with the goal of improving the quality and equity of care for birthing persons who are Black, rural residents, and/or have low-income. A strength of this study is the attention given to measuring the impact of implementation strategies on intermediate outcomes. Of particular note, we operationalize the National Academy of Medicine's ACE model [21] to measure the impact of engagement strategies on relationships, implementation strategies, and community connections. A second strength is the emphasis on promoting care that is respectful and equitable, with a particular focus on birthing persons who are at greatest risk for poor health outcomes. We do so by engaging with birthing persons and other community members to understand their experiences of pre- and post-natal care and how they define respectful care. We then measure the impact of our strategies on the delivery of respectful and equitable care, followed by qualitative inquiry to explain variations in impact. Additional strengths of this study are attention to determinants of sustainability as recommended by Zurynski and colleagues [46] and the use of simulation as both an implementation strategy and a measure of fidelity to evidence-based guidelines. Simulation is a promising and understudied approach to guideline implementation for rare, high impact events [29].

The O-HTN Bundle is a compilation of evidence-based guidelines and recommended processes. This protocol provides a model for how to disaggregate elements of a Bundle into these two classes, each of which serves a distinct function and together comprise the innovation being implemented. Distinguishing between guidelines and processes is key to identifying the core clinical elements that must be implemented with fidelity versus processes that may be adapted to fit the local context.

This study applies a multiple baseline design with implementation occurring across three sequential cohorts, in different counties. This design allows us to iteratively tailor implementation strategies to address the needs of each county's clinic settings and populations. We expect that this will yield rich findings on how and when strategies work and how they might be tailored across diverse contexts. This design also introduces challenges. Although clinics are in different counties, there also is some risk for contamination across clinics.

The AC^{3}HIEVE study is innovative in both its approach to reducing disparities in pregnancy-related severe hypertension, and in its study design which captures influences at both the community and clinic levels. Implementing the O-HTN Bundle in the outpatient setting increases the likelihood of delivering high quality, respectful care to the most vulnerable pregnant and postpartum patients. Incorporating the experiences of birthing persons, their support network, and members of the broader community helps to address the structural issues that lead to inadequate Recognition of and Response to episodes of severe hypertension. This study's design incorporates many of the recommendations for conducting rigorous multilevel implementation research such

as specifying the context for different study populations and settings, defining the levels of each construct and how they relate to each other, and aligning measures with selected theories and frameworks [47]. If successful, the scale-up and spread of the AC^{3}HIEVE multicomponent strategy for implementing the O-HTN bundle will occur more rapidly and effectively because of the emphasis on sustainability planning and measurement.

Abbreviations

AIM/FIM	Acceptability/Feasibility Implementation Measures
AIM	Alliance for Innovation on Maternal Health
ACE	Assessing Meaningful Community Engagement
BP	Blood Pressure
CAN	Certified Nursing Assistant
CSAT	Clinical Sustainability Assessment Tool
CFIR	Consolidated Framework for Implementation Research
ERIC	Expert Recommendations for Implementation Change
FRAME	Framework for Reporting Adaptations and Modifications
FRAME-IS	Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies
HIPAA	Health Insurance Portability and Accountability Act
O-HTN Bundle	Hypertension Bundle for the Outpatient Setting
IHI	Institute for Healthcare Improvement
ITT	Intention-To-Treat
NHLBI	National Heart, Lung and Blood Institute
NC	North Carolina
ORIC survey	Organizational Readiness to Implement Change
O-HTN Bundle	Outpatient Severe Hypertension During Pregnancy and Postpartum Period Safety Bundle
PAG	Patient Action Group
REST	Research Engagement Survey Tool
REM	Ripple Effect Mapping
HTN Bundle	Severe Hypertension During Pregnancy and Postpartum Period Safety Bundle

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

MKM, AL, JMC, NF, and NT conducted initial formative research to adapt the AIM HTN Bundle and tailor the implementation strategies used in this study. MKM, AL, JMC, NF, KH, NT, CLR, MV, FCL, JNQ, SW, and JL conceptualized the protocol reported here. JL led manuscript writing with AL and JMC contributing to sections on community engagement, MV and FCL contributing to sections on data measures and analysis, and CR editing the manuscript. MKM, AL, JMC, NF, KH, NT, CLR, MV, FCL, JNQ, SW, and JL read and approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The AC^{3}HIEVE Clinical Trial was approved by the Office of Human Research Ethics at The University of North Carolina at Chapel Hill, IRB#23–0968, on 8/17/23. All study participants will provide informed consent.

Consent for publication

Not applicable.

Trial sponsor

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Competing interests

The authors declare no competing interests.

Author details

[1]School of Nursing, University of North Carolina at Chapel Hill, Carrington Hall, S Columbia St, Chapel Hill, NC 27599, USA
[2]Center for Women's Health Research, University of North Carolina at Chapel Hill, 104B Market Street, Chapel Hill, NC 27516, USA
[3]Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, 3105G McGavran-Greenberg Hall, Chapel Hill, NC 27599, USA
[4]Department of Health Behavior, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, 1700 Martin Luther King Jr. Blvd, CB#7426, Chapel Hill, NC 27599, USA
[5]Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, USA
[6]Department of Family Medicine, School of Medicine, University of North Carolina at Chapel Hill, 321 S Columbia St, Chapel Hill, NC 27599, USA
[7]UNC Center for Maternal and Infant Health, Department of Obstetrics and Gynecology, School of Medicine, University of North Carolina at Chapel Hill, 321 S. Columbia St, Chapel Hill, NC 27599, USA
[8]Division of Maternal and Fetal Medicine, Department of Obstetrics and Gynecology, School of Medicine, University of North Carolina at Chapel Hill, 321 S. Columbia St, Chapel Hill, NC 27599, USA
[9]Division of Maternal-Fetal Medicine, Department of Obstetrics, Gynecology & Reproductive Sciences, School of Medicine, University of California at San Diego, 9300 Campus Point Dr., La Jolla 92037, CA, USA
[10]Department of Health Behavior, Gillings School of Global Public Health, Center for Health Promotion and Disease Prevention, University of North Carolina at Chapel Hill, 1700 Martin Luther King Jr. Blvd, CB#7426, Chapel Hill, NC 27599, USA
[11]Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, School of Medicine, Duke University, 2608 Erwin Road, 27710 Durham, NC, USA

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References

1. Hogan MC, Foreman KJ, Naghavi M, Ahn SY, Wang M, Makela SM, et al. Maternal mortality for 181 countries, 1980–2008: a systematic analysis of progress towards Millennium Development goal 5. Lancet. 2010;375(9726):1609–23.
2. Wanderer JP, Leffert LR, Mhyre JM, Kuklina EV, Callaghan WM, Bateman BT. Epidemiology of obstetric-related ICU admissions in Maryland: 1999–2008. Crit Care Med. 2013;41(8):1844–52.
3. Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States. Obstet Gynecol. 2009;113(6):1299–306.
4. Centers for Disease Control and Prevention. Pregnancy Mortality Surveillance System [Internet], Atlanta CDC. 2023 [cited 2023 Oct 9]. https://www.cdc.

gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm#causes
5. Hitti J, Sienas L, Walker S, Benedetti TJ, Easterling T. Contribution of hypertension to severe maternal morbidity. Am J Obstet Gynecol. 2018;219(4):405.e1-405.e7.
6. Coutinho T, Lamai O, Nerenberg K. Hypertensive disorders of pregnancy and cardiovascular diseases: current knowledge and future directions. Curr Treat Options Cardiovasc Med. 2018;20(7):56.
7. Tooher J, Thornton C, Makris A, Ogle R, Korda A, Hennessy A. All hypertensive disorders of pregnancy increase the risk of future cardiovascular disease. Hypertension. 2017;70(4):798–803.
8. Johnson JD, Louis JM. Does race or ethnicity play a role in the origin, pathophysiology, and outcomes of preeclampsia? An expert review of the literature. Am J Obstet Gynecol. 2022;226(2S):S876–85.
9. Judy AE, McCain CL, Lawton ES, Morton CH, Main EK, Druzin ML. Systolic hypertension, Preeclampsia-related mortality, and stroke in California. Obstet Gynecol. 2019;133(6):1151–9.
10. Martin JN, Thigpen BD, Moore RC, Rose CH, Cushman J, May W. Stroke and severe preeclampsia and eclampsia: a paradigm shift focusing on systolic blood pressure. Obstet Gynecol. 2005;105(2):246–54.
11. Gestational hypertension and preeclampsia. ACOG practice bulletin summary, number 222. Obstet Gynecol. 2020;135(6):1492–5.
12. American College of Obstetricians and Gynecologists, Council on Patient Safety in Women's Health Care. Patient safety bundle: Hypertension [Internet]. ACOG. 2015 [cited 2023 Jan 11]; https://saferbirth.org/wp-content/uploads/Severe-Hypertension-Bundle.pdf
13. Alliance for Innovation on Maternal Health, American College of Obstetricians and Gynecologists. Severe Hypertension in Pregnancy Patient Safety Bundle [Internet]. ACOG. 2022 [cited 2023 Jan 11]; https://saferbirth.org/wp-content/uploads/FINAL_AIM_Bundle_SHP2022.pdf
14. Shields LE, Wiesner S, Klein C, Pelletreau B, Hedriana HL. Early standardized treatment of critical blood pressure elevations is associated with a reduction in eclampsia and severe maternal morbidity. Am J Obstet Gynecol. 2017;216(4):415. e1-415.e5.
15. Kumar NR, Borders A, Young DR, Welty L, Lee King PA. 349: System improvements associated with reduced time-to-treatment for maternal hypertension in a statewide quality improvement Initiative. Am J Obstet Gynecol. 2019;220(1):S242–3.
16. Gupta M, Greene N, Kilpatrick SJ. Timely treatment of severe maternal hypertension and reduction in severe maternal morbidity. Pregnancy Hypertens. 2018;14:55–8.
17. Martin C, Pappas J, Johns K, Figueroa H, Balli K, Yao R. Semiautonomous treatment algorithm for the management of severe hypertension in pregnancy. Obstet Gynecol. 2021;137(2):211–7.
18. World Health Organization. Health equity [Internet]. Geneva: WHO. 2024 [cited 2023 Dec 29]. https://www.who.int/health-topics/health-equity#tab=tab_1
19. Harshe N. Respectful maternity care - A-ID [Internet]. Agenda for International Development (A-ID); 2021 [cited 2023 Dec 23]. https://www.a-id.org/respectful-maternity-care/
20. Wallerstein N, Oetzel JG, Sanchez-Youngman S, Boursaw B, Dickson E, Kastelic S, et al. Engage for equity: a long-term study of community-based Participatory Research and Community-Engaged Research practices and outcomes. Health Educ Behav. 2020;47(3):380–90.
21. Aguilar-Gaxiola S, Ahmed SM, Anise A, Azzahir A, Baker KE, Cupito A et al. Assessing Meaningful Community Engagement: A Conceptual Model to Advance Health Equity through Transformed Systems for Health: Organizing Committee for Assessing Meaningful Community Engagement in Health & Health Care Programs & Policies. NAM Perspectives. 2022;2022;22(2).
22. Soto E. Outpatient bundle for severe hypertension [Internet]. University of North Carolina School of Medicine; 2023 [cited 2023 Dec 29]. https://www.mombaby.org/outpatient-bundle-for-severe-hypertension/
23. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert recommendations for Implementing Change (ERIC) project. Implement Sci. 2015;10(1):21.
24. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implement Sci. 2013;8(1):139.
25. Deardorff DK. Story circles. Deardoff, DK Manual for developing intercultural competencies: story circles. 1st ed. France: UNESCO; 2020. pp. 13–69.
26. McCall B, Shallcross L, Wilson M, Fuller C, Hayward A. Storytelling as a research tool and intervention around public health perceptions and behaviour: a protocol for a systematic narrative review. BMJ Open. 2019;9(12):e030597.
27. Rieger KL, Gazan S, Bennett M, Buss M, Chudyk AM, Cook L, et al. Elevating the uses of storytelling approaches within indigenous health research: a critical and participatory scoping review protocol involving indigenous people and settlers. Syst Rev. 2020;9(1):257.
28. Institute for Healthcare Improvement. Quality Improvement Essentials Toolkit [Internet]. IHI. 2017 [cited 2023 Dec 29]. https://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx
29. Lamé G, Dixon-Woods M. Using clinical simulation to study how to improve quality and safety in healthcare. BMJ Simul Technol Enhanc Learn. 2020;6(2):87–94.
30. Damschroder LJ, Reardon CM, Opra Widerquist MA, Lowery J. Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR outcomes Addendum. Implement Sci. 2022;17(1):7.
31. Goodman MS, Ackermann N, Pierce KA, Bowen DJ, Thompson VS. Development and validation of a brief version of the research engagement survey tool. Int J Environ Res Public Health. 2021;18:19.
32. Miller CJ, Barnett ML, Baumann AA, Gutner CA, Wiltsey-Stirman S. The FRAME-IS: a framework for documenting modifications to implementation strategies in healthcare. Implement Sci. 2021;16(1):36.
33. Washburn LT, Traywick L, Thornton L, Vincent J, Brown T. Using Ripple effects Mapping to evaluate a community-based Health Program: perspectives of Program Implementers. Health Promot Pract. 2020;21(4):601–10.
34. Sadeghzadeh C, Sheppard B, de Groot J, De Marco M. Evaluating the benefits of a SNAP-Ed-Funded Community Garden intervention using Ripple Effect Mapping. Health Educ Behav. 2022;49(1):141–9.
35. Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. Organizational readiness for implementing change: a psychometric assessment of a new measure. Implement Sci. 2014;9:7.
36. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12(1):108.
37. Ehrhart MG, Aarons GA, Farahnak LR. Assessing the organizational context for EBP implementation: the development and validity testing of the implementation climate scale (ICS). Implement Sci. 2014;9:157.
38. Wiltsey Stirman S, Baumann AA, Miller CJ. The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. Implement Sci. 2019;14(1):58.
39. Finley EP, Huynh AK, Farmer MM, Bean-Mayberry B, Moin T, Oishi SM, et al. Periodic reflections: a method of guided discussions for documenting implementation phenomena. BMC Med Res Methodol. 2018;18(1):153.
40. Malone S, Prewitt K, Hackett R, Lin JC, McKay V, Walsh-Bailey C, et al. The clinical sustainability Assessment Tool: measuring organizational capacity to promote sustainability in healthcare. Implement Sci Commun. 2021;2(1):77.
41. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res. 2005;15(9):1277–88.
42. Dedoose. Cloud application for managing, analyzing, and presenting qualitative and mixed method research data. Los Angeles, CA: SocioCultural Research Consultants, LLC; 2023.
43. Baron RM, Kenny DA. The moderator–mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. J Pers Soc Psychol. 1986;51(6):1173–82.
44. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research. 3rd ed. United States: Sage; 2018.
45. Silverman D, Marvasti A. Doing qualitative research. 5th ed. London: SAGE; 2008.
46. Zurynski Y, Ludlow K, Testa L, Augustsson H, Herkes-Deane J, Hutchinson K, et al. Built to last? Barriers and facilitators of healthcare program sustainability: a systematic integrative review. Implement Sci. 2023;18(1):62.
47. Lengnick-Hall R, Williams NJ, Ehrhart MG, Willging CE, Bunger AC, Beidas RS, et al. Eight characteristics of rigorous multilevel implementation research: a step-by-step guide. Implement Sci. 2023;18(1):52.
48. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. Implement Sci. 2022;17(1).

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