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ARAM V. CHOBANIAN & EDWARD AVEDISIAN SCHOOL OF MEDICINE

Thesis

THE EFFECTS OF A COMMUNITY DOULA PROGRAM ON PERINATAL OUTCOMES AND RESPECTFUL CARE

by

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THE EFFECTS OF A COMMUNITY DOULA PROGRAM ON PERINATAL OUTCOMES AND RESPECTFUL CARE

KRISTINA TORENO

ABSTRACT

The United States maternal mortality ratio has been increasing for several decades with persistent disparities negatively impacting birthing people of color. Health inequity in perinatal care is often attributed to obstetric racism and a lack of access to continuous birthing support. While research on the specific impacts of community-based doulas on perinatal outcomes and respectful care is lacking, a growing body of evidence supports the positive impacts of doula support on perinatal outcomes and patient experiences during pregnancy care. Numerous studies have also demonstrated that doula support can mitigate the effects of systemic racism on birthing people of color. Despite the evidence of positive outcomes associated with doula services, marginalized communities, such as Black and low-income birthing people, often lack access to this essential care.

The proposed study aims to measure the impacts of a community doula program on improving perinatal outcomes, including rates of cesarean sections, preterm births, breastfeeding, and experiences of respectful care among birthing individuals. This project will be conducted as a parallel-group, pragmatic single-center trial with 1:1 randomization at Boston Medical Center. The intervention group will receive services from the Birth Sisters Program, which includes prenatal home visits, continuous labor and birthing support, and postpartum home visits. The usual care control group will receive standard interdisciplinary maternity care.

Data collection will involve extracting outcomes from electronic medical records and conducting postpartum interviews. The analysis will include intent-to-treat and post hoc per-protocol analyses to assess the intervention's practical effectiveness and potential efficacy. The primary outcome will be the proportion of cesarean births, while secondary outcomes will include preterm birth, low birth weight, breastfeeding initiation and exclusivity, and respectful care. Exploratory subgroup analyses will focus on the intervention's impact on Black non-Hispanic participants compared to other races/ethnicities.

This project aims to contribute to future research on the benefits of doula care and fill a gap in the existing literature by focusing on community doula programs and their impact on health equity and respectful care. This study has the potential to inform clinical practice and public health policy, advocating for expanded access to doula services and addressing perinatal health disparities.

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INTRODUCTION

Background

Maternal health outcomes in the United States reveal a troubling landscape, particularly for birthing people of color. The maternal mortality ratio has been steadily increasing for decades, making the United States an outlier among other high-income, industrialized nations.[1] Further, Black women are more than three times as likely to die from pregnancy-related causes as white women.[2] This disparity is not solely a result of socioeconomic factors; it is deeply rooted in systemic inequities and obstetric racism.[3,4]

Continuous support during childbirth, such as that provided by doulas, has been shown to improve maternal and infant outcomes.[5,6] Doulas offer non-medical support, including emotional, physical, and informational assistance throughout pregnancy, labor, and postpartum. Doula care has been shown to reduce the incidence of cesarean sections, shorten labor, and improve overall satisfaction with the birthing experience.[7–9] However, access to doula services is limited, particularly for marginalized communities.[10]

Community-based doula programs, like the Birth Sisters Program at Boston Medical Center, aim to bridge this gap. These programs employ doulas from the same community as their clients, fostering trust and cultural competence.[11]

Statement of the Problem

The increasing maternal mortality ratio in the United States, particularly among women of color, highlights significant disparities in perinatal care. Obstetric racism and systemic inequities contribute to these adverse outcomes, underscoring the urgent need for interventions that promote respectful and equitable care.[4] While doula support has

been shown to improve perinatal outcomes, there is a notable gap in the literature regarding its effects on psychosocial outcomes. Specifically, there is a lack of comprehensive studies evaluating how community-based doula programs impact perinatal outcomes and respectful care. Addressing this gap is crucial for informing public health policies and clinical practices that aim to reduce perinatal health disparities and promote patient-centered care.

Hypothesis

A community doula intervention will significantly improve perinatal outcomes among lower-risk, nulliparous birthing people. Compared to routine care, it will reduce cesarean and preterm birth rates and increase breastfeeding initiation and continuation rates. Additionally, the intervention is expected to increase participants' reporting of respectful care during labor and childbirth.

Aims

This study seeks to explore the effects of a community doula program on perinatal outcomes and respectful care. It aims to provide evidence that doula services provide benefits to nulliparous, low-risk individuals from a diverse, low-income population by assessing cesarean birth rates, preterm birth rates, breastfeeding outcomes, and respectful care. The findings may inform clinical practice and public health policies, advocating for broader implementation and coverage of doula services to reduce perinatal health disparities. Specific aims of the proposed study include:

1. To assess the impact of the community doula intervention in reducing cesarean births and preterm births and improving breastfeeding outcomes.

2. To assess the impact of the community doula intervention on the rates of respectful care.

REVIEW OF THE LITERATURE

Overview

Perinatal Health Inequity

Addressing the rising number of adverse perinatal outcomes is an urgent public health issue in the United States. Over the last 30 years, maternal mortality has increased, rising from 7.2 deaths per 100,000 live births in 1987 to 17.6 in 2019, according to the Centers for Disease Control and Prevention (CDC) Pregnancy Mortality Surveillance System (PMSS).[1] Significant racial and ethnic disparities exist within the rising numbers of pregnancy-related mortality.[12] Notably, non-Hispanic Black birthing people have a 3- to 4-fold increased risk of death due to pregnancy complications compared to white individuals.[2] From 2017 to 2019, the pregnancy-related mortality ratios (PRMRs) provided by the CDC were 39.9 deaths per 100,000 live births among non-Hispanic Black persons compared to 14.1 for non-Hispanic white persons.[1] Additionally, Black birthing people have the highest proportion of severe maternal morbidity during antepartum, intrapartum, and postpartum hospital admissions in the United States.[13] Many of these sobering statistics hold true in Massachusetts as well. Despite having one of the best healthcare systems in the country, the severe maternal morbidity rate for Black birthing individuals in Massachusetts is 2.5 times higher than that of white birthing individuals.[14]

Racial disparities also exist in rates of cesarean delivery. Black and Latinx birthing individuals are more likely to undergo cesarean section compared to white birthing individuals.[15] The risk of cesarean section is highest among Black birthing

individuals and these disparities persist even after adjusting for chronic diseases, complications of pregnancy, and sociodemographic factors.[15,16] Higher rates of preterm birth and lower rates of breastfeeding exist among non-Hispanic Black people and Hispanic people compared to white people.[17,18] Low socioeconomic status is also associated with higher rates of preterm birth.[19]

Factors Contributing to Inequity

The racial inequities in perinatal health outcomes are rooted in systemic and structural racism, sexism, and classism.[3] Extensive research supports structural racism as the source of many of the disparities in adverse perinatal outcomes between Black and white patients in the United States.[4] Black people along the entire reproductive lifespan have identified several domains of structural racism that they experienced with potential adverse impacts on maternal and infant outcomes, including inadequate access to medical care, neighborhood segregation, lack of resources tailored toward Black communities, unequal access to education, racial discrimination in employment, and over-policing of Black families.[20] Many Black people's descriptions of their pregnancies, labors, births, and postnatal experiences within maternity care services highlight the pervasive obstetric racism they experience; they describe instances of neglect, dismissiveness, disrespect, withholding of information regarding their care, and obstetric violence in the perinatal period.[21] Women of color describe how power and privilege influence the provider-patient dynamic and can decrease their ability to be meaningfully involved and actively participate in their healthcare decisions.[22]

Respectful Care

Leading health agencies, including the World Health Organization (WHO), are prioritizing person-centered, respectful maternity care.[23,24] The WHO Framework for improving the quality of perinatal care emphasizes that birthing people's experiences of care are equally important to clinical care provision.[25] The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) developed evidence-based guidelines and implementation tools for provider and organizational improvement in providing respectful perinatal care.[26] Respectful maternity care protects a birthing person's right to dignity and privacy, facilitates informed choice in their care, ensures freedom from harm and mistreatment, and enables continuous support during labor and birth.[27]

However, not all birthing people experience respectful care and many experience mistreatment.[28,29] Many women (17%) report experiencing mistreatment while receiving perinatal care and rates of mistreatment for low-income women of color are exceptionally high.[28] Mistreatment may include physical or verbal abuse, discrimination, non-consented exams or procedures (e.g., cesarean section, episiotomy, induction of labor), lack of privacy, lack of supportive care, and neglect.[29] The experience of mistreatment can deter people from seeking further essential perinatal care, impede provider-patient communication, and affect medical decision-making, which further exacerbate inequities in perinatal health.[30–32]

Efforts to measure and implement respectful care practices in perinatal services are growing but there is currently no core outcome set and few existing validated tools

for measuring respectful care or mistreatment.[33] Additionally, few studies have focused on addressing the disparities in respectful care adversely impacting birthing people of color.[28,34–36] The Changing Childbirth in British Columbia and Giving Voice to Mothers studies were conducted to respond to these gaps and lead to the development of the Mothers on Respect Index.[28,37] The Mothers on Respect (MOR) index is a tool for assessing birthing individuals' experience of respect and ability for self-determination in perinatal care.[37] It is a patient-informed quality and safety indicator that can assess the nature of provider-patient relationships and access to person-centered care. It is a validated and reliable measure of respectful maternal care and has been administered to birthing people in the US and Canada.[37,38] It comprises a 14-item scale with Likert response options to rate their level of comfort, impact on their willingness to ask questions, and perceptions of racism or discrimination when receiving care. The tool has many potential uses, including evaluating the psychosocial aspect of informed consent processes, informing institutional quality improvement initiatives, and assessing patient-oriented outcomes in perinatal research.

Overview and Benefits of Doulas

A doula is a non-clinical, trained birth worker who provides continuous physical, emotional, and educational support to people during labor and birth and intermittent support during pregnancy and postpartum.[39] Like community health workers, they work alongside healthcare providers to support their clients but do not offer medical care. The scope of doula services may expand beyond labor and birth to include the full spectrum of pregnancy outcomes, including support in instances of spontaneous and medical

abortion, stillbirth, and perinatal loss.[40] Over 100 independent organizations offer doula training and certification, such as DONA International (formerly Doulas Of North America) and Childbirth and Postpartum Professional Association (CAPPA), though not all doulas seek certification.[41] There are currently no mandatory licensure or certification requirements for doulas to practice in the United States.

Continuous birthing support, such as what a doula offers, significantly improves many perinatal outcomes.[6] Continuous birthing support typically includes emotional and physical support, comfort measures, information regarding the progress of labor, coping techniques, and advocacy for the birthing individual.[6] A review of studies found that individuals provided with continuous birthing support, such as a doula, had shorter duration of labor and increased rates of spontaneous vaginal birth compared to those with usual care.[6] Continuous birthing support was also associated with decreased cesarean birth rates, reduced intrapartum analgesia use, and higher satisfaction with labor and birth.[6]

In addition to providing the noted benefits of continuous birthing support, doulas may also offer support during pregnancy and in the postpartum period.[39] This continuity of care allows doulas to build a trusting relationship with the birthing person, understand their concerns and expectations for birth, and assess their labor coping skills and specific emotional needs.[42] Doulas may also provide health education, fostering health literacy and confidence for clients to make more informed medical decisions.

A robust literature on doula support demonstrates that they improve several perinatal outcomes and have the potential to be cost-effective or even cost-saving.[6,7]

Doula-supported births are associated with lower rates of nonindicated cesarean deliveries, lower rates of low birth weight, fewer obstetric interventions, fewer complications, less use of pain medication, shorter duration of labor, higher infant APGAR scores, and higher breastfeeding rates.[6–9,43] Their support contributes to fewer perinatal complications, improves postpartum mental health, and is associated with higher satisfaction in labor and birth.[6,44,45] A consensus statement made in 2014 by the American College of Obstetricians and Gynecologists explicitly endorsed the use of "one of the most effective tools to improve labor and delivery outcomes, the continuous presence of support personnel, such as a doula."[46]

Doula support in the perinatal period may also be an effective tool to address the persistent health inequities among birthing people of color and other at-risk communities. A meta-analysis of randomized controlled trials revealed that doula support has a particularly positive impact on birthing individuals who have low income, are socially disadvantaged, or face cultural or language barriers to healthcare access.[47] Doulas have also been shown to disrupt the pathways between negative social determinants of health and poor perinatal outcomes by improving access to healthcare and social services and boosting health literacy.[48] Physicians, certified nurse midwives, and nurses have described how doulas foster accountability within the healthcare team and mitigate racism and implicit bias in the perinatal setting.[49] They also acknowledge that doulas fill critical gaps in perinatal care, including offering continuous labor support, which is often not feasible for clinicians to provide.

Community-Based Doulas

Community-based doula care has recently become a focus as a potential intervention to address racial disparities in perinatal health. Community-based doulas are members of the communities they serve, often sharing the same background, culture, experiences and language as their clients.[11] This gives them a more personal perspective of the birthing person's lived experiences and insight to effectively address unique challenges they may face in the perinatal period, such as racial discrimination and language barriers. Racial and cultural congruence within the doula-client relationship helps foster trust and confidence in care, which may positively impact birth outcomes.[50,51] This is particularly important for Black communities, as they report significantly higher levels of mistrust of the medical care system.[52] Compared to traditional or private doulas, community-based doula programs typically provide more extensive support to clients, including more pre- and postpartum home visits and a broader range of services and referrals tailored to the client's needs. Community doulas are knowledgeable in local resources and can refer clients to appropriate social services for issues outside of pregnancy and birth, such as housing insecurity, mental health, and intimate partner violence. Community-based doula models also prioritize education, mentorship, and ongoing training for doulas to provide culturally competent, trauma-informed care and adapt to the changing needs of their community. These services are low or free of cost to clients to ensure access for at-risk communities with complex social needs. The intimate knowledge and skills of community doulas make them uniquely equipped to mitigate the effects of discrimination and inadequate social support on perinatal health.[11]

Access to Doulas

Despite the benefits and cost-effectiveness of doula care, only six percent of birthing people receive support from a doula during labor in the United States.[10] One barrier to access is cost. Although doula services have been shown to contribute to significant cost savings, their services are typically not covered by private insurance and few states provide Medicaid reimbursement for doula services.[40,53] This disproportionally affects racially and ethnically minoritized birthing people. Both Black and low-income birthing people, who face the highest risk of poor perinatal outcomes, are also the most likely groups to express the desire for doula support but lack access to it.[8] As such, doulas are most utilized by white middle- and upper-class communities.[54] Several Black-led advocacy organizations, including Black Mamas Matter Alliance (BMMA) and Every Mother Counts (EMC), advocate for legislation to expand access to community doula care, the expansion of Medicaid coverage for doula care, the adjustment of reimbursement rates to ensure doulas earn a livable wage, and funding to train and certify a diverse doula workforce.[11,55]

Boston Medical Center's Birth Sisters Program

The Birth Sisters model of community doula support, which provides perinatal support from racially and culturally congruent, trained birth workers from the community, began as a pilot program in 1999 at Boston Medical Center.[56] Today, approximately 20 Birth Sisters are staffed at Boston Medical Center. Reflecting the diverse population they serve, the Birth Sisters speak over ten languages, represent over

fifteen ethnicities, and primarily support minority communities in the Boston area.[56,57] The program, funded entirely by philanthropy, costs about $1,000 per client.

Birth Sisters receive standardized didactics and on-site training through the Birth Sisters Program before starting in their role. Didactics include topics on anatomy and physiology, labor support techniques, patient health education, and community resources. Following didactics, Birth Sisters shadow experienced trainers and complete a competency checklist. Monthly meetings provide ongoing education and supervision. They can also elect to join a Community Health Worker training program.[56]

The Birth Sisters services span the client's entire pregnancy and postpartum period. Prenatal care providers typically refer patients to the program and Birth Sisters are matched with clients based on language and cultural congruency. Services include up to eight prenatal visits, attendance through labor, and four postpartum visits. Visits are customized based on the birthing person's preferences and needs. Prenatal home visits allow the Birth Sister to build a relationship with their client before labor and birth and provide guidance and education on labor, birth, and breastfeeding. They may also identify any specific needs of the client, such as housing insecurity, and connect the client to community resources and social services. During labor and birth, the Birth Sister offers physical and emotional support, advocates for the client, and acts as a liaison between the birthing person and the other healthcare providers. During postpartum visits, Birth Sisters assist with newborn care and education, companionship and emotional support, and navigation of medical and social services.[56]

Existing Research

Doulas' Impacts on Clinical Outcomes

Five novel studies investigating the impacts of doula support on perinatal outcomes, such as rates of cesarean birth, preterm birth, low birthweight, and breastfeeding, will be reviewed here. These studies were selected based on their inclusion of the clinical outcomes of interest, specific investigation of community-based doulas, setting in a diverse, low-income study population, and/or assessment of impacts based on race/ethnicity. The first two studies examine the effects of a community doula program integrated into a safety-net hospital in Boston, Massachusetts. The third and fourth studies examine a community doula program that serves low-income birthing people in Brooklyn, New York. The final study investigates the incorporation of doula services into the healthcare teams of Medicaid-insured birthing people in Jefferson County, Alabama.

A randomized control trial published in 2023 investigated the clinical outcomes of one of the few hospital-based community doula programs in the United States, the Boston Medical Center's Birth Sister doula program.[58] The intervention group received doula services from a Birth Sister, including prenatal visits, support throughout labor and birth, and postpartum visits, while participants in the control group received routine perinatal care. The intervention group received services from the Medical-Legal Partnership of Boston (MLPB) in addition to the doula services. MLPB provided legal assistance, appropriate resources for participants, and relevant training for the doulas. Eligible pregnant people were randomized into the intervention group or usual care. Outcomes of the study included rates of cesarean section, preterm birth, low birth weight,

breastfeeding outcomes, Apgar scores, neonatal intensive care unit (NICU) admissions, and postpartum depression screening scores. Intent-to-treat and per-protocol analyses of the data were conducted, along with exploratory analyses by race/ethnicity.

There was no significant difference in outcomes in the intent-to-treat or per-protocol analysis.[58] However, the exploratory analysis found an absolute reduction in cesarean sections of 12.9% and an increase in breastfeeding exclusivity of 11.5% for Black non-Hispanic participants.

This study is significant as prior research specifically investigating hospital-based community doulas is sparse. Additionally, little data exists on the benefits of doulas who are racially and culturally congruent with their clients. Though not statistically powered, the exploratory analysis suggests that the Birth Sisters model, in combination with MLPB services, is associated with improved outcomes for Black, non-Hispanic patients. Statistical differences in outcomes between groups were not detected, likely due to low enrollment and smaller than anticipated sample size, a significant limitation to the study's results. Furthermore, the study excluded individuals with high-risk pregnancies, such as those with pre-existing diabetes and hypertension, conditions that disproportionately affect Black people, who may have significantly benefited from the community doula intervention.[59,60]

A retrospective cohort analysis of the Birth Sisters doula model found more promising results.[61] Using data from 11,471 women from an obstetric database, the study compared differences in birth outcomes between those who received doula support from a Birth Sister to those without over seven years. Log-binomial regression models

evaluated differences in perinatal outcomes, including cesarean section rates, use of epidural anesthesia, operative vaginal delivery rates, Apgar scores, breastfeeding intent, and early breastfeeding initiation. The study also examined risk factors likely to affect outcome measures, such as breech presentation and malposition, placenta previa, abruption, and labor induction. Trend analysis using a Cochran-Mantel-Haenszel test was conducted to assess for outcome changes over time as the program strengthened and developed.

For the entire cohort, those who received doula support were significantly more likely to intend to breastfeed and initiate breastfeeding.[61] Intent to breastfeed and early initiation of breastfeeding increased over time for both those with Birth Sister support and those without. No significant change over time was observed in total or primary cesarean deliveries, epidurals with vaginal delivery, operative vaginal delivery, or Apgar scores between groups. However, subgroup analysis found that primiparous people cared for by a midwife provider showed a significant reduction in cesarean births with the addition of doula support.

This evaluation provides strong evidence supporting the Birth Sister Program as a model for increasing rates of breastfeeding intention and early breastfeeding initiation, which are correlated with higher rates of long-term breastfeeding in the postpartum period.[61,62] Additionally, these findings suggest that perinatal care involving midwives and Birth Sister doula support together leads to excellent birth outcomes, especially for primiparous people. However, these results are inherently limited by the possibility of

bias due to the population differences between the groups, despite controlling for confounding and the use of the propensity score.

Another study, published in 2023, examined the effects of a community doula program based in Brooklyn on birth outcomes.[63] The study aimed to determine whether participation in Healthy Start Brooklyn's By My Side Birth Support Program improved birth outcomes by comparing the proportions of preterm birth, birthweight, and cesarean section with similar birthing people in the community. Data were collected using birth certificate records from 2010 through 2017. A matched cohort design was used to match intervention participants, those who participated in the By My Side Birth Support Program, with controls from the community based on age, race/ethnicity, education, and trimester of prenatal care initiation. Participants (n=603) were matched to three controls (n=1809) and odds of birth outcomes between the groups were estimated using conditional logistic regression. Eligibility for receiving By My Side support was restricted to residents in one of six ZIP codes in Brooklyn, New York and those eligible for the Women, Infants, and Children nutrition program (WIC). The control group was limited to the same ZIP codes used for the doula program eligibility.

Compared to the control group, the By My Side intervention group had significantly fewer preterm births (5.6% vs 11.9%, $P < .0001$) and fewer low birthweight babies (5.8% vs 9.7%, $P = .0031$).[63] These differences persisted even after adjusting for factors that could influence birth outcomes, such as gestational hypertension, gestational diabetes, and pre-pregnancy BMI. However, no statistically significant difference was present in the odds of cesarean birth between groups (OR = 0.92; 95% CI = 0.79-1.19).

Participants in the doula intervention group were also found to be more likely to report sociodemographic risk factors, such as receiving Medicaid and WIC benefits, than the controls.

Despite some limitations, this study provides another example of how community-based doula support may effectively improve adverse perinatal outcomes.[63] One limitation of the study is that it is unknown if any control group participants received doula support during their pregnancy and birth, as this was not recorded in birth records at the time of the study. However, the authors note that the national prevalence of doula support is reportedly low, likely reflecting a low prevalence in the control group. Additionally, participants who received By My Side doula support may have received a different number of prenatal visits depending on their gestational age at enrollment, which may have impacted birth outcomes. This study reinforced the results of a previous analysis of the By My Side doula program by using an analytical approach that controlled for additional covariates described below.

A study published in 2017 comparing birth outcomes of the By My Side Birth Support Program with those of residents overall in the program area yielded similar results.[64] The study found significantly lower rates of both preterm birth (6.3 vs. 12.4%, $p < 0.001$) and low birthweight (6.5 vs. 11.1%, $p = 0.001$) among those who received By My Side support compared to others in the program area. No statistically significant difference was found in the cesarean section rates between the groups. This outcome is unexpected, as continuous birthing support that doulas provide has been shown to improve labor progression and reduce the need for medical interventions, including

cesarean section.[5,6] However, emerging research suggests that cesarean rates are also influenced by factors such as the type of primary birth provider (obstetrician or midwife) and specific hospital management practices, all factors unaffected by a birthing person's use of doula services.[65,66] It would be beneficial for future research to explore how specific hospital practices or policies might restrict doula support and attenuate their ability to impact the mode of delivery, which may help explain this unexpected outcome. The researchers are currently creating an assessment tool for By My Side doulas to record the barriers and biases they and their clients experience in hospital settings to investigate this further.

Incorporating doula care into the birth care team was also shown to be associated with lower rates of epidural anesthesia use and cesarean births, as well as a ten-fold increase in breastfeeding initiation among low-resource birthing people in Alabama.[67] This study retrospectively compared perinatal birth outcomes from a reference population of all Medicaid-covered births in Jefferson County, Alabama to a subgroup of births supported by doulas from 2013 to 2014. BirthWell Partners, a nonprofit in Central Alabama, incorporated doula services into an interprofessional birth care team for birthing people at little to no cost. Outcomes of the study included rates of birth by induction, preterm birth, low birth weight, epidural anesthesia use, cesarean section, and breastfeeding initiation. These outcomes were compared between those with and without doula support using the maximum likelihood odds ratios and 95% confidence intervals. A separate analysis was conducted on the birth outcomes of Black and white people in the groups.

Birthing people in the reference population insured by Medicaid were three times more likely to receive epidurals for pain management than those in the doula-supported group (OR = 3.0; 95% CI 2.1–4.4; $p < 0.0001$).[67] Those in the reference population were 1.8 times more likely to have a cesarean birth than those with doula support (OR = 1.8; 95% 1.1–2.9; $p = 0.008$) and those in the doula-supported group were 10.5 times more likely to initiate breastfeeding in the hospital than the reference population (OR = 10.5, 95% 5.4–23.2; $p < 0.001$). When analyzing the data of Black and white birthing people separately, these outcomes persisted, except for cesarean rates among Black birthing people.

These findings support doula services as a cost-effective intervention for improving perinatal outcomes and a tool to mitigate birth disparities in Black birthing people.[67] However, the study failed to show a reduction in preterm birth rates and induction rates among the doula-supported group. The small sample size of doula-supported births and limited power may have contributed to these findings. Additionally, the study did not control for selection bias. Lastly, 80% of the doulas providing support for the study population were white, which limited racial congruence among the doula-client pairs.

Doulas' Impacts on Patient Experiences and Respectful Care

While much of the literature explores clinical outcomes associated with doula support, few studies have examined its impacts on client experiences in labor and childbirth and even fewer specifically focus on community-based doulas. The limited research that does exist suggests that doulas play an important role in clients' birthing

experiences.[52,68,69] The two studies reviewed here investigate the impacts of community-based doulas on birthing people's experiences. The first is a qualitative study exploring Black doula clients' motivations for seeking out and experiences with doula care. To our knowledge, the second is the only study to date that quantifies the impact of doulas on respectful care.

A mixed methods process evaluation of a free community doula program in San Francisco, California found that community doulas benefitted participants' experiences by helping participants feel understood, supported, and emotionally prepared during their pregnancies and births.[70] The doula program, SisterWeb, provides no-cost doula services to Black, Pacific Islander, and Latinx clients. Fourteen participants completed two in-depth interviews, one in the antepartum and one in the postpartum period. The first interview focused on clients' motivations for seeking doula care and the second explored clients' experiences and feelings about the doula care they received. Data were analyzed using a Rapid Assessment Process and a modified reflexive thematic analysis approach.

All fourteen participants identified as Black, one identified as Pacific Islander, and ten were Medicaid insured.[70] Most participants had not heard of a doula before learning about the SisterWeb program and, of those that had, knowledge of their services was limited. Most participants described the need for support as the primary motivating factor for seeking doula services due to lack of support from their partners or families, past negative experiences with medical staff, or the health inequities affecting Black women. One participant noted:

> "*When you are a foreigner with [an] accent, maybe the color speaks before you. Like, I'm well educated, and I can do my research, and I can be self-sufficient, but sometimes you feel like people, you know, there are stereotypes, and people might… undermine you in a way, or reach to conclusions. And sometimes when you come with someone who has experience in that area it helps."*

Participants also highlighted the care they received as comforting, reassuring, and comparable to relationships with their family, which often stemmed from a shared culture and community with their doulas.[70] This allowed them to feel comfortable to communicate openly and express their needs. Participants also described appreciating the educational support from their doulas, including learning about their rights in the hospital setting and developing a birth plan. They also described how their doulas' services extended beyond pregnancy and birth, providing them with referrals to social and structural support. Other participants noted how their doulas supported them in their medical decision-making. One stated:

> *"[Preparing with my doulas] made me feel good, definitely offered some reassurance that this is my experience and I wanted to make it as comfortable as possible. Them listening to what I had to say, and also being a support system for me, really helped make the decision in regard to the pain management."*

This analysis found that community doulas provide needed support, offer essential services distinct from clinical care, and benefit participants' birthing experiences.[70] It also suggests that racial and cultural congruence between doulas and

clients may improve birth experiences for people of color. The study is limited by its sampling from a single organization and specific geographical context.

Another study, published in 2022, analyzed the data of 1,977 birthing people in California to examine the association between doula support and respectful care.[71] Data were collected from the Listening to Mothers in California survey conducted in 2018, which surveys the experiences of birthing people in the perinatal period. The investigators defined respectful care based on responses to questions regarding the patient's experience during labor and birth. This included questions on communication with staff during labor, involvement in the decision-making process, and overall support from the healthcare team. These responses were compared among those with self-reported doula support and those without using multivariable logistic regressions. Associations were also examined based on the birthing person’s race/ethnicity and insurance status.

Analysis revealed that 15.7% of participants reported doula support.[71] Non-Hispanic multiracial participants reported the lowest prevalence of high respectful care. Respectful care was higher among privately insured participants compared to those insured by Medicaid and those who received primary birth care from a midwife compared to a physician. Those with doula support were 40% more likely to receive high respectful care. Among non-Hispanic Black individuals, the odds of respectful care were 2.7 times higher in individuals supported by a doula. And, among those insured by Medicaid, individuals with doula support had 80% higher odds of receiving respectful care than those without.

The literature review reveals substantial evidence that doula support improves perinatal outcomes, including lower rates of cesarean sections, shorter labor durations, and enhanced overall satisfaction with the birthing experience. Despite these benefits, access to doula care remains limited, particularly for marginalized communities. The review also highlights a significant gap in research specifically examining the effects of community-based doula programs on respectful care. Addressing this gap is crucial for informing public health policies and clinical practices aimed at reducing perinatal health disparities.

METHODS

The following study proposal is based on a randomized control trial investigating the effects of a community doula intervention on perinatal outcomes in a safety-net hospital in Boston, Massachusetts.[58] The proposed study will extend its efforts by focusing on the enhancement of the doula intervention internally via staff training, education, and mentorship. In addition to the primary and secondary outcomes of the prior study, this will also include an assessment of the impacts of participants' experiences of respectful care during labor and childbirth. This outcome will be assessed quantitatively using MOR Index scores (Appendix A). Additionally, a smaller anticipated absolute reduction in the primary outcome, cesarean births, will be used. The enrollment period will be extended to achieve the adjusted required sample size.

Study Design

Investigators will conduct a parallel-group, pragmatic single-center trial with 1:1 randomization to assess the impacts of a community doula program intervention on perinatal outcomes, including rates of cesarean birth, preterm birth, breastfeeding outcomes, and respectful care for nulliparous, lower-risk pregnant individuals with public insurance coverage. Participants will be randomized into the doula intervention group or routine care. Informed consent will be obtained from all participants, ensuring they understand the study design and their potential group assignment.

Study Population and Sampling

The study will occur at Boston Medical Center, a safety net hospital serving a diverse population of approximately 2400 births per year, of which 85% are publicly

financed. The source population from which participants will be recruited will include nulliparous pregnant patients who are covered by Medicaid or public insurance and between 16- and 24-weeks gestation. Research assistants will assess eligibility and recruit participants at routine ultrasound visits. Exclusion criteria will include patients under 18 years of age, multiple gestation pregnancies, known fetal anomalies, or high-risk pregnancies.

Assuming a baseline cesarean rate of 33.1% (based on the most recent CDC birth data[72]) and an expected reduction with the study intervention to 25.1% (an 8% absolute reduction), a two-tailed test with 80% power and a significance level of 0.05 was used to calculate the sample size. An estimated 502 participants will be needed per group. Adjusting for dropouts (estimated 5%), loss to follow-up (estimated 10%), and scheduled cesarean rate (estimated 5%), a sample size of approximately 652 participants per group will be required.

Intervention

The intervention group will receive comprehensive services from the Birth Sisters Program. Participants will be matched with a Birth Sister who is racially congruent as available. Eligible participants will receive Birth Sister services starting at 24 weeks gestation, which will include between one and eight 2-hour prenatal home visits, continuous labor and birthing support, and between one and four 2-hour postpartum home visits through 6-8 weeks postpartum, tailored to the client's needs and preferences.

Prenatal visits will be focused on establishing a trusting and supportive doula-client relationship. The Birth Sisters will provide anticipatory guidance on labor, childbirth, and

breastfeeding, ensuring clients are well-prepared for childbirth. They will also assess the clients' psychosocial and emotional support needs, help develop personalized birth plans that align with their preferences and address any concerns. Additionally, the doulas will assist clients in understanding and accessing necessary medical services and will evaluate social determinants of health, such as housing insecurity, food insecurity, and intimate partner violence. As needed, clients will be connected to relevant social service agencies and community resources.

Birth Sisters will offer continuous birthing support during labor and birth, providing physical and emotional comfort measures such as massage, positioning, and breathing techniques. They will facilitate communication between the client and the healthcare team to ensure clear communication. Doulas will support the client’s needs and birth preferences, ensuring their voice is heard in medical decision-making. Doulas will also assist the client with the initial stages of breastfeeding immediately after birth.

At postpartum visits, Birth Sisters will conduct ongoing evaluations of social needs, ensuring the client has access to necessary follow-up care and support services. They will also provide guidance and assistance with breastfeeding techniques and newborn care and offer emotional and practical support to help the client adjust to parenthood.

Birth Sisters will receive relevant training on the core components of the intervention before the study initiation to maximize fidelity. Monthly group meetings will be held with Birth Sisters and the Program Director to discuss cases, share experiences, address challenges, and provide ongoing education. Supervision and mentorship will be

available where experienced Birth Sisters can support and guide newer members, increasing consistency in the intervention. Birth Sisters will be allowed to create personalized care plans that cater to each client's specific needs and preferences to ensure that the intervention is relevant and responsive to individual circumstances.

Routine Care

Participants in the usual care group will receive standard, interdisciplinary maternity care services provided at the study site. Services will include individual care from physicians and midwives, group prenatal care with social support from other pregnant patients, childbirth education classes, social work support, in-patient lactation consultants, and 24-hour interpreter services.

Project Variables and Measures

The primary outcome will be the proportion of cesarean births. Secondary outcomes will include preterm birth (before 37 weeks 0 days of gestation), low birth weight (under 2500 g at birth), breastfeeding initiation and exclusivity during delivery hospitalization, continuation of breastfeeding at the postpartum interview, Apgar scores below 4 at 5 minutes, neonatal intensive care unit (NICU) admissions, obstetrical hemorrhage (quantitative blood loss >1000 mL), hypertension (defined as at least two blood pressure readings >140/90 at least 4 h apart recorded in the medical record or billing data), and respectful care (defined as a high MOR Index score of 67-84 [Appendix B]).

Data Collection

Data for outcomes measured during delivery hospitalization will be obtained from the electronic medical record. Data on breastfeeding continuation and MOR Index scores (Appendix A) will be gathered during the postpartum interview.

Data Analysis

Data will be analyzed with SAS. Intent-to-treat and *post hoc* per-protocol analyses will be conducted to assess the intervention's practical effectiveness and potential efficacy. A significance level of 0.05 will be used. Categorical variables will be compared using either chi-square or Fisher's exact test. *p*-values for the primary outcome and odds ratios with 95% confidence intervals for secondary outcomes will be calculated. Logistic regression will be used to control for covariates for breastfeeding continuation outcomes. Exploratory subgroup analyses will be conducted to explore the intervention's potential to reduce disparities for Black non-Hispanic participants compared with all other races/ethnicities.

Timeline and Resources

Planning and preparation will occur in the first three months, during which the study protocol will be finalized, International Review Board (IRB) approval will be obtained, study staff will be recruited and trained, and data management systems will be established. The participant enrollment timeframe will be January 2025 to January 2030, and data collection will occur through August 2030. Data analysis and interpretation will occur in the final three months and the study will conclude in November 2030. The key personnel needed for the successful implementation of the project include a primary

investigator (PI) who will oversee the entire study, co-investigators to assist with study design and data interpretation, and a statistician to design and perform data analysis. A study coordinator will manage day-to-day operations, research assistants will handle participant recruitment, data collection, and follow-up, clerical staff will manage administrative tasks, and student workers will assist with data collection and preliminary analysis.

Institutional Review Board

The study will be submitted to the Institutional Review Board (IRB) for expedited review. This study involves minimal risk to participants as it primarily consists of data collection from electronic medical records and surveys to gather data on birthing individuals' health outcomes and experiences. Although the study includes pregnant people, who are considered a vulnerable population, the research focuses on non-invasive data collection methods and aims to improve maternal health outcomes and care quality. Adequate measures will be taken to ensure participant confidentiality, informed consent, and safety. Given the minimal risk and the straightforward nature of the data collection process, an expedited review is justified. IRB approval will be obtained before commencing the study to ensure adherence to all ethical guidelines and protections for the participants.

CONCLUSION

Discussion

The Birth Sisters program provides a model for incorporating community doula care into perinatal care services in a safety-net hospital setting and the proposed study will evaluate its impact on improving health outcomes and reducing racial disparities in birthing people.

Several limitations may restrict the proposed study outcomes and generalizability. The study will be conducted at a single urban safety net hospital, which may limit the generalizability of the findings to other settings, such as rural or suburban areas or hospitals with different patient demographics and resources. Despite adjustments in sample size calculations to account for dropouts and loss to follow-up, these factors could still introduce bias and affect the robustness of the findings. Additionally, the number of prenatal and postpartum visits can vary widely depending on client preferences and needs, which might lead to variability in the intervention's dose and effectiveness. The exclusion of high-risk pregnancies will also limit the full understanding of the potential impacts of doula support.

The ethical considerations of randomization in this study are also important to note. While existing evidence supports the benefits of doula care, there remains a need to understand its effects within specific community-based programs and on specific outcomes such as respectful care. It is also important to note that the program currently has only 20 Birth Sister doulas available, meaning not everyone who wants support receives it outside the study. This scarcity underscores the need for a systematic

evaluation of the program's impact to justify potential expansion and increased resource allocation. Furthermore, given the limited availability of doulas, the study's design reflects the real-world context where not everyone can access doula support. This realistic setting allows for a fair comparison of outcomes between those receiving doula support and those receiving usual care, thereby providing valuable insights into the program's impact. Informed consent will be obtained, and the usual care group participants will receive standard perinatal care, maintaining ethical standards and clinical equipoise.

Conversely, the study population at Boston Medical Center is racially and linguistically diverse, which may enhance the generalizability of findings to similar urban populations with high levels of racial and ethnic diversity. Since the study focuses on individuals with public insurance coverage, the findings may be particularly relevant to other safety-net hospitals and public health programs targeting low-income populations.

Assessing both clinical outcomes (e.g., cesarean rates, preterm birth) and psychosocial outcomes (MOR Index scores) provides a more comprehensive assessment of the intervention's impact. Incorporating the Mothers on Respect Index to measure experiences of respectful care during labor and childbirth adds a valuable dimension to the research, emphasizing patient-centered care.

Future research should continue to address improving access to community-based doula care. Emphasis should be placed on increasing the diversity of the doula workforce to reflect the communities most in need of their services. Efforts should also be made to expand doula access to rural areas to support birthing people who experience poor health

outcomes due to limited access to healthcare services and other supportive resources.[73] Continued research on the cost-saving potential of doula services and advocacy for equitable, fair pay for doulas is also needed.

Summary

Through an extensive background and literature review, we have synthesized the existing evidence on the impacts of community doula programs, the disparities in perinatal outcomes, and the importance of respectful care in pregnancy and childbirth. Our review underscores the significant impact of doula support on improving perinatal outcomes, such as reducing cesarean rates and preterm births and improving breastfeeding outcomes. Additionally, we identified a critical gap in the literature: the need for interventions that not only improve clinical outcomes but also address the psychosocial aspects of childbirth, particularly among marginalized populations. While many studies focus on clinical outcomes, integrating measures of respect, such as with the MOR Index, provides a more holistic understanding of the impact of doula interventions. This approach can help identify the broader benefits of doula support and inform more patient-centered care practices.

Our proposed study aims to address these gaps by investigating the effectiveness of an enhanced community doula intervention on both clinical and psychosocial perinatal outcomes in a diverse, urban safety-net hospital. By incorporating the MOR Index, we will gain valuable insights into respectful care experiences among birthing individuals, particularly those from marginalized backgrounds. This dual focus on clinical and

psychosocial outcomes is innovative and provides a more comprehensive assessment of the intervention's impact.

In conclusion, our review has led to a deep understanding of the multifaceted benefits of community doula programs and the critical need for targeted interventions to address disparities and enhance patient experiences in childbirth. Our proposed project will build on this understanding, offering innovative insights and practical solutions to improve perinatal care and outcomes for marginalized populations.

Clinical/Public Health Significance

Policies must be enacted to ensure that community doula services are accessible to all birthing individuals, particularly those from marginalized and low-income backgrounds, to promote health equity. The data from the proposed study can provide a strong evidence base for policymakers advocating for the inclusion of doula services in public health programs. This evidence can support the integration of doula care into Medicaid and other public insurance programs.

MassHealth's announcement in 2023 to cover doula services for pregnant, birthing, and postpartum members marks a significant victory for advocates of accessible doula care and advancing perinatal health equity.[74] MassHealth covers about 40 percent of births in Massachusetts, so this policy change can substantially impact the health outcomes of a large segment of the state's population. However, these new regulations exclude coverage for hospital-employed doulas, which may limit the expansion and impact of hospital-based doula programs, such as Boston Medical Center’s Birth Sisters.

Continued advocacy for expanding doula coverage and access across the United States is essential for addressing perinatal health disparities. Integrating doula services into standard healthcare practice could play a critical role in improving perinatal outcomes, especially among marginalized and underserved populations.

APPENDIX

Appendix A

MOR: MOTHERS ON RESPECT INDEX

Please tell us about your discussions with your doctor or midwife about your options for care (for example: prenatal testing, starting your labour, medications, where to give birth, newborn care, whether to have a cesarean, etc.)

My answers describe my conversations or experiences with a:

Family doctor
Obstetrician/OB-GYN doctor
Midwife
Not applicable, did not have a doctor or midwife.

A: Overall while making decisions about my pregnancy or birth care: (select or circle one answer for each statement)

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
I felt comfortable asking questions	1	2	3	4	5	6
I felt comfortable declining care that was offered	1	2	3	4	5	6
I felt comfortable accepting the options for care that my doctor or midwife recommended	1	2	3	4	5	6
I felt pushed into accepting the options my doctor or midwife suggested	6	5	4	3	2	1
I chose the care options that I received	1	2	3	4	5	6
My personal preferences were respected	1	2	3	4	5	6
My cultural preferences were respected	1	2	3	4	5	6
	SECTION A TOTAL SCORE:					

B: During my pregnancy I felt that I was treated poorly by my doctor or midwife because of: (select or circle one answer for each statement)

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
My race, ethnicity, cultural background or language*	6	5	4	3	2	1
My sexual orientation and / or gender identity*	6	5	4	3	2	1
My type of health insurance or lack of insurance*	6	5	4	3	2	1
A difference of opinion with my caregivers about the right care for myself or my baby*	6	5	4	3	2	1
ADD ALL SCORES IN SECTION B:	SECTION B TOTAL SCORE:					

C: During my pregnancy I held back from asking questions or discussing my concerns because: (select or circle one answer for each statement)

	Strongly Disagree	Disagree	Somewhat Disagree	Somewhat Agree	Agree	Strongly Agree
My doctor or midwife seemed rushed*	6	5	4	3	2	1
I wanted maternity care that differed from what my doctor or midwife recommended*	6	5	4	3	2	1
I thought my doctor or midwife might think I was being difficult*	6	5	4	3	2	1
ADD ALL SCORES IN SECTION C:	SECTION C TOTAL SCORE:					

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Appendix B

Scoring Table	
Enter total score section A	
Enter total score section B	
Enter total score section C	
A + B + C = TOTAL SCORE	

The range of scores is 14-84, with higher score indicating more respectful care.

KEY **Level of Respect Experienced** **(by quartiles)**	
Total Score	***Indication of Respect***
14 - 31	Very Low Respect
32 – 49	Low Respect
50 – 66	Moderate Respect
67 – 84	High Respect

* Reverse-scored items

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