

Cover Page for Protocol

Official Study Title:	Labor and Delivery Doula Program to Reduce Perinatal Morbidity and Mortality in Kansas
NCT Number:	NCT07157059
Document Date:	10/03/2023

University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS

Version date: 03 Oct 2023

Principal Investigator: Dr. Angela Sue Martin, M.D.

Study Title: Labor and Delivery Doula Program to Reduce Perinatal Morbidity and Mortality in Kansas

Co- Investigator(s): Dr. Annabel Mancillas, M.D., Dr. Carrie L Wieneke Broghammer, M.D., Dr. Sharla Annette Smith, Ph.D., Dr. Noria McCarther, M.D.

I. Purpose, Background and Rationale

A. Aim and Hypotheses

1. Black-birthing people are at increased risk of adverse outcomes during pregnancy and childbirth compared to their White counterparts. The aim of this study is to determine if Doula enhanced care can improve the perceived communication and quality of maternal care among Black-birthing people compared to routine pregnancy care, to minimize adverse perinatal outcomes in Black-birthing people in the long-term.
2. Hypothesis: Patients who receive Doula enhanced care will have higher satisfaction due to improved perceived communication and quality of care. Doula enhanced care will lower instances of cesarean delivery, preterm birth, and postpartum depression rates, and improved rates of breastfeeding for Black-birthing people.

B. Background and Significance

3. Study Significance: This study will hopefully provide evidence that Doula enhanced care improves the quality of the healthcare process through improved communication and satisfaction for Black birthing people (primary outcome). In addition, we hope to show Doula enhanced care will improve specific disparities for Black birthing people including cesarean delivery, preterm birth, postpartum depression, and breastfeeding rates (our secondary outcomes). If our study is successful in showing these improvements in birth equity, we will submit an NIH (National Institutes of Health) R01 proposal to conduct a large-scale study on Doula enhanced care to improve the quality of health care for all birthing people. Black mothers have increased risk of cesarean delivery, preterm birth, postpartum depression, and lower rates of breast feeding (1). Poor pregnancy outcomes among Black-birthing people are multifactorial. Doula support during pregnancy and childbirth is associated with improved engagement and communication with the healthcare team, increased satisfactions with the birth experience, and decreased maternal stress (2,3). These factors may explain why Doula support has also proven to lower rates of cesarean delivery, preterm birth, postpartum depression and improve breast feeding rates (3,4,5).
4. Literature Review: Several studies suggest doula services help address birth inequities. First, doula services for pregnant people at risk of poor birth outcomes because of low-income or racial diversity may help disrupt influence of social determinants as predisposing factors for health during pregnancy and childbirth. Second, doula supported people have shortened labor and a decreased need for cesarian deliveries and other high-

risk procedures. They also rate childbirth as less difficult and painful than those without support. This can lead to lowering costs of care for pre-term and cesarian sections. Furthermore, doula services may also facilitate a higher rate of breast feeding.

C. Rationale

1. Based on associations between Doula enhanced care and reductions in cesarean delivery and preterm birth, coverage reimbursement for Doula services have proven to be cost-effective (6). However, there are significant socioeconomic, structural, and systemic barriers to Doula access, often preventing the most vulnerable patients from receiving Doula enhanced services.
2. By better understanding if Doula enhanced care improves communication and quality of maternal care, we can begin to understand how to improve maternal care for Black birthing people. Also, by having Doula enhanced care available, we might reduce the chances of cesarean delivery and preterm birth and increase the likelihood of breastfeeding.

II. Research Plan and Design

A. Study Objectives:

1. The primary objective of the study is to demonstrate improved perceived communication and quality of maternal care among Black birthing people with Doula enhanced care compared to routine pregnancy care at the University of Kansas Health System. This study's primary outcome is to provide evidence that Doula enhanced care improves communication and satisfaction for Black-birthing people by improving the quality of healthcare with the addition of Doula enhancement to the health care team. In addition, the secondary outcome is to show how Doula enhanced care will improve specific disparities between Black birthing people and their White counterparts, including cesarean delivery, preterm birth, postpartum depression, and breastfeeding rates.

B. Study Type and Design:

This study will be an interventional randomized control trial that will have a control group and an experimental group. These groups will be randomly assigned at the patient's enrollment into the study.

C. Sample size, statistical methods, and power calculation

1. Two test Run patients will receive Doula Care from Cierra Conway. This will consist of two prenatal visits.
2. Randomization will be 1:1 and will stop after reaching our desired sample size of forty total patients. Forty patients will be enrolled in the study. Twenty patients will receive Doula enhanced care and Twenty patients will receive routine pregnancy care.

D. Subject Criteria (See Vulnerable Populations appendix, if applicable):

1. Inclusion criteria:

- a. Black birthing people receiving prenatal care with planned delivery at University of Kansas Health System between the ages of 16 and 50 years old.
 - i. Parental consent is not required for minors less than 18 years old because this study is directly related to their pregnancy.
- b. A positive social determinants of health screen.

- c. Patients must have an estimated gestational age of at least 14 weeks, but less than 28 weeks (27.6) when enrolled in the study.
 - d. Patients may have the following fetal anomalies and participate in the study, but these are not requirements for inclusion:
 - i. soft markers (including pyelectasis), intracardiac echogenic foci, mild ventriculomegaly, thickened nuchal fold, absent or hypoplastic nasal bone, isolated echogenic bowel, short long bones and polydactyl.
2. **Exclusion criteria:**
- a. Pregnancy not viable or pregnancy not intrauterine on ultrasound
 - b. Patients who are not willing to be randomized into not receiving doula enhanced
 - c. Patients who do not plan to delivery at the University of Kansas Health System
 - d. Non-Black birthing people.
 - e. Planned cesarean section
 - f. Patients with a known major fetal anomaly
 - g. Non-English speaking
3. Withdrawal/Termination criteria: Patients who transfer care to another facility or attend fewer than two prenatal appointments will be terminated from the study. Patients who wish to withdrawal may at any time.
4. Participants may participate in other studies at the same time.

E. Specific methods and techniques used throughout the study

1. Laboratory tests: No lab tests will be needed for this study. Study Procedures: We plan to use RedCap electronic data collection tool provided by the University of Kansas Health System. A chart review will be performed to obtain maternal demographic information and secondary outcomes including maternal age, gravity/parity, gestational age at delivery, indication for delivery, mode of delivery, neonatal birthweight, presence of maternal comorbidities such as hypertension, preeclampsia, diabetes, fetal growth restriction, and complications of labor including protracted labor, chorioamnionitis, shoulder dystocia, perineal lacerations, and postpartum hemorrhage. Breastfeeding status at time of postpartum visit will also be collected. This information will be recorded in the RedCap data collection tool. A mixed-methods survey, including eight qualitative and four open ended questions, will be administered by the research coordinator at the postpartum follow-up for both groups. Quantitative questions will assess prenatal, labor and delivery, and postpartum perceived quality of care and satisfaction. Questions will aim to evaluate healthcare communication and perceived quality and respectfulness of care. Qualitative questions will provide the opportunity to comment on the aspect of care that improved the quality of care and contributed to the satisfaction of care. Qualitative responses will be coded to identify common themes. Participants randomized to "Routine Pregnancy Care" will continue to receive routine prenatal care at The University of Kansas and routine pregnancy care during the labor and delivery hospitalization. All postpartum patients at the University of Kansas Health System are screened for postpartum depression using the Edinburgh scale on the day of discharge and at 2 weeks following their delivery by a phone call from a nurse. This will be done for both groups per routine protocol at the University of Kansas Health System. All routine care patients will complete the quantitative survey, have a postpartum follow-up appointment with a provider within 2-6 weeks, and their EHR (Electronic Health Record) will be reviewed to assess the study secondary outcomes. Participants randomized to "Doula Enhanced Care"

will receive doula care for four visits, two prenatal visits, one labor and delivery visit, and one postpartum visit. When the study patient is admitted for the delivery hospitalization, the Doula will be notified and present for labor and delivery of the participant. The Doula will provide a minimum of one postpartum visit for each study participant. Timeline: Month 1-2: Doula interviews and selection, RedCap data collection tool and survey creation. Make flyers to advertise the study. Month 3-9: Enroll patients and collect data. Month 9-12: Continue to collect data as pregnancies deliver and postpartum visits occur. Chart abstraction and statistical analysis. Doula Enhanced Care participants will have two prenatal visits with a Doula, one labor and delivery visit, and a minimum of one postpartum visit. All postpartum patients at the University of Kansas Health System are screened for postpartum depression using the Edinburgh scale on the day of discharge and at 2 weeks following their delivery by a phone call from a nurse. This will be done for both groups per routine protocol at the University of Kansas Health System. All routine care patients will complete the quantitative survey, have a postpartum follow-up appointment with a provider within 2-6 weeks, and their EHR will be reviewed to assess the study secondary outcomes.

F. Risk/benefit assessment:

1. Physical risk **N/A**
2. Psychological risk **N/A**
3. Social risk **N/A**
4. Economic risk **N/A**
5. Potential benefit of participating in the study
 - a. Benefits of participants with Doula enhanced care may have higher satisfaction and perceived communication and quality of care. They may have lower cesarean delivery, preterm birth, and postpartum depression rates, and higher rates of breastfeeding.
 - b. Benefits of Black birthing people no longer have increased risk of adverse outcomes during pregnancy and childbirth compared to White counterparts.
 - c. The benefit of inequalities between Black and White birthing people may be addressed.

G. Location where study will be performed:

1. Routine Pregnancy Care and Enhanced Doula Care will take place at The University of Kansas Hospital. Surveys will happen at The University of Kansas Hospital and over the phone. Records will be stored in Redcap.

H. Single IRB (Institutional Review Board) Review for a Multi-site study (if applicable):

1. For which sites will KUMC (University of Kansas Medical Center) serve as the IRB of record? **N/A**
2. Indicate which study activities will occur at each site. If all study procedures will be identical across study sites, state this. **N/A**
3. Describe how you will assess the capacity of each site to perform the research (e.g., expertise, staffing, space, equipment, etc.) If applicable, include site evaluation tools in your IRB submission. **N/A**

4. Describe how the lead investigators will ensure that all participating sites use the IRB-approved version of the protocol, consent, recruitment materials and other study documents. **N/A**
5. Describe how the lead investigators will communicate with and disseminate new information to other sites (e.g., training meetings, regularly scheduled conference calls, notifications, etc.) **N/A**
6. Describe how the lead investigator will assess protocol compliance, unanticipated problems, and adverse events at other sites. **N/A**
7. Name the member of the KUMC study team who will be the point of contact to coordinate oversight and communication with the sites. **N/A**

I. Community-Based Participatory Research

N/A

J. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s): Routine Pregnancy Care, Doula, PIs (Principal investigators)
2. Primary responsibility for the following activities, for example:
 - a. Determining eligibility: Clinical Research Coordinator
 - b. Obtaining informed consent: Clinical Research Coordinator
 - c. Providing on-going information to the study sponsor and the IRB: Clinical Research Coordinator
 - d. Maintaining participant's research records: Clinical Research Coordinator
 - e. Completing physical examination: Routine Pregnancy Care
 - f. Taking vital signs, height, weight: Routine Pregnancy Care
 - g. Drawing / collecting laboratory specimens: Routine Pregnancy Care
 - h. Performing / conducting tests, procedures, interventions, questionnaires: Routine Pregnancy Care
 - i. Completing study data forms: Clinical Research Coordinator, study team
 - j. Managing study database: Clinical Research Coordinator, study team, PIs, Statistician

K. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Elements of the plan include:
 - a. Persons/groups who will review the data (study team; independent safety monitor, data monitoring committee or formal DSMB (Data and Safety Monitoring Board)) The study does not interview with routine pregnancy care, minimal risk only.
 - b. Data/events that will be reviewed **N/A**
 - c. Frequency of review **N/A**
 - d. Types of analyses to be performed **N/A**
2. Safety-related triggers that would cause the PI (Principal Investigator) to stop or alter the study: The study does not intervene with routine pregnancy care, minimal risk only.

3. The study does not intervene with routine pregnancy care, minimal risk only.
4. The study does not intervene with routine pregnancy care, minimal risk only.

III. Subject Participation

A. Recruitment:

1. Recruiting for the study will be done in the waiting rooms, clinic exam rooms, and via telephone at the University of Kansas Medical System.
2. The study team will screen for black patients presenting to the University of Kansas Health System Department of OBGYN for prenatal care using the "Social Determinants of Health" screening tool in Epic, the electronic medical record (EMR), utilized in the outpatient settings. Patients with one or more positive question in any of the following areas equals positive social determinants of health screen: tobacco use, alcohol use, financial resource strain, transportation needs, social connections, housing stability, food insecurity, stress, postpartum depression, and health literacy. Patients with a positive screen will meet with our clinical research coordinator to discuss their interest in enrollment. If the patient meets inclusion criteria and agrees to enrollment, they will be randomized to Doula enhanced care or routine care.
3. A flyer will be placed in the waiting room and clinic rooms at the University of Kansas Medical System.
4. Patients with a positive screen will meet with our research coordinator to discuss their interest in enrollment. If the patient meets inclusion criteria and agrees to enrollment, they will sign a consent form and be randomized to Doula enhanced care or routine care.

B. Screening Interview/questionnaire:

Black patients presenting to University of Kansas Health System Department of OBGYN for prenatal care will be screened using the "Social Determinants of Program Page Health" screening tool in Epic, the electronic medical record (EMR), utilized in the outpatient settings.

C. Informed consent process and timing of obtaining of consent:

- 1 Clinical Research Coordinator or Investigators will give potential participants comprehensive information about the study and obtain their written consent.
- 2 Clinical Research Coordinator or Investigator will speak directly to the patient either in person or via telephone to explain the study, Doula enhanced care, and discuss interest in enrollment. They will go through the consent form with them, answer questions to satisfaction of the patient, and provide a copy to the patient, as well as contact information should they have questions later
- 3 Only patients able to provide informed consent will be included in this study. Research Coordinator or Investigator will determine if patient is eligible to provide consent. If there is any question to the patient's capacity to give consent, they will consult with the medical team and PI.
- 4 If the PI is the physician responsible for providing direct patient care, to avoid coercion, the patient must be consented by the Clinical Research Coordinator or another Co-Investigator. The care team will not be notified of the patient's enrollment until they participate in study procedures in the office.

D. Alternatives to Participation:

1. Patients may seek Doula enhanced care independent of the study and can be referred to the consulting Doulas assisting in this study.

E. Costs to Subjects:

2. No cost to patient, the grant will pay for the Doula enhanced care.

F. How new information will be conveyed to the study subject and how it will be documented:

3. No new information will be presented to the participants throughout the study. Surveys will be conducted both in person and via phone. Participants answers will be recorded in RedCap.

G. Payment, including a prorated plan for payment:

N/A, part of routine pregnancy care

Payment for a research-related injury:

N/A, part of routine pregnancy care

IV. Data Collection and Protection**A. Data Management and Security:**

1. Participant information will be de-identified by the Clinical Research Coordinator, who will assign an alphanumerical study ID to the patient. Only the Clinical Research Coordinator and PI will have access to identifiable information, which will be stored securely in Redcap and CRIS/Velos systems.
2. All collected data will be stored securely in Redcap or CRIS/Velos systems. There will be no paper source.
3. Subjects will only be identified by an alphanumerical study ID assigned by the Research Coordinator when the survey is conducted.
4. Clinical Research Coordinator and PI will maintain and have access to the key to the assigned groups.
5. Data will be linked to subjects with an alphanumerical identifier and will only include pertinent PHI (Protected Health Information) for the study.
6. Data will be stored and protected in RedCap
7. Clinical Research Coordinator may consent patients over the phone and with a link to the Redcap survey. Coordinator may use a physical paper copy of the consent, or an iPad provided by KUMC to link directly to the Redcap Survey.
8. No data sent outside KUMC.

B. Procedures to protect subject confidentiality:

1. Data will be kept securely in research databases, password protected, and de-identified. Participants will be assigned a random alphanumerical study ID to associate survey responses with the data.

C. Quality Assurance / Monitoring

1. Self-assessment will be used to assure the data collected are accurate, consistent, complete, and dependable.
2. No plans to have ongoing third-party monitoring.

V.Data Analysis and Reporting

A. Statistical and Data Analysis:

1. The department of OBGYN statistician will perform all statistical analysis. For the primary and secondary outcomes, t-tests will be used to compare continuous variables and chi-squared tests will be used to compare categorical variables. Risk ratios will be computed using simple logistic regression and 95% confidence intervals will be reported. Qualitative questions will be coded, and common themes will be identified.

B. Outcome:

1. Our primary objective is to demonstrate improved perceived communication and quality of maternal care among Black birthing people with enhanced Doula enhanced care compared to routine pregnancy care at the University of Kansas Health System. We will use quantitative surveys to assess satisfaction and perceived quality of prenatal, labor and delivery and early postpartum care.

C. Study results to participants: Participants will receive a letter with the study results.

D. Publication Plan: If successful in improving pregnancy care with an increase in perceived quality of care and reduction adverse pregnancy outcomes, we will use our results to write a pilot study and submit a poster or abstract for ACOG or SMFM.

VI. Bibliography / References / Literature Cited

Reference:

1. Society for Maternal-Fetal Medicine and National Birth Equity Collaborative infographic, Strategies to Overcome Racism's Impact on Pregnancy Outcomes." Accessed June 16, 2022 at: https://s3.amazonaws.com/cdn.smfm.org/media/2315/Strategies_to_Overcome_Racism_Infographic.pdf.
2. Kozhimannil KB, Vogelsang CA, Hardeman RR, Prasad S. Disrupting the Pathways of Social Determinants of Health: Doula Support during Pregnancy and Childbirth. J Am Board Fam Med. 2016 May-Jun;29(3):308-17. doi: 10.3122/jabfm.2016.03.150300. PMID: 27170788; PMCID: PMC5544529.
3. Scott KD, Klaus PH, Klaus MH. The obstetrical and postpartum benefits of continuous support during childbirth. J Womens Health Gend Based Med. 1999 Dec;8(10):1257-64. doi: 10.1089/jwh.1.1999.8.1257. PMID: 10643833.
4. Thomas MP, Ammann G, Brazier E, Noyes P, Maybank A. Doula Services Within a Healthy Start Program: Increasing Access for an Underserved Population. Matern Child Health J. 2017

Dec;21(Suppl 1):59-64. doi: 10.1007/s10995-017-2402-0. PMID: 29198051; PMCID: PMC5736765.

5. Kozhimannil KB, Attanasio LB, Hardeman RR, O'Brien M. Doula care supports near-universal breastfeeding initiation among diverse, low-income women. *J Midwifery Womens Health*. 2013 Jul-Aug;58(4):378-82. doi: 10.1111/jmwh.12065. Epub 2013 Jul 9. PMID: 23837663; PMCID: PMC3742682.
6. Kozhimannil KB, Hardeman RR, Alarid-Escudero F, Vogelsang CA, Blauer-Peterson C, Howell EA. Modeling the Cost-Effectiveness of Doula Care Associated with Reductions in Preterm Birth and Cesarean Delivery. *Birth*. 2016 Mar;43(1):20-7. doi: 10.1111/birt.12218. Epub 2016 Jan 14. PMID: 26762249; PMCID: PMC5544530.

APPENDIX I: VULNERABLE POPULATIONS

- I.** Research Coordinator will speak directly to the patient either in person or via telephone to explain the study, Doula enhanced care, and discuss interest in enrollment. Coordinator will go through the consent form with them, answer questions to satisfaction of the patient, and provide a copy to the patient, as well as contact information should they have questions later
- II. Cognitively or decisionally impaired individuals:** N/A
- III. Children:** N/A
- IV. Pregnant women:** Pregnant people are the focus of the study.
- V. Prisoners:** N/A
- VI. Students and/or Employees:** N/A