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Maternal And Newborn Outcomes For Women Living With Hiv In Adapted Group Prenatal Care

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MATERNAL AND NEWBORN OUTCOMES FOR WOMEN LIVING WITH HIV IN

ADAPTED GROUP PRENATAL CARE

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

CIZIK SCHOOL OF NURSING

BY

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The University of Texas
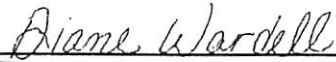**Health Science Center at Houston** | School of Nursing

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Date

To the Dean for the School of Nursing:
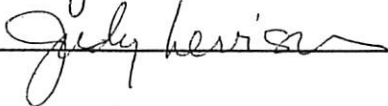
I am submitting a dissertation written by Jodi Behr and entitled "Maternal and Newborn Outcomes for Women Living with HIV in Adapted Group Prenatal Care." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Diane Wardell
Diane Wardell, PhD, Committee Chair

We have read this dissertation
and recommend its acceptance:

Cathy Rozmus

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Accepted

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Dean for the School of Nursing

Acknowledgements

Abstract

Maternal and Newborn Outcomes for Women Living with HIV in
Adapted Group Prenatal Care

By Jodi Herron Behr

May 2020

Purpose

The aims of this study were to evaluate group differences between WLWH who attended individual prenatal care appointments (IC) compared to WLWH who attended the HIV-adapted CenteringPregnancy® Program (CP-H) for adequacy of prenatal care utilization, maternal plasma HIV RNA levels, newborn gestational age, and newborn birth weight.

Methods

A secondary data analysis was used with a total sample size of 233. Univariate analyses of Chi-square of Independence and Fisher's Exact test were completed to identify confounding variables. Univariate analyses for the APNCU index score, maternal viral load levels, and for newborn gestational age and birth weight. As one confounding variable was identified, an Analysis of Covariance was also completed for newborn gestational age and birth weight.

Results

Previous preterm birth was the only confounding variable to be statistically significant. Significant differences were found for improved outcomes in the CP-H group for an undetectable viral load ($p = .011$), newborn gestational age ($p = .013$), and newborn birth weight ($p = .002$). When controlling for previous preterm birth, statistical significance was found for newborn gestational age ($p = .014$) and newborn birth weight

(p = .003). The mean and median gestational age and birth weight were higher in the CP-H group compared to the IC group.

Conclusion

The APNCU index scores for both groups provide updated information for WLWH. The improvements in undetectable viral load levels for WLWH in CP-H also provided newer information related for WLWH, while increased newborn gestational age and increased birth weight for the CP-H group were consistent with improvements seen in other studies and provided new information regarding group prenatal care for WLWH.

Keywords: CenteringPregnancy®, Women Living with HIV, Newborns

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Behr, J. H., Wardell, D. W., Rozmus, C., & Levison, J. (2020). Maternal &

Newborn Outcomes for Women Living with HIV in adapted group prenatal care.

Summary of Study

This study was completed to examine maternal and newborn outcomes for women living with HIV and their newborns who attended an adapted form of CenteringPregnancy® program compared to women and their newborns who attended individual one-on-one prenatal care appointments and did not attend the adapted CenteringPregnancy® program. The outcomes that were identified were Adequacy of Prenatal Care Index Score, maternal HIV plasma levels, newborn gestational age, and newborn birth weight.

This study was conducted as stated in the proposal except for two changes. The first change was that education level could not be collected as this was not in the original HIV Perinatal Study database. Second, the maternal HIV plasma levels had to be changed from an ordinal variable to a dichotomous variable due to laboratory values of being considered undetectable changed throughout the year.

Proposal

Specific Aims

Pregnant women living with HIV (WLWH) have increased educational needs due to the complexity of managing HIV and pregnancy, including the need to understand the importance of maternal plasma HIV RNA level and its role in transmission of HIV, an adverse outcome (Centers for Disease Control & Prevention, 2018a; Leyva-Moral et al., 2017). Along with transmission, other adverse outcomes for newborns born to WLWH include premature birth and low birth weight (Xiao et al., 2015). Newborn adverse outcomes have been found to be decreased when prenatal care utilization is found to be considered adequate, a categorical label given to define prenatal care utilization when prenatal care is begun early and the expected the number of prenatal care visits per the ACOG guidelines are completed (Cox et al., 2009; Partridge et al., 2012).

Prenatal care provided one-on-one with an obstetrical provider is an established intervention with the purpose of providing education and preventing poor outcomes (American College of Obstetricians & Gynecologists, 2018). Group prenatal care, including CenteringPregnancy®, which provides a three-prong approach to prenatal care: health assessment, education, and support, has been associated with decreased rates of both premature and low birth weight infants for both low and high-risk mothers (Byerly & Haas, 2017; Carter et al., 2016). The CenteringPregnancy® program was adapted by Judy Levison, MD, MPH and Yvette Peters, APRN, in 2013 for pregnant WLWH by including education related to HIV medications, management of the disease, and the disease's potential effect on the newborn (Hickerson et al., 2019; Rising & Quimby, 2017). Outcomes of the HIV-adapted CenteringPregnancy®

program comparing group prenatal care and traditional prenatal care have not yet been evaluated. The *critical need* is to determine the best model of care delivery for WLWH. The *long-term goal* will be to determine if adapting the CenteringPregnancy® program will be beneficial to other high-risk groups. The *overall objective* of this study is to evaluate the effects of the increased HIV education included in the HIV-adapted CenteringPregnancy® program for WLWH and their newborns. The *central hypothesis* is that WLWH who attend the HIV-adapted CenteringPregnancy program® will have improved outcomes for both the mother and the newborn. The *rationale* for this project is that once outcomes are known, the program may be implemented in other cities and/or countries to determine generalizability. To obtain the overall objective, the following three *specific aims* will be pursued:

1. To evaluate adequacy of prenatal care for WLWH who attended the HIV-adapted CenteringPregnancy® program prenatal care appointments. The hypothesis is that WLWH who attend the HIV-adapted CenteringPregnancy® program will have increased prenatal care adequacy compared to pregnant WLWH who attend traditional prenatal care.

2. To evaluate maternal plasma HIV RNA levels for WLWH who attend the HlV- adapted CenteringPregnancy® program. The hypothesis is that WLWH who attend the HIV-adapted CenteringPregnancy® program will have a lower plasma HIV RNA level prior to delivery compared to WLWH who attend traditional prenatal care appointments.

3. To evaluate the gestational age and birth weight of newborns born to WLWH

who participate in the HIV-adapted CenteringPregnancy® program. The hypothesis is that newborns born to WLWH who attend the HIV-adapted CenteringPregnancy® program will have increased gestational ages and birth weights compared to WLWH who attend traditional prenatal care appointments.

The expected outcomes of these aims are to identify improvements in the educational and group components of prenatal care for WLWH and their newborns. With WLWH attending the HIV-adapted CenteringPregnancy® program and receiving increased education related to HIV in a supportive group setting, WLWH will be able to engage in promoting their own health during pregnancy for themselves and for their newborn.

Significance

With the success of antiretroviral therapy (ART), HIV is now considered a chronic illness (Deeks et al., 2013). There are an estimated 255,900 WLWH in the United States (US) of which approximately 8,500 will give birth each year (Centers for Disease Control & Prevention [CDC], 2019b). Adverse outcomes have been found to affect newborns born to WLWH, including premature birth and low birth weight (Macdonald et al., 2015).

As women manage both their pregnancy and HIV, their focus is on preventing HIV transmission to their newborn and having a healthy outcome for both themselves and their newborn. To do this, WLWH must manage both their disease and pregnancy at the same time (Craft et al., 2007). Management of both, along with decreasing the fear of transmission is facilitated by comprehensive education. With adherence to medications, the risk of mother to child transmission (MCT) is approximately 1-2%

(Centers for Disease Control & Prevention [CDC], 2019). While the risk of transmission is zero if a woman is virally suppressed from conception to delivery (Mandelbrot et al., 2015).

Prenatal care is a long-standing and widely used public health intervention for the prevention of pregnancy-induced hypertension in US and other developed countries. Prenatal care is also important as it identifies ongoing risk during the pregnancy and includes assessment of medical, psychosocial, nutritional, cultural, and educational needs of the mother (American Academy of Pediatrics Committee on Fetus and Newborn & The American College of Obstetricians and Gynecologists Committee on Obstetric Practice and Gynecologists [(AAP Committee on Fetus & Newborn & ACOG Committee on Obstetric Practice)], 2012). Prenatal care guidelines set forth by ACOG include appointments with a healthcare provider every four weeks for the first 28 weeks, every two weeks until 36 weeks, and then weekly until delivery. However, this schedule is modifiable based upon findings at each assessment. These appointments allow the healthcare provider to provide ongoing assessments of the mother and fetus, complete health screenings, provide education, and detect any medical or psychosocial complications that the mother may be experiencing (Alexander & Kotelchuk, 2001).

Even with the suggested visits, the actual utilization of prenatal care is needed to determine the care that is being provided. Utilization has been defined as adequate if care is initiated early in the pregnancy and visits are fulfilled according to the ACOG standards (Partridge et al., 2012). To quantify prenatal care related to the amount of care provided, different index scores may be used, including the Adequacy of Prenatal Care

Utilization Index (Kotelchuck, 1994a).

The delivery of prenatal care has been traditionally a one-on-one appointment with a healthcare provider. However, since the 1990s when group prenatal care was introduced, group prenatal care demonstrated improvement in patient education and satisfaction with no detrimental effects to the mother or the fetus. Group care has recently been endorsed by AGOG (2018). Unlike traditional one-on-one prenatal care that was not studied utilizing strong research rigor, group prenatal care models have continued to undergo scientific scrutiny to determine its effects on outcomes for both low and high- risk mothers during the antenatal period of pregnancy (Benediktsson et al., 2013, Chae, et al., 2017; Cunningham et al., 2019; Earnshaw et al., 2016; Heberliein et al., 2016, Ickovics et al., 2003, Ickovics et al., 2007, Ickovics et al., 2016, Picklesimer et al., 2012, Zorrilla et al., 2017).

The structure of group prenatal care consists of women with similar due dates coming together in a group setting to learn about and discuss pregnancy, newborn, and post-partum topics. Women receive individual care for their physical assessment by a healthcare provider and they actively participate in collecting their own healthcare data such as their weight and blood pressure. In the group session led by healthcare providers or social workers, different topics are discussed, and group members ask questions and are encouraged to share information (Rising, Kennedy, & Klima, 2004).

One formalized group prenatal care program is the CenteringPregnancy® program offered through the CenteringHealthcare Institute. CenteringPregnancy® was started by Sharon Rising, a certified nurse midwife, in 1995 and as of March 2019, CenteringPregnancy® is now practiced at 424 sites across the US

(CenteringHealthcare Institute, 2019). The CenteringPregnancy® program follows a systematic program on specific education topics. Yet, the CenteringPregnancy® program has also approved the adding of specific topics for high risk groups including WLWH. The programing for WLWH was adapted by Judy Levison, MD, and Yvette Peters, APRN, to not only include the CenteringPregnancy® topics, but to also include information related to HIV disease during and after pregnancy and newborn concerns (Hickerson et al., 2019).

Group prenatal care has shown improvements in the percentages of premature births and birth weights in low risk mothers. Improvement in newborn birth weights have also been noted in high-risk mothers such as those with gestational diabetes who participated in group prenatal care (Cunningham et al., 2019; Ickovics et al., 2003, Ickovics et al., 2007, Ickovics et al, 2016; Mazzoni et al., 2015; Schellinger et al., 2016; Pickelesimer et al., 2012; Schellinger et al., 2016; Zorrilla et al., 2017). Pregnant women reported it allowed them time with the healthcare provider for a physical assessment but also gave them increased time for education and support through the group format (Benediktsson et al., 2013, Chae et al., 2017; Cunningham et al., 2019; Earnshaw et al., 2016; Heberliein et al., 2016, Ickovics et al., 2003, Ickovics et al., 2007, Ickovics et al., 2016, Picklesimer et al., 2012, Zorrilla et al., 2017).

The *gap in knowledge* lies in determining if there are different outcomes related to WLWH and their newborns who attend the HIV-adapted CenteringPregnancy® program compared to WLWH who completed traditional one-on-one prenatal care prior to group care being offered. This information is essential in understanding the impact of the HIV- adapted CenteringPregnancy® program for WLWH and their newborns. It

is yet to be determined if the HIV-adapted CenteringPregnancy® program has a positive effect on program indicators and clinical outcomes: (1) adequacy of prenatal care, (2) maternal HIV plasma viral load, and (3) newborn's gestational age and (4) their birth weight.

The significance of this research will be to evaluate two aspects of the HIV-adapted CenteringPregnancy® program, adequacy of prenatal care and HIV viral load, along with evaluating two outcomes, the newborn's gestational age and birth weight. *The contribution of this research is to provide new information to maternal-child healthcare providers regarding the HIV-adapted CenteringPregnancy® program for WLWH and its impact on newborns' gestational ages and birth weights.*

The theoretical framework that will guide this research is the CenteringPregnancy Conceptual Model (Manat & Dodgson, 2011). This model is guided by the feminist, midwifery, social cognitive, and adult learning theories. These theories support the relationship-based care, active learning, and self-efficacy components of the CenteringPregnancy® program. Self-efficacy includes how people feel, motivate themselves, and act to accomplish a specific goal. Guided by these theories, the CenteringPregancy model identifies the group process and the purposeful self-reflection as key components of the process which propels women to their optimum self which will lead to a healthy pregnancy and positive birth outcomes (Manant & Dodgson, 2011).

Adequacy of prenatal care. Adequacy of prenatal care has been measured by several utilization indexes, including the Adequacy of Prenatal Care Utilization Index (APNCU). The APNCU index uses the number of prenatal care visits and the timing of

the initiation of prenatal care into consideration to determine a status of adequacy. The

index is a summation score based upon the gestational month prenatal care began and the

ratio of observed versus expected visits and the timing of the initiation of prenatal care.

The calculated index is categorized as either adequate plus, adequate, intermediate, or

inadequate (Kotelchuck, 1994a). WLWH have been shown to have inadequate prenatal

care (Ng et al., 2015) and newborns born to WLWH who had inadequate prenatal care

had increased odds of having a low birth weight or being born premature compared to

newborns born to women who did have HIV (Turner et al., 1996).

  Plasma HIV RNA levels. For WLWH, the goal of ART is to obtain an

undetectable maternal plasma HIV RNA level as this helps decrease the risk of perinatal

transmission of HIV to the newborn (CDC, 2019a; U.S. Department of Health &

Human Services, 2018). Medication adherence to ART is known to have the largest

impact on viral load suppression in pregnant women (Zahedi-Spung, Young, Haddad,

& Badell, 2018). Therefore, WLWH must understand the relationship among

medication adherence, maternal plasma HIV RNA level, and decreased transmission to

the newborn. Medication adherence among pregnant WLWH has been reported at

approximately 75% (Bardeguez et al., 2008; Mellins et al., 2008; Zahedi-Spung et al.,

2018). Combination interventions that include education have been noted to be effective

at increasing ART adherence compliance and a lack of education has been identified as

a barrier to medication adherence during pregnancy which can lead to increased plasma

HIV RNA levels (Chaiyachati et al., 2014).

  Newborn gestational age and birth weight. The percentage of premature birth

in the US in 2017 was 9.9% of all live births while the percentage of births considered

low birth weight was 8.3% in the US. A newborn is considered premature if it is born before 37 weeks gestation. Low birth weight is defined as a birth weight of less than 2.5 kilograms or 5 pounds, 5 ounces (Centers for Disease Control & Prevention, 2017). Some of the maternal risk factors that can lead to either premature birth or low birth weight are previous preterm birth, mother who smoked during pregnancy or consumed other substances such as marijuana and/or alcohol, and if the mother had other infections during the pregnancy (Bowers, 2014). Newborns born to WLWH are at twice the risk of being premature and/or low birth weight compared to newborns who are not exposed to the virus (Xiao et al., 2015).

Preliminary Studies

No preliminary studies have been conducted by this researcher. What is known from the literature follows:

Adequacy of Prenatal Care

Aim 1: To evaluate adequacy of prenatal care for WLWH who attended the HIV-adapted CenteringPregnancy® program prenatal care appointments.

During the 1990s WLWH were found to have inadequate prenatal care despite needing to initiate zidovudine, the primary drug prescribed to WLWH to decrease maternal-child transmission (Lanksy et al., 1999; Turner et al., 1996). WLWH have been shown to struggle to initiate and engage in prenatal care during the course of their pregnancy. More recently, 43.3% of WLWH compared to 36.1% not living with HIV received inadequate prenatal care (Ng et al., 2015). Studies involving the use of group prenatal care have shown improvement in improving the adequacy of prenatal care utilization. In one randomized control trial, 26.6% of adolescents who participate in

CenteringPregnancy® had inadequate prenatal care based upon the APNCU index compared to 33% of adolescents having inadequate prenatal care in a traditional one-on- one care (Ickovics et al., 2007). Another improvement in prenatal care utilization was found with group care with Latina women as those who attended CenteringPregnancy® had higher prenatal care adequacy ratios compared to Latina women in traditional one- on-one care (Tandon et al, 2013).

Three risk factors that have been identified for inadequate prenatal care are the age, race, and education level of the mother (Patridge et al., 2012; Lambert, Mugaver, Najjar, Enah, & Guthrie, 2018; Xaverius et al., 2016). In 2016, approximately 27% of women under 20 years of age had inadequate prenatal care along with approximately 20% of mothers between the ages of 20 and 24 (U.S. Department of Health & Human Services, 2018). The association with mothers who were younger with less education has been identified with receiving less adequate prenatal care (Patridge et al., 2012; Xaverius et al., 2016). Black women have also been identified as having less adequate prenatal care compared to other races (Lambert et al., 2018).

Plasma HIV RNA Levels

Aim 2: To evaluate plasma HIV RNA levels for WLWH who attend the HIV-adapted CenteringPregnancy® program.

An undetectable HIV RNA level in pregnant WLWH is the goal to decrease the risk of maternal-child transmission of HIV (Bardeguez et al., 2008; Patel et al., 2018). An undetectable viral load is achieved by taking daily medication. Understanding the relationship of daily medication use and its effect on the maternal HIV plasma RNA

level on the newborn is a key piece of education in prenatal care for pregnant WLWH (The American College of Obstetricians & Gynecologists, 2017). Despite the importance of medication adherence, current studies have shown that with traditional prenatal care, medication adherence is considered at a non-compliant rate and therefore puts the newborn at risk for maternal child transmission (Zahedi-Spung et al., 2018). Maternal age and race have been identified as factors for having and increased HIV Plasma RNA level. Women who are younger and who are Black have been shown to have increased plasma HIV RNA levels (Patel et al., 2018).

Newborn Gestational Age and Birth Weight

Aim 3: To evaluate the gestational age and birth weight of newborns born to WLWH who participate in the HIV-adapted CenteringPregnancy® program.

Newborns of WLWH are at risk for decreased gestational age and birth weight. Despite overall decreases in preterm birth and decreased birth weight among all newborns in the US, the percentage of preterm births and low birth weight newborns born to WLWH are still greater compared to women who do not have HIV (Macdonald et al., 2012). In the US, race and maternal substance abuse were factors for both preterm delivery and low birth weight newborns born to WLWH (Schulte, Dominguez, Sukalac, Bohannon, & Fowler, 2006).

The contribution of this research study will be to identify the positive effects of the CenteringPregnancy® group prenatal care model for WLWH and their newborns. It will identify the role of CenteringPregnancy® has on prenatal care adequacy, HIV RNA plasma levels, and the newborn's gestational age and birth weight. WLWH are an increasing population as these women are living longer lives and desiring to

become pregnant. With the advancements in ART, pregnancy outcomes can be

positive with effective education and support. The group aspect of

CenteringPregnancy® can also provide the education and support needed by WLWH.

Currently prenatal care one-on-one appointments are the model of care for WLWH.

This research will help identify if the CenteringPregnancy® program model can

provide WLWH a group format for education and care that will enhance their

understanding of the importance of medication adherence and provide overall

improved newborn outcomes for an at-risk population.

Innovation

The CenteringPregnancy® program is an innovate alternative care model to

the status quo traditional care model for pregnant WLWH. With pregnant WLWH

having increased education needs, a group prenatal care setting specific to WLWH

can provide the healthcare they need in a supportive setting. As this is a new model

of care for WLWH, outcomes need to be evaluated.

Approach

Design

The proposed study will be a secondary data analysis from the Baylor

College of Medicine HIV Perinatal Study (IRB Number 14-01-0733). This sample

will include WLWH who sought care at the Harris Health/Baylor College of

Medicine Northwest Obstetrical & Gynecology Clinic in Houston, Texas. This

investigator has been added to the HIV Perinatal Study and has been granted access

to the electronic database involved in this study. The dates of inquiry for this study

will include data extracted from Harris Health patients' charts from 2006-2018 and

entered into the Baylor College of Medicine Clinical Trial Management System
(BCM CTMS). The groups being compared will be WLWH who attended
traditional prenatal care and their newborns (control) and WLWH who attended the
HIV-adapted CenteringPregnancy® program prenatal care program and
their newborns (intervention). The control group will be WLWH who attended
traditional one-on-one prenatal care from 2006-2012 and the intervention group will
be the WLWH who attended the HIV-adapted CenteringPregnancy® program from
2013-2018.

In 2013, HIV-related topics were added to the traditional
CenteringPregnancy® program. This program of care became known as the HIV-
adapted CenteringPregnancy® curriculum. The following HIV topics and related
speakers were added to enhance the traditional prenatal care topics (see Table 1):

Table 1

Schedule for HIV Education Topics

Session (weeks of pregnancy)	HIV topic
1 (Weeks 12-16)	Coping with HIV diagnosis; what is was like at the time of diagnosis; psychiatry speaker
2 (Weeks 16-20)	HIV basics; HIV & pregnancy
3 (Weeks 20-24)	Retention in care; HIV medication adherence/breastfeeding; primary care speaker
4 (Weeks 24-28)	HIV and birth control
5 (Weeks 26-30)	Birth facility; breastfeeding
6 (Weeks 28-32)	HIV and medication adherence; disclosure of HIV
7 (Weeks 30-32)	Pediatric speaker
8 (Weeks 32-36)	Caring for baby (no new HIV topic)
9 (Weeks 34-38)	Identifying a primary care provider for self and baby
10 (Weeks 36-40)	How to obtain medications, serodiscordance- PrEP; retention in care –Mentors

The population of interest for this study will be pregnant WLWH and their newborns. The sample will be drawn from WLWH who were provided prenatal care at the Harris Health Northwest Health Center and their newborns. The Northwest Harris Health Center and is part of Harris Health System and is staffed by Baylor College of Medicine physicians. The investigator will first separate patients into two groups, WLWH who attended traditional prenatal care from 2006 to 2012 and their newborns and WLWH who attended the HIV-adapted

CenteringPregnancy® program from 2013 –2018 and their newborns. These years

are included as they are the years during which only traditional one-one-one care

was provided and years when the HIV-adapted CenteringPregnancy® program was

implemented. A convenience sample will be used. Inclusion criteria will include

WLWH who had a single pregnancy, 18 years of age and older, started prenatal

care at Harris Health by gestational week 30, and the pregnancy resulting in a live

birth. Exclusion criteria includes WLWH with a multiple gestation pregnancy,

WLWH less than 18 years of age, any newborn with known congenital anomalies,

or if the pregnancy resulted in a fetal demise or miscarriage. An a priori sample size

was determined using G Power 3.1.9.2 statistical software. The a priori power will

be at 0.80 and an a priori alpha level will be set at .05. The effect size for the

logistic regression will be when the odds ratio is 2.88. For the linear regression

model, the effect size will be .034. For this study, a sample size of 225 subjects'

records will be needed.

Procedure for Data Collection

By being part of the Baylor HIV Perinatal study, the principal investigator

already has been approved for access to information to the Baylor College of Medicine

Clinical Trials Database. This database currently holds the information for the HIV

Perinatal Study (BCM CTMS HIV Perinatal Study database. Baylor College of

Medicine monitors the Clinical Trial Management System (BCM CTMS), as it is a

password-protected system. See Appendix A for data management and codebook. The

information entered into the SPSS workbook will be validated by reviewing every 10th

entry into the SPSS workbook. The SPSS and SAS workbook will be saved on a

secure Cizik School of Nursing's password-protected online database. Informed

consent will not be garnered as this is a retrospective chart review. Data will be

extracted and entered into SPSS v. 25 by this investigator and will include

demographics of age and race and exclusion variables of multiple pregnancy and fetal

demise will be noted and known factors that also contribute to preterm birth of

infections, smoking status, and previous preterm birth. For each of the aims the

following variables will be collected:

Aim 1

Data points to calculate the APNCU Index will include the following:

1. Number of prenatal care appointments attended at Harris Health

2. The gestational month prenatal care was initiated

3. Newborn gestational age in weeks

Aim 2

Data for the outcome variable for Aim 2 will also be extracted from the BCM CTMS

HIV Perinatal Study database. The last viral load recorded prior to date of delivery

will be used. The levels of the maternal HIV plasma RNA levels will be categorized

as less than 20, 20-999, and 1,000 and greater. A plasma level is considered

undetectable at less than 20.

Aim 3

Data for the outcome variable for Aim 3 will be found in the BCM CTMS Perinatal

HIV Study database will include the newborn's gestational age and the newborn's

birth weight. The newborn's gestational age will be provided in weeks and days. To

include the days in SPSS, the gestational age will need to include the weeks of

gestation and the decimal interpretation of the number of days divided by 7. See

Table 2 for variables.

Table 2

Data Collection Table

Variable	Variable Type
Age	Continuous
	Number of years
Race	Categorical
	Caucasian
	Black
	Hispanic
	Other
Maternal Educational Level	Continuous
	Grade level achievement
APNCU Index (Adequacy Index)	Ordinal
	1 = inadequate
	2 = intermediate
	3 = adequate
	4 = adequate plus
Plasma HIV RNA levels	Ordinal
	0 = less than 20
	1 = 20 to 999
	2 = 1,000 or greater
Newborn gestational age	Continuous
	Weeks of gestation
Newborn birth weight	Continuous
	Kilograms

Measurements

There will be no instruments used in this study. All the variables are

located in the BCM CTMS and were collected for the Perinatal HIV Study.

Data Analysis Plan

Descriptive statistics for the demographic variables of age and race will be completed for each group. All variables will be assessed for normal distribution.

To calculate the APNCU Index Score, the below three variables will be transferred from SPSS into SAS for calculation. The APNCU Index Score program was written in SAS by the original APNCU Index Score author, Milton Kotelchuch, PhD.

1. The number of prenatal care appointments will be labeled as NPCVBC (number of prenatal care visits).

2. The gestational month prenatal care was initiated will be labeled MPCBBC (month prenatal care began). This will be calculated by taking the estimated weeks into the Harris Health program and dividing by 4 to determine the month.

3. The gestational age will be labeled as GAGEBC (gestational age in weeks).

An index score will be calculated using the SAS Computational program developed by Milton Kotelchuck, PhD, MPH (1994b). The index score is a summative score that includes the month of gestation that prenatal care began, and the ratio of observed visits compared to expected visits. The Utilization Index score can be categorized into 4 groups:

1. Inadequate: Prenatal care began after the 4th month or less than 50% of recommended visits occurred.

2. Intermediate: Prenatal care began by the 4th month and 50-79% of

recommended visits occurred.

3. Adequate: Prenatal care began by the 4th month and 80-109% of

recommended visits occurred.

4. Adequate Plus: Prenatal care began by the 4th month and 110% or

more of recommended visits occurred.

Once calculated, the APNCU index scores will be transferred back to SPSS

for the logistic regression analysis. To assess for statistical differences

between the two groups (traditional prenatal care and HIV-adapted

CenteringPregnancy®) for the following dependent variables, these

statistical tests will be calculated (See Table 3).

Table 3

Dependent Variables & Corresponding Statistical Test

Dependent Variable	Statistical Test
Age	t-test
Race	Chi-Square
Maternal Education Level	t-test
Other Infections	Chi-Square
Smoking Status	Chi-Square
Other substance abuse	Chi-Square
Preeclampsia diagnosis	Chi-Square
Previous preterm birth	Chi-Square

If a statistical difference is found between the group means of each group of any of the above variables, these will then be included in a multivariate analysis. For the dependent variable Adequacy of Pregnancy Index Score and for the plasma HIV RNA level, a logistic regression will be completed. For gestational age and low birth weight, a linear regression model will be completed. If no statistical difference is found for the above variables between the two groups, then univariate analyses will be completed (See Table 4).

Table 4

Dependent Variable & Corresponding Statistical Test for Univariate Analyses

Dependent Variable	Statistical Test
Adequacy of prenatal care index score	Wilcoxon-Mann-Whitney Test
Maternal plasma HIV RNA level	Wilcoxon-Mann-Whitney Test
Newborn gestational age	t-test
Newborn birth weight	t-test

Potential Limitations & Risk to Subjects

There are several limitations of this study that may occur. The first limitation potentially will be a lack of data due to the study being a secondary data analysis. If data is missing, a smaller sample size might be obtained than what is proposed by the power analysis. Another limitation could be that since data extraction from the Harris Health patients' charts was completed by several data collectors, despite having a guide sheet, the data may have been found in different areas of the chart leading to different interpretations by the data collectors. A third limitation is that care was not

simultaneous for each group. Finally, the care providers could be different as the years included in this study are over a 9-year period. As this is a secondary data analysis, the risk to subjects will be minimal. The information will be de-identified once it is removed from the BCM CTMS.

Human Subject Protection

As this will be a secondary data analysis, no informed consent will be obtained. Once a subject is included in the study, the data collected will be de-identified. The original HIV Perinatal Study was approved by the Baylor College of Medicine Institutional Review Board (see Attachment 1). This secondary data analysis of the HIV Perinatal Study data was approved by the Principal Investigator, Judy Levison, MD. The letter of support from Dr. Levison is attached as Attachment 2.

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Manuscript

Nancy K. Lowe, PhD, CNM, FACNM,
FAAN Editor, JOGNN
Association of Women's Health,
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1800 M Street, NW, Suite
740S Washington, DC
20036

Re: Manuscript – Maternal and Newborn Outcomes for Women Living with HIV in
Adapted Group Prenatal Care

Dear Dr. Lowe:

Attached please find the manuscript *Maternal and Newborn Outcomes for Women Living with HIV in Adapted Group Prenatal Care*. This manuscript was written for my dissertation from The University of Texas Health Science Center at Houston Cizik School of Nursing PhD program. This manuscript identifies improved outcomes for women living with HIV that attended an adapted form of group prenatal care and will provide updated information regarding pregnancy outcomes for women living with HIV along with adding to the literature regarding group prenatal care.

Thank you for considering this manuscript for publication. If you have any further questions, please contact me at Jodi.h.behr@uth.tmc.edu.

Sincerely,

Jodi Herron Behr, PhD, APRN, RNC-NIC, ACCNS-P

Maternal and Newborn Outcomes for Women Living with
HIV in Adapted Group Prenatal Care

Of the approximately 255,900 women living with HIV (WLWH) in the

United States (US), approximately 8,500 give birth each year. With the success of

women's adherence to prescribed combined antiretroviral therapy (cART) during

pregnancy, the risk of mother to baby transmission is approximately 1-2% (Centers

for Disease Control and Prevention, 2019b; Leyva-Moral et al., 2017), while the

risk decreases to 0% if a WLWH is virally suppressed from conception to delivery

(Mandelbrot, 2015). Despite the decreased risk of viral transmission, newborns

born to WLWH have been identified as being at risk for both prematurity and low

birth weight (Xia et al., 2015). As with any pregnancy, WLWH desire healthy

outcomes for both themselves and their newborns. To accomplish a healthy

outcome, they must both successfully manage their pregnancy and HIV infection

(Craft, Delany, Bautista, & Serovich, 2007).

Management of the pregnancy and HIV infection is accomplished through

prenatal care and ongoing self-management between prenatal care appointments.

During one-on-one visits established as the standard of prenatal care by The

American College of Obstetricians and Gynecologists (ACOG) (American

Academy of Pediatrics (AAP) Committee on Fetus & Newborn & ACOG

Committee on Obstetric Practice, 2012), the health care provider evaluates mothers

and their fetuses through ongoing assessments, health screenings, and through

detection of any further medical and/or psychosocial complication that may occur

during pregnancy. Education also is provided during these appointments regarding

pregnancy, birth, and issues related to HIV, such as the importance of medication

adherence (ACOG, 2017).

Changes related to traditional prenatal care were introduced in the 1990s through group prenatal care. One formalized group prenatal care program is the CenteringPregnancy® program, developed in 1995 by Sharon Rising, a certified nurse midwife, and is now offered through the CenteringHealthcare Institute (CenteringHealthcare Institute, 2019; Rising et al., 2004; Rising & Quimby, 2017). With a group model of care, pregnant women receive one-on-one assessments along with education and support in a group setting. The program allows other women to not only learn from the health care provider but also from each other (Chae et al., 2017; Earnshaw et al., 2016; Heberliein et al., 2016). According to Carter et al. (2016), observational studies have shown improved newborn outcomes for newborns born to mothers who attended group prenatal care.

The purpose of this study was to assess outcomes for both pregnant women living with HIV and their newborns through a retrospective data review. The four aims and the hypotheses for this study were: (1) to evaluate the adequacy of prenatal care utilization for WLWH who attended the HIV-adapted CenteringPregnancy® program (CP-H) program compared to WLWH who attended individual one-on-one care (IC). The hypothesis was that WLWH who attended CP-H would have increased prenatal care adequacy utilization compared to pregnant WLWH who attend IC; (2) to evaluate maternal plasma HIV RNA levels for WLWH who attended CP-H compared to WLWH who attended IC. The hypothesis was that WLWH who attended CP-H would have a lower plasma HIV RNA levels prior to delivery compared to WLWH who attended IC; (3) to evaluate

the gestational age of newborns born to WLWH who participate in CP-H compared to gestational age of newborns born to WLWH who participated in IC. The hypothesis was that newborns born to WLWH who attended CP-H will have increased gestational ages compared to newborns born to WLWH who attended IC; and (4) to evaluate the birth weight of newborns born to WLWH who participate in the CP-H compared to newborns born to WLWH who participated in IC. The hypothesis was that newborns born to WLWH who attend the CP-H will have increased birth weights compared to newborns born to WLWH who attended IC.

Background

The primary goal of every pregnancy is for the mother and newborn to be healthy. This goal can be more challenging for pregnant women living with a chronic illness, such as HIV, as they must take cART, the standard of care medications, daily to avoid mother- to-child transmission (Deeks et al., 2013). With a low to non-existence mother-to-child transmission of HIV and the desire of WLWH to have children, the pregnancy rate among WLWH in the US has increased (Rahangdale et al., 2014). However, despite the desires to have children, it has been shown that WLWH may not have the appropriate level of awareness and understanding regarding management of HIV during pregnancy to achieve healthy outcomes. Therefore, education of WLWH pre-conception and intra- pregnancy is of the utmost importance to help them understand the knowledge needed to manage their disease and pregnancy (Finocchario-Kessler et al., 2010).

Prenatal Care

Prenatal care is a long-standing and widely used public health intervention for the prevention of pregnancy-induced hypertension in the US and other developed countries. Prenatal care also is important to identify ongoing risk during the pregnancy and includes assessment of medical, psychosocial, nutritional, cultural, and educational needs of the mother (AAP Committee on Fetus & Newborn & ACOG Committee on Obstetric Practice, 2012). Prenatal care guidelines set forth by ACOG include appointments with a healthcare provider every four weeks for the first 28 weeks, every two weeks until 36 weeks, and then weekly until delivery. However, this schedule is modifiable based upon findings at each assessment. These appointments allow the healthcare provider to provide ongoing assessments of the mother and fetus, complete health screenings, provide education, and detect any medical or psychosocial complications that the mother may be experiencing (AAP Committee on Fetus and Newborn & The ACOG Committee on Obstetric Practice and Gynecologists, 2012).

Group Prenatal Care

The delivery of prenatal care has been historically an individual one-on-one appointment with a healthcare provider. However, since the 1990s when group prenatal care was introduced, group prenatal care demonstrated improvement in patient education and satisfaction with no detrimental effects to the mother or the fetus. Group care has recently been endorsed by ACOG (2018). Unlike individual prenatal care that was instituted as a guideline without strong research rigor, group prenatal care models have continued to undergo scientific scrutiny to determine its

effects on outcomes for both low and high-risk mothers during the antenatal period of pregnancy. Studies which support group prenatal care include those by Benediktsson et al. (2013), Chae et al. (2017), Cunningham et al. (2019), Earnshaw et al. (2016), Heberliein et al. (2016), Ickovics et al. (2003), Ickovics et al. (2007), Ickovics et al. (2016), Picklesimer et al. (2012), and Zorrilla et al (2017).

The structure of group prenatal care consists of women with similar due dates coming together in a group setting to learn about and discuss pregnancy, newborn, and post-partum topics. In the group session led by healthcare providers or social workers, these topics are discussed, and group members ask questions and are encouraged to share information (Rising et al., 2004; Rising & Quimby, 2017). Women also receive

individual care for their physical assessment by a healthcare provider and they actively participate in collecting their own healthcare data such as their weight and blood pressure. By participating in CenteringPregnancy®, women have increased time for education and support along with individual time with a health care provider (ACOG,

2018).

As of December 2019, CenteringPregnancy® is practiced at over 500 sites across the US (CenteringHealthcare Institute, 2019). The CenteringPregnancy® program follows a systematic program on specific education topics. Yet, the CenteringPregnancy® program also has approved the adding of specific topics for high risk groups including WLWH. The CenteringPregnancy® programing for WLWH was developed to not only include the CenteringPregnancy® topics, but to

also include information related to HIV disease during and after pregnancy, and newborn concerns. These topics included: coping with HIV, HIV and pregnancy, importance of medication and retention in care, disclosure of HIV, breastfeeding specifics to WLWH, and birth control concerns for WLWH. These topics are in addition to the traditional prenatal care topic of each of the 10 sessions. One recent study conducted by Hickerson et al. (2019) with WLWH who participated in the program found improvements in social support and decreased depression scores.

In observational studies, group prenatal care has shown improved birth weights and a decrease in premature births in low risk mothers (Carter et al., 2016). Improvement in newborn birth weights also have been noted in high-risk mothers such as those with gestational diabetes who participated in group prenatal care (Byerly & Haas, 2017; Mazzoni et al. 2015).

Adequacy of Prenatal Care

Utilization of prenatal care can be used to quantify the care that is being provided to women during the prenatal period. Utilization has been defined as adequate if care is initiated early in the pregnancy and visits are fulfilled according to ACOG standards (Partridge et al., 2012). To quantify prenatal care, different utilization scores have been developed, such as the Kotelchuck Index, the R-GINDEX, and the Adequacy of Prenatal Care Utilization (APNCU) Index (Alexander & Kotelchuk, 1996; Alexander & Kotelchuck, 2001; Kotelchuck, 1994a; Heaman et al., 2008). The APNCU index score is a multi-dimensional score that takes into consideration when prenatal began based upon the month of initiation and the actual number of visits in a woman's time in prenatal care based

upon the delivery date. WLWH have struggled with the initiation and engagement of traditional prenatal care. During the 1990s, women were found to have inadequate prenatal care despite needing to initiate zidovudine, the primary drug prescribed to WLWH at the time (Lanksy et al., 1999). This pattern of lower prenatal engagement also was found by Turner et al (1996) among pregnant WLWH.

Maternal Viral Load Levels

For WLWH, the goal of cART is to obtain an undetectable maternal HIV RNA levels, also known as viral load levels, to decrease the risk of perinatal transmission of HIV to the newborn (CDC, 2019b; US Department of Health & Human Services, 2018). Medication adherence with cART is known to have the largest impact on viral load suppression in pregnant women (Zahedi-Spung et al., 2018). One way to achieve viral load suppression is to take cART daily. Despite its utmost importance, cART adherence among pregnant WLWH has been reported at approximately 75% which is considered to be in the non-compliant range (Bardeguez et al., 2008; Zahedi-Spung et al., 2018). Reasons that WLWH give for this noncompliance include "forgetting to take medication daily", concern that the cART will harm the newborn instead of helping him/her, lack of transportation to refill medication, and lack of general knowledge regarding mother-to- child transmission (Hodgson et al., 2014). Interventions that include education along with psychosocial support and/or other types of reminder systems have been noted to be effective at increasing cART adherence (Bardeguez et al., 2008; Chaiyachati et al., 2014).

Birth Outcomes for WLWH

With the improvements in preventing of mother-to-child transmission, attention has turned to other newborn outcomes. Two significant factors noted to affect newborns born to WLWH are prematurity and low birth weight (Macdonald et al., 2015; Xiao et al, 2015). The overall percentage of premature birth (birth before 37 weeks gestation) in the US in 2018 was 10.0% of all live births (March of Dimes, 2019). While 8.3% of newborns born in the US in 2017 were defined as low birth weight (CDC, 2019a). According to Xiao et al. (2015), newborns born to WLWH are estimated to be at a two- fold risk increase of being either premature or low birth weight, yet it is not associated with cART. Low birth weight is defined as a birth weight of less than 2.5 kilograms or 5 pounds, 5 ounces (AAP Committee on Fetus & Newborn & ACOG Committee on Obstetric Practice, 2012). Researchers continue to examine reasons for prematurity and low birth weight outcomes for newborns born to WLWH.

Social factors such as age and race/ethnicity have been identified as risk factors for decreased adequacy of prenatal care, increased maternal viral load levels, premature birth, and low birth weight for newborns (Lambert et al., 2018; Patel et al., 2018; Schulte et al., 2006; Xaverius et al., 2016). Behavioral risk factors such as smoking and substance abuse often are found in this population and have been shown to have an impact on adequacy of prenatal care, maternal viral load levels and the newborn's gestational age and birth weight (Chaiyachati et al., 2014; Lambert et al., 2018; Patridge et al., 2012; Xaverius et al., 2016;). Along with behavioral risk factors, other medical diagnoses such as preeclampsia and previous

preterm birth could also affect a newborn's outcomes (Yang et al., 2016).

Conceptual Framework

This study was guided by the CenteringPregnancy® Conceptual Framework which incorporates Feminist Theory, the Midwifery Theory of Care, Social Cognitive Theory, and Adult Learning Theory (Manant & Dodgson, 2011). These theories support the relationship-based care, active learning, and self-efficacy components of the CenteringPregnancy® program (Rising & Quimby, 2017). Self-efficacy includes how people feel, motivate themselves, and act to accomplish a specific goal (Bandura, 1997). The components of these four theories come together in the centering model of healthcare to make the group interactive process supportive for participants through shared knowledge and reflection. This process is designed to lead to successful individual outcomes during pregnancy which when combined, may lead to a cohort of improved maternal and newborn outcomes (Manant & Dodgson, 2011).

Methods

Institutional Review Board approval was granted by Baylor College of Medicine (BCM) for the HIV Perinatal Study to Judy Levison, MD. Along with obtaining IRB approval from BCM, a Data Use Agreement between BCM's Obstetrical & Gynecological Department and the University of Texas Health Science Center at Houston, Cizik School of Nursing was obtained for use of the data collected in the HIV Perinatal Study. Institutional Review Board approval was also obtained from University of Texas Health Science Center Committee for the Protection of Human Subjects (CPHS).

Sample and Participant Selection

After obtaining approval from BCM and CPHS, subjects were identified from a master list of participants of WLWH who participated in prenatal care at a specialized clinic in an academic hospital setting in a large metropolitan, ethnically diverse area. A power analysis using G Power 3.1.9.4 with the a priori power set at 0.80, an a priori alpha level set at .05, and with an effect size of .1 determined that a sample size of 225 participants would be needed.

A data sheet listing inclusion and exclusion criteria was created by the principal investigator to systematically review each of the potential subjects. Data for a total of 489 patients receiving prenatal care during 2006 to 2018 were obtained from the Baylor Clinical Trial Management System (CTMS). Inclusion criteria were maternal age 18 years and older, singleton pregnancy, prenatal care at Harris Health initiated by gestational week 30, pregnancy resulted in a live birth, and individual one-on-one prenatal care (IC) between 2006 and 2012 or group prenatal care in the HIV-adapted CenteringPregnancy® Program (CP-H) between 2013-2018. Exclusion reasons included women who did not participate in group care from 2013-2018, newborns with congenital anomalies and pregnancies that ended in fetal demise, miscarriage, or other loss, or if prenatal care began after 30 weeks gestation. Two-hundred thirty-three charts met inclusion criteria an additional 256 were excluded (See Figure 1).

Procedure

A master list of WLWH who received prenatal care through Harris Health/Baylor College of Medicine between 2006 and 2018 was used. All subjects

were first determined for eligibility based on the inclusion and exclusion criteria. If a prenatal care patient met the inclusion/exclusion criteria, they were assigned a unique identifier for this study. Two groups were identified: individual one-on-one care (IC) and HIV-adapted CenteringPregnancy® group (CP-H) for the study. For both groups, the following variables were collected: maternal age, maternal race/ethnicity, newborn gestational age, newborn birth weight, maternal viral load recorded closest to or at delivery, month of which prenatal care began at Harris Health, number of prenatal care appointments at Harris Health, if any infections were present during the pregnancy, maternal smoking status, and illicit drug and/or alcohol use during the pregnancy, diagnosis of preeclampsia, and previous preterm birth. For the CP-H group the number of individual and group sessions were collected.

After all of the eligible subjects' data were entered into SPSS, the data in each group were reviewed by the principal investigator for additional accuracy. The review consisted of comparing every fifth subject of each group's information to the corresponding data in the CTMS. Six data entry errors were found in the IC group and two data entry errors were found in the CP-H group for an error rate of 0.286%. If a mistake was found the corrected information was entered in SPSS from the CTMS.

Measures

Variables that were collected for the study were:

Prenatal care

The two groups were defined by the type of prenatal care that was provided. From 2006-2012, IC was done by two primary providers. There was no minimum or maximum number of visits for IC. From 2013-2018, prenatal care was defined by WLWH participating in the CP-H in 3 or more sessions. This number was selected in order to exclude those WLWH that may have attended 1 or 2 group sessions only to evaluate the program.

Adequacy of Prenatal Care Utilization (APNCU) Index

To calculate this index score, the month prenatal care began, the number of prenatal care visits, and the gestational age of the newborn at birth were collected to calculate the index score in the publicly available Adequacy of Prenatal Care Index SAS Program (Kotelchuck, 1994b). and then transferred back into SPSS for group analysis.

The scores for the APNCU index score start at "1" for being inadequate based upon late initiation of prenatal care after the 4th month or less than 50% of expected prenatal care visits attended. A score of "2" was labeled Intermediate as prenatal care began by the 4th month of pregnancy and 50-79% of the expected prenatal care visits are attended. The score of 3 was labeled "Adequate" for prenatal care began by the 4th month and between 80-109% of recommended appointments occur. The final score of "4" was considered "Adequate Plus." This group consisted of women who began prenatal care by the 4th month and attended

110% or more of recommended prenatal care visits (Kotelchuck, 1994a).

Maternal Viral Load Levels

The maternal viral load levels were listed in the CTMS as a numerical laboratory value along with it being categorized as "undetectable." The numerical value was first collected. During the data collection, a list of laboratory values that were noted to be undetectable was kept by the principle investigator. Based on the values that were undetectable, they were then converted into a dichotomous variable of either detectable level or an undetectable level. The dichotomous labeling was needed to account for the differing lab values that were assigned to the undetectable category over the 12-year span of the study. Over time, laboratory analysis was able to detect viral levels at lower levels. The viral load level that was included in this study was the lab value that had been recorded closest to or on the date of delivery.

Newborn Gestational Age

The age of the newborn included both weeks and days of gestation (and converted to a decimal number) as determined by gestational age reported by a health care provider at delivery.

Newborn Birth Weight

The weight of the newborn that was routinely documented in the chart within the first hours of birth in kilograms.

Analysis

SAS® (version 9.4, SAS Institute, Cary, NC). and SPSS® (version 24, SPSS Inc., Chicago, IL) software was utilized for the data analysis. The data were initially

entered into SPSS. The variables of month prenatal care began, the number of prenatal care visits attended, and the gestational age of the newborn at birth were then transferred into SAS to determine the APNCU index score. This analysis was conducted by a senior statistician and score results were then transferred into SPSS for analysis by the principal investigator.

Univariate analyses for potential confounding variables were completed using Chi-Square test of Independence for presence of other infection(s), maternal smoking status, maternal substance abuse, and diagnosis of preeclampsia. A Fisher's exact test for previous preterm birth was utilized due to a cell number count of less than 5. To determine potential confounding variables in the outcome variables analyses, the alpha level was set at .10. A higher p value was used for this analysis as when confounding variables are unknown, a value of .10 may be used to help identify all potential variables that may need to be controlled (Petrie & Sabin, 2019; Thiese et al., 2016).

For the outcome variables, univariate analyses were completed. The Mann Whitney U test was used to analyze the APNCU index score, an ordinal variable, and a Chi-Square of Independence test was used for the maternal viral load levels, a dichotomous variable. As both the IC newborn gestational age and newborn birth weight groups included outliners, transformation of these variables was attempted with no difference in distributions noted. Therefore, the original newborn gestational age and newborn birth weight variables were used with the distribution as a limitation. Independent sample t-tests were first utilized to examine group differences for newborn gestational age and newborn birth weight. Mann Whitney

U tests were also utilized due to the IC distributions. As previous preterm birth was a potential confounding variable for newborn gestational age and newborn birth weight, an analysis of covariance was also used to determine if controlling for previous preterm birth influenced group differences between the IC and CP-H groups for newborn gestational age and birth weight.

Results

A total of 233 participants were included in this study, with 178 being in the IC group and 55 being in the CP-H group for all analyses except for birth weight. Due to missing birth weight data, the total subjects for the IC group subjects was 159 and 50 subjects in the CP-H group. The IC and the CP-H groups' demographics are summarized in Table 1. Minorities made up the majority of the total sample with blacks being 60.9% and Hispanics being 33.0%. Both groups had similar percentages of participants compared to the overall sample demographics. The age range for all three groups was 18-43 years and the mean and median age being similar for the total sample with a $M= 28.42$, $SD= 6.14$ and $Mdn = 28.00$. The mean and median age for the IC group was $M= 28.35$, $SD= 6.13$ and $Mdn = 27.50$ and $M= 28.62$, $SD= 6.23$ and $Mdn = 28.00$ for the CP- H group. As age did not follow a normal distribution, a Mann-Whitney U test was run to determine any differences among the groups. There was no statistical difference in age between the IC and the CP-H groups $(U= 4748$, $z = - .339$, $p = .736)$.

Along with age and race, other potential confounding variables could have included the presence of infection (other than HIV), maternal smoking status,

maternal substance abuse, diagnosis of preeclampsia, and previous preterm birth. Each of these factors are known to impact birth and newborn outcomes. Since all of the potential confounding variables were dichotomous, a Chi-square test of Independence was used for analysis. (See Table 2). Due to having a low sample size for the previous preterm birth confounding variable, a Fishers Exact Test was used and was found to be significant ($p =.051$) when compared to a p value of .10. A higher p value was used for this analysis to identify any potential confounding variable that may need to be included in further analyses. (Petrie & Sabin, 2009; Thiese et al., 2016).

As previous preterm birth did not relate to the APNCU index score or the maternal viral load levels, univariate analyses were completed for the APNCU index score and the maternal viral load levels. The Mann-Whitney results for differences in the APNCU index scores ($U = 4398.500$, $z = -1.197$, $p = .231$) did not show statistical difference between the two groups. In reviewing the APNCU index scores, the CP-H group participants did have greater "adequate" prenatal care utilization (See Table 3) and initiation of prenatal care during the first trimester (See Table 4) compared to the IC group participants but no significant difference was found. For the undetectable maternal viral load levels, the Chi-Square results were significant for differences between the IC and CP-H groups ($X^2 (1) = 6.543$, $p = .011$) with the CP-H group having a higher percentage of undetectable viral load levels (See Table 5).

Independent t-tests and Mann Whitney U tests were first completed for both newborn gestational age and newborn birth weight. A significant difference was

found with both the t-tests (See Table 6) and the Mann Whitney U test. Newborns born to WLWH in the CP-H group had a higher gestational age compared to newborns born to WLWH in the IC (See Table 7) ($U = 3816$, $z = -2.471$, $p = .013$). There was also a significant difference in birth weights for newborns born to WLWH in the CP-H group compared to newborns born to WLWH in the IC group with newborns born to WLWH in the CP-H group having higher birth weights (See Table 8) ($U = 2803.500$ $z = -3.14$, $p = .002$). Further analyses also were completed with an analysis for covariance for both newborn gestational age and newborn birth weight. After controlling for previous preterm birth for both outcome variables, a statistically significant difference was still found between the CP-H and IC groups for both newborn gestational age and newborn birth weight (See Table 9 & Table 10).

Discussion

This study compared outcomes for WLWH who attended individual prenatal care appointments and the HIV-adapted CenteringPregnancy® Program. These two prenatal care groups were found to be similar in age, race, infections, preeclampsia, and behaviors including smoking and substance abuse. The sample was representative of the percentage of black WLWH in the US. The difference in this sample is the higher percentage of Hispanic WLWH compared to general populations of WLWH as 33% of WLWH were Hispanic in this study compared to 16% in a general population study of people living with HIV (CDC, 2019b). This higher percentage of Hispanic WLWH identified in these prenatal groups may be due to this southern US city having the third highest Hispanic population in the US

(World Population Review, 2019).

Despite not finding statistical significance between the two groups for the adequacy of prenatal care, the APNCU index scores between the IC and the CP-H groups do provide updated information for utilization of prenatal care for WLWH. WLWH in both groups achieved greater than 50% of the level of prenatal care that is desired. There also was new information regarding initiation of prenatal care for WLWH. For WLWH in the CP-H group, 72.7% began prenatal care during the first three months (first trimester) of the pregnancy while 50.6% of IC participants began prenatal care in the first three months. This increased adequacy of index scores for both groups were improvements upon earlier reports for WLWH (Turner et al., 1996) and also were improved for "adequate" and "adequate plus" compared to WLWH in Canada who had 36.1% of WLWH receiving "adequate" care (Ng et al., 2015).

By 2006, the guidelines for the overall treatment of HIV in WLWH included early initiation of cART to decrease the maternal viral load and to stop maternal to child transmission (El Beitune et al., 2004; Lynch & Johnson, 2018). The goal for WLWH is to have an undetectable viral load during the pregnancy (ACOG, 2017). For WLWH in the CP-H group, an increase in undetectable maternal viral loads levels was found. For WLWH who attended HIV-adapted CenteringPregnancy® program, 90.9% of the participants had an undetectable viral load at the viral load closest to delivery compared to 74.7% of WLWH who attended individual one-on-one prenatal care. As viral load levels are one measure of medication adherence, an undetectable viral load may indicate an improvement with medication adherence.

Compared to WLWH in Zahedi-Spung et al.'s study (2018) that found that 25% of the respondents reported medication nonadherence, WLWH in the CP-H group , the detectable viral load levels in this study was 9.1%.

Zahedi-Spung et al. (2018) also noted barriers to medication adherence included "forgetting to take pills" and difficulty understanding that the medication is to help both mother and baby and will not harm the baby. These two items (reminders and education) are addressed and reinforced in the HIV-adapted CenteringPregnancy® program (Hickerson et al., 2019) which may account for the improved undetectable viral load levels in the intervention group.

Newborns born to WLWH in the CP-H group had a statistically significant higher gestational age with a mean gestational age of 38.891 weeks compared to the mean gestational age of 38.005 weeks to newborns born to WLWH in the IC group. The longer gestational age was consistent with Tanner-Smiths et al.'s (2014) findings of increased gestational ages among low-risk women who participated in CenteringPregnancy group prenatal care program at five different sites in Tennessee. This extra week may be helpful as newborns born before 39 weeks may have increased adverse outcomes, including potential respiratory issues, and the lengthened gestational age may be helpful to the newborn (ACOG & Society of Maternal-Fetal Medicine, 2013).

Along with newborn gestational age, newborn birth weight was also significantly higher for newborns born to WLWH in the CP-H group ($M = 3.219$ kg; $Mdn = 3.144$ kg) compared to newborns born to WLWH in the IC group ($M = 2.912$ kg; $Mdn = 2.892$ kg). The increased birth weight is consistent with the increased

gestational age finding among the CP-H group as these two outcome variables are positively related (Tappero et al., 2016) and mirrors the current study's data that showed an increase in WLWH who had previous preterm birth in the IC group. The findings also are also consistent with the Ickovics et al. (2003) study and Tanner-Smith et al.'s (2014) study which found that newborns born to women who had participated in a CenteringPregnancy Program delivered newborns with increased birth weight compared to newborns born to women who participated in individual care.

Strengths & Limitations

Strengths of this study were that these findings provide up-to-date quantitative information for WLWH and their newborns and that the sample size met the a priori criteria of 225 for three of the four outcome variables. However, there are several limitations with this study. First, this is a secondary, retrospective data analysis and only information that had been collected in the HIV Perinatal Study could be examined. Therefore, there are potential variables that might have influenced the groups that were not collected such as educational level, housing issues, domestic violence issues, and other social determinants of health. A second limitation was that this data was collected over 12 years and that the IC group's data were collected during a different time frame than the CP-H group. Even though the treatment for HIV during pregnancy was comparable during the years, potential changes related to newer medications may need to be considered as newer medications may have increased effect on viral load suppression and/or decreased side effects. As the

specific medications were not collected for this study, this could not be determined. A third limitation was that selection bias may also be a limitation as WLWH who participated in the CP-H group self-selected if they met criteria. A fourth limitation was that there were unequal sample sizes between the groups and the distribution for newborn gestational age and newborn birth weight included outliers. A final limitation was that the data had been initially entered into the data base by multiple data collectors through the years.

Recommendations for Future Research

More research regarding WLWH and their newborns needs to be conducted. As this was a quantitative analysis of the two groups, only certain outcomes of the groups were studied. Therefore, to understand more about WLWHs' experiences in a group model of care and potentially explain more about the quantitative results, a qualitative analysis should be conducted. Also, a prospective study may also be considered to be able to control for other variables that may affect outcomes that could not be collected in this retrospective analysis study.

<p align="center">**Conclusion**</p>

For WLWH and their newborns, prenatal care is an important part of their pregnancy. By participating in an HIV-adapted CenteringPregnancy® group model of care, the maternal viral loads, the newborn gestational age, and newborn birth weight both may be improved compared to individual one-on-one prenatal care. This study helps supports the use of the CenteringPregnancy® program delivery method of group care and specifically for WLWH.

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    11

489 subjects' charts assessed for eligibility

256 excluded

88 - Did not participate in group prenatal care during 2013-2018.

59 - Unknown birth outcomes

51 - Prenatal care after 30 wks

30 - Fetal loss (miscarriage/fetal demise/ectopic/aborted

12 - maternal age < 18

8 - Twin pregnancies

6 - Congenital Anomaly

178 subjects included
IC group

55 subjects included
CP-H group
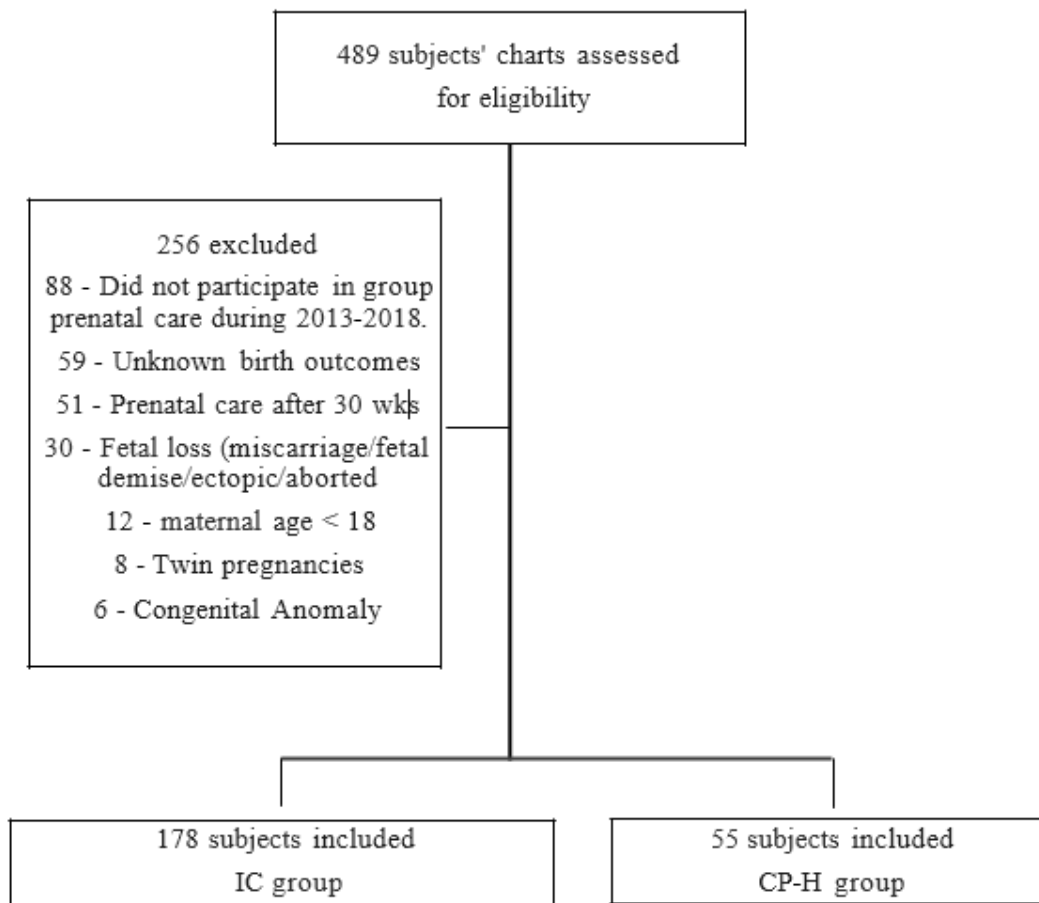
Figure 1. Subjects Inclusion & Exclusion Flow Chart

Table 1

Race/Ethnicity by Group

Group	Black	Hispanic	Caucasian	Asian/Pacific	Other
IC	60.7%	31.5%	6.7%	0.6%	0.6%
CP-H	61.8%	38.2%	0%	0%	0%

Table 2

Other Risk Factors

Risk Factor	Chi Square	p Value
Presence of Other Infection	1.26 (1, N=233)	.26
Smoking Status	2.02 (1, N=233)	.16
Substance Abuse	1.31 (1, N=233)	.25
Preeclampsia Diagnosis	2.39 (1, N=233)	.12

Table 3

Percentages of APNCU Index Scores

Group	Inadequate	Intermediate	Adequate	Adequate Plus
IC	32.6%	14.0 %	32.0%	21.3 %
CP-H	16.4%	14.5	56.4%	12.7

Table 4

Percentage of WLWH Initiating Prenatal Care during Trimesters

Group	1st Trimester	2nd Trimester	3rd Trimester
IC	50.6%	45.5%	3.9%
CP-H	72.7%	25.5%	1.8%

Table 5

Percentage of Undetectable Maternal Viral Load Levels

Group	Undetectable	Detectable
IC	74.7%	25.3%
CP-H	90.9%	9.1%

Table 6

T-test for Newborn Gestational Age & Newborn Birth Weight

	df	*t*	*p*
Gestational Age	231	-2.503	.013
Birth Weight	207	-3.217	.002

Table 7

Mean & Median Gestational Age Weight

Group	*M* Gestational Age (weeks)	*Mdn* Gestational Age (weeks)
IC	38.005	38.571
CP-H	38.891	39.143

Table 8

Mean & Median Newborn Birth Weight

Group	*M* Birth Weight (kilograms)	*Mdn* Birth Weight (kilograms)
IC	2.912	2.892
CP-H	3.219	3.144

Table 9

ANCOVA for Gestational Age

	df	*F*	*p*
Gestational Age	1	32.177	.014
Previous Preterm Birth	1	2.400	.123

Table 10

ANCOVA for Newborn Birth Weight

	df	*F*	*p*
Birth Weight	1	3.159	.003
Previous Preterm Birth	1	1.493	.223

Appendix A

Baylor IRB Approval: Perinatal HIV Study

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-18412
Status: Approved
Initial Submit Date: 11/10/2005
Approval Period: 10/22/2018 - 10/21/2019

Section Aa: Title & PI

A1. Main Title

HIV PERINATAL DATA BASE

A2. Principal Investigator

Name:	JUDY LEVISON	Phone:	713-798-4491
Id:	131823	Fax:	
Department:	OB-GYN: MATERNAL FETAL MEDICINE	Email:	jlevison@bcm.tmc.edu
Center:		Mail Stn:	

A3. Administrative Contact

Name:	CYNTHIA DEVERSON	Phone:	713-798-4344
Id:	183601	Fax:	713-798-2670
		Email:	deverson@bcm.tmc.edu
		Mail Stn:	BCM450

A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?
No

Section Ab: General Information
A4. Co-Investigators

Name: Id:	JENNIFER ROBICHEAUX MCKINNEY	Phone:	713-826-7371
Department:	168166	Fax:	
Center:	OB-GYN: MATERNAL FETAL MEDICINE	Email:	robichea@bcm.tmc.edu
		Mail Stn:	BCM610

Name: Id:	LATIA M.W HICKERSON	Phone:	713-440-7313
Department:	178964	Fax:	713-440-0916
Center:	OB-GYN: ADMINISTRATIVE	Email:	lmwade@bcm.tmc.edu
		Mail Stn:	BCM610

Name: Id:	KYLIE LEE KLEIN	Phone:	713-798-4600
Department:	182278	Fax:	
	OB-GYN: MATERNAL FETAL MEDICINE	Email:	kyliek@bcm.tmc.edu
		Mail Stn:	BCM368

Name:	JODI BEHR	Phone:	832-826-7311
Id:	202037	Fax:	
Department:	OB-GYN: GYNECOLOGY	Email:	behr@bcm.tmc.edu
Center:		Mail Stn:	BCM610

A5. Funding Source:
Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:
HCHD: Harris County Hospital District
HCHD: Harris County Hospital District Ben Taub
HCHD: Harris County Hospital District Lyndon Baines Johnson Hospital
HCHD: Harris County Hospital District Northwest Clinic
HCHD: Northwest Clinic
TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:
Country: Facility/Institution: Contact/Investigator: Phone Number:
If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent
Does this trial have therapeutic intent?
No

Section B: Exempt Request

B. Exempt From IRB Review
Not Applicable

Section C: Background Information
Prior to the introduction of antiretroviral therapy the risk of transmission of HIV from mother to baby was 25% in the United States; in the mid-1990's zidovudine (AZT) given antenatally, during labor, and postpartum to the newborn was found to reduce transmission to 8%. By the late 1990's triple drug therapy was added to most prenatal regimens and transmission further dropped to 1-2%.
The Harris County Hospital District Women's Program has been providing specialized perinatal care for HIV-positive women since 2000. Clients are referred from other community health centers and Ben Taub General Hospital to Northwest Health Center for care by a multidisciplinary team of practitioners including an obstetrician and two nurse practitioners credentialed as HIV specialists, a nurse educator, social workers and case managers.
By 2013 nearly 500 women have delivered their babies through the program. HIV transmission to infants has occurred in three cases.

Section D: Purpose and Objectives
Although some data regarding the demographics and details of patient care have been recorded by Harris County

Hospital District, no systematic review designed by clinicians has been done. Our goal is to create a data base

and to use the information gleaned for quality assurance purposes and to direct future research.
For each of the clients enrolled from 2006 to 2018, we will review clinic and hospital charts to obtain
the targeted information.
The following items will be evaluated:
-Source of referral (BTGH, outlying clinics) -Zip code of patient -Age -Race/ethnicity Gravidity/parity -Date of
diagnosis
-Diagnosed during pregnancy: Past, Current -In care during the 6 months prior to pregnancy -Partner
notification - Notified: Prior to first visit, During pregnancy, Postpartum, Not notified -Partner + or - -Details of
antiretroviral treatment history -Past HIV-associated laboratory results -HIV-associated laboratory results during
the current pregnancy - Pregnancy-associated laboratory results -HIV or AIDS diagnosis -Estimated gestational
age at entry into program - Medications in current pregnancy -Number of prenatal visits -Anemia (Hct<30 or
Hgb<10) -Pap smear (normal/abnormal) -Triple screen (normal/abnormal) -One hour glucose challenge
(normal/abnormal) -Mode of delivery: If Cesarean: for HIV indications, or OB indications -AZT or other ARVs in
labor (yes/no): If other than AZT, specify; If not given, provide explanation -Gestational age at delivery -
Miscarriage rate -Pregnancy complications - Baby outcome -Weight -Length -HIV status -At birth up to one
month of age -One month to six months of age -Baby HIV provider -Retrovirology -Allergy and Immunology
(A&I) -LBJ -Mother seen for postpartum visit within 3 months of delivery -Mother assigned to PCP if not
previously with PCP -Numbers/characteristics of those with a second pregnancy under our watch -Current
smoking, illicit drug use, alcohol use -HIV Genotype resistance testing

Section E: Protocol Risks/Subjects
E1. Risk Category
Category 1: Research not involving greater than minimum risk.
E2. Subjects
Gender: Female
Age:
Adolescent (13-17 yrs), Adult (18-64 yrs), Fetus
Ethnicity:
All Ethnicities
Primary Language:
Groups to be recruited will include:
Asymptomatic patients with chronic conditions, healthy
Which if any of the following vulnerable populations will be recruited as subjects?
Vulnerable populations require special protections. How will you obtain informed consent, protect subject
confidentiality, and prevent undue coercion?
Not applicable. This is a chart review.
E3. Pregnant woman/fetus
Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No
E4. Neonates
Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in
the research?

No

E5 Children

Will children be enrolled in the research?   No

Section F: Design/Procedure

F1 Design

Select one category that most adequately describes your research:

a) Chart/scan/record review

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

Retrospective chart review: Charts from 2006 through June 30, 2018 will be reviewed.

Inclusion Criteria

The subject/research population will include all women enrolled in the Harris County Hospital District Women's Program and UCSF's prenatal program providing obstetrical care for HIV-positive women. Includes those who transfer care or have a miscarriage. The control group will be comprised of HIV-negative women obtaining obstetrical care at the Harris County Hospital District Vallbona Health Center. This includes patients who transfer care or have a miscarriage.

Exclusion Criteria

Non-pregnant women

F2 Procedure

NA

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 1000   Worldwide: 1000

Please indicate why you chose the sample size proposed:

There have been 486 women enrolled in the Harris County Hospital District Women's Program at Northwest Clinic since 2000. We will focus on women who delivered between 2006 and June 30, 2018, since their records are available electronically.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

This study is primarily a descriptive study of the outcomes of this program for quality improvement and research purposes. However, these outcomes will also be compared to a control population in order to determine statistical and clinical significance which in turn can lead to quality improvement and spawn further research. Because only three women have delivered an HIV-infected child, hypothesis testing of the correlates of avoiding vertical transmission cannot be done. We will instead describe our patient population characteristics, HIV treatment characteristics, and obstetric/gynecologic care characteristics. Any statistical methods to compare such characteristics will use the chi- square test for categorical data, the t-test or ANOVA for continuous data that is normally distributed, and the Wilcoxon or Kruskal-Wallis test for non-parametric data. Standard multivariate regression techniques may also be used

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

Since the subjects can be identified by medical record number, there is a risk of loss of confidentiality. However, records will be kept in a locked file cabinet to reduce this risk.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

None.

Describe potential benefit(s) to society of the planned work.

The study will help us to focus our future efforts to improve our program.

1) Demographic information, e.g. zip code, will tell us which parts of the city we should be targeting with preventive messages and where HIV services are perhaps needed.

2) Partner notification: We need to know the baseline number of clients who disclose their HIV status to sexual partners. Thereafter, we might develop an intervention strategy and study whether the disclosure rate subsequently increases.

3) Time of diagnosis: The percentage diagnosed via routine prenatal screening will support or refute advantages of routine prenatal screening (may support the Texas approach as a model for other states).

4) Correlation of viral load (VL) and CD4 counts with obstetric complications

5) Viral loads at time of delivery: if the percentage of women that do not achieve an undetectable VL by the time of delivery is high, then we might need to repeat VLs more frequently to provide time before delivery for more intensive counseling about adherence.

6) Gestational age at delivery: Is the incidence of prematurity greater than in the general population? Is preterm delivery associated with lower CD4s, particular drugs, or other HIV-related problems?

7) Postpartum care: What fraction of women return for postpartum care? How many women stop antiretroviral (ARV) therapy because they were instructed to (CD4 prior to treatment <350)? How many stop ARV therapy by their own choice (against medical advice)?

8) Will assess how rapidly viral loads decrease after initiation of antiretroviral therapy. The results may influence national guidelines for who is advised to have a Cesarean and who may have a vaginal delivery. The current recommendation for women who present at 36 weeks gestation with HIV and not on therapy is for Cesarean section at

38 weeks. If we can show that viral loads below a certain level can be reduced to less than 1000 in 2 weeks or less, then more women may be allowed to safely deliver vaginally.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Yes. We may significantly improve our program. The data base may suggest trends that warrant further research. There is no risk to the clients. There is no change from the past in risk to benefit ratio.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

Yes\

Please describe the portion of the research for which a waiver is required. (Example: chart review to determine subject eligibility)

Chart review to look at demographics and clinical dataExplain why the research and the use or disclosure of protected health information involves no more than minimal risk(including privacy risks) to the individuals.
This is a retrospective chart review to create a database. PHI will be de-identified and kept in a secure BCM database.

Explain why the waiver will not adversely affect the privacy rights and the welfare of the research subjects.This is a retrospective chart review to create a database. PHI will be de-identified and kept in a secure BCM database.

Explain why the research could not practicably be conducted without the waiver and could not practicably be conducted without access to and use of the protected health information.Since this is a retrospective review, we no longer have contact information for many clients. We cannot access the necessary information without reviewing charts.

Describe how an adequate plan exists in order to protect identifiers from improper use and disclosure.We are using a carefully protected database program created by the Institute for Clinical and Translational Research

(ICTR) at BCM.

Describe how an adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.The list of patients is in a secure Harris Health database which can only be accessed by protocol investigators.

Describe how adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.All investigators have completed education on human subjects protection and understand that information is not to be shared.

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse: Yes

Specific information concerning drug abuse: Yes

Specific information concerning sickle cell anemia: Yes

Specific information concerning HIV: Yes

Specific information concerning psychiatry notes: Yes

Demographic information (name, D.O.B., age, gender, race, etc.): Yes

Full Social Security #: No

Partial Social Security # (Last four digits): No

Billing or financial records: No

Photographs, videotapes, and/or audiotapes of you:

No

Other:

    No

Will additional pertinent information be provided to subjects after participation?

No

If No, explain why providing subjects additional pertinent information after participation is not appropriate.

Since this is a retrospective chart review covering a >5 year time period, we no longer have contact information for many clients.

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

Yes

Explain how the only record linking the participant and the research would be the consent document, and how the principal risk would be potential harm resulting from a breach of confidentiality, and how each participant will be asked whether he or she wants documentation linking the participant with the research and their wishes will govern.

Consent is not relevant to this study as outlined above.

J2. Consent Procedures

Who will recruit subjects for this study?

PI

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Harris County Hospital District has maintained a list of clients who have been enrolled in prenatal care through the Women's Program. The electronic charts of clients identified by the HHS as being enrolled in the Women's Program will be electronically viewed at Northwest Health Center on their system. This will also include electronic birth outcome records for deliveries that occur at Ben Taub General Hospital. Occasionally, hard copy charts may be pulled at the Northwest Clinic to obtain information for this database that may not be included in the HHS electronic medical record. All electronic medical record and hard copy record data collection will occur at Northwest Health Clinic.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

    No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

No

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Yes

Specific information concerning alcohol abuse: Yes

Specific information concerning drug abuse: Yes

Specific information concerning sickle cell anemia: Yes

Specific information concerning HIV: Yes

Specific information concerning psychiatry notes: Yes

Demographic information (name, D.O.B., age, gender, race, etc.): Yes

Full Social Security #: No

Partial Social Security # (Last four digits): No

Billing or financial records: No

Photographs, videotapes, and/or audiotapes of you: No

Other: No

At what institution will the physical research data be kept?

The data will be entered into a secure BCM database created by the Institute for Clinical and Translational Research at

BCM.

How will such physical research data be secured?

Information will go directly into the secure online database.

At what institution will the electronic research data be kept?

BCM

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

Yes

Such electronic research data will be secured via Other: No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data

(including PHI sponsors and/or collaborators).

Co-investigators must enter secure online database.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

None

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

NA

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan: NA

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.
Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug that is not approved by the FDA?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
No

Section Q.   Consent Form(s)

None

Section R: Advertisements

None

Appendix B

Baylor & UTHealth Cizik School of Nursing Data Use Agreement

DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is made and entered into as of this 12th_ day of _July, 2019_ by and between <u>BAYLOR COLLEGE OF MEDICINE</u> ("BAYLOR") with principal offices located at One Baylor Plaza, Houston, Texas 77030, and, UTHealth Cizik School of Nursing ("RECIPIENT") with principal offices located at 6901 Bertner Avenue, Houston, Texas, 77030, individually, a "Party," and collectively, the "Parties." The effective date of this Agreement is the date of the last signature.

   WHEREAS, BAYLOR may Disclose or make available to RECIPIENT certain Protected Health Information ("PHI") in the form of a Limited Data Set, as defined below, and RECIPIENT may receive, Use, Disclose, transmit, maintain or create from the Limited Data Set certain information for purposes of research, public health, or health care operations as provided below; and

   WHEREAS, BAYLOR, a Covered Entity as defined by the HIPAA Rules, and RECIPIENT are committed to comply with the Privacy, Security, Breach Notification, and Enforcement Rules at 45 C.P.R. Parts 160 and 164 of the Health Insurance Portability and Accountability Act of 1996, known collectively as the HIPAA Rules, and the Health Information Technology for Economic and Clinical Health Act (HITECH) amendments to the HIPAA Rules; and

   WHEREAS, BAYLOR is required to obtain assurances from RECIPIENT that RECIPIENT will only Use or Disclose PHI as permitted by this Agreement, and;

   WHEREAS, the Parties enter into this Agreement as a condition to BAYLOR furnishing the Limited Data Set to RECIPIENT once RECIPIENT has provided assurances about its Use and Disclosure of the Limited Data Set.

   NOW, THEREFORE, in consideration of the mutual covenants and representations contained herein, the Parties agree as follows:

A.   DEFINITIONS

Capitalized terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the HIPAA Rules.

1. <u>Limited Data Set</u> of direct identifiers shall have the same meaning as the term "limited data set" in 45 CPR 164.514(e) of the Privacy Rule. Unless otherwise required by the HIPAA Rules, the term "Limited Data Set" shall include only the following direct identifiers of the Individual or of relatives, employers or household members of the Individual:

   a) Dates of treatment, admission, discharge
   b) Birth date, date of death
   c) Age (including age 90 or over)
   d) Geographic subdivisions such as state, country, town, city, precinct, and zip code
   e) Unique codes or identifiers that are not direct identifiers or replicates of a part of direct identifiers.

2. <u>Direct Identifiers</u>, other than those of a Limited Data Set, may not be disclosed with this Agreement. The following direct identifiers of the Individual or of relatives, employers, or household members of the Individual are as follows:
   a) Nameb) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geographic codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: (l)The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
   c) All elements of dates (except year) for dates directly related to an individual, including birth

date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

d) Telephone numbers, fax numbers

e) Electronic mail addresses

f) Social Security numbers, medical record numbers, health plan beneficiary numbers g) Account numbers, Certificate/license numbers

h) Vehicle identifiers and serial numbers, including license plate numbers i) Device identifiers and serial numbers

j) Web Universal Resource Locators (URLs)

k) Internet Protocol (IP) address numbers

I) Biometric identifiers, including finger and voice prints

m) Full face photographic images and any comparable image

n) Any other unique identifying number, characteristic, or code, except as permitted as a means of record identification to allow information de-identified to be re-identified.

3. **Commercial purposes:** The sale, lease, license, or other transfer of the Limited Data Set to a for-profit organization (other than RECIPIENT) and shall also include uses of the Limited Data Set by any organization, including RECIPIENT, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Limited Data Set to a for-profit organization.

B. SCOPE AND PURPOSE

1. This Agreement sets forth the terms and conditions pursuant to which BAYLOR will Disclose certain

   PHI in the form of a Limited Data Set to RECIPIENT.

2. Except as otherwise specified by this Agreement, RECIPIENT may make all Uses and Disclosures of the Limited Data Set necessary for the designated research, public health, or health care operations as described herein: HIV-adapted CenteringPregnancy® Program Outcomes for Women Living with *HN* and their Newborns

   {Permitted Data Use"). If the Permitted Data Use is for research, provide the protocol number: *HN*

   Perinatal Database, Protocol Number: H-18412

3. Any and all other studies or uses of the Limited Data Set are expressly prohibited and may not be pursued by the RECIPIENT, any member of the RECIPIENT'S staff or any agent or subcontractor of the RECIPIENT without written approval of BAYLOR.

4. The Limited Data Set shall not be used for any commercial purposes.

5. In addition to the RECIPIENT, there are no other individuals, or classes of individuals, who are permitted to use or receive the PHI contained within the Limited Data Set for the Permitted Data Use.

6. The Limited Data Set to be provided by BAYLOR to the RECIPIENT per the Data Use Agreement for

   the Permitted Data Use consists of the following direct identifiers: Dates of prenatal care appointments (labeled as traditional or Centering), age, and Clinical Trials Management System Patient Accession Number

7. Additional data to be provided with the Limited Data Set that are not direct identifiers are as follows: race, education level, presence of infection other than HIV during pregnancy, smoking status, previous preterm birth, diagnosis of preeclampsia, gestational age of newborn, plasma RNA level (viral load) prior to delivery, live birth, fetal demise, miscarriage, single or multiple pregnancy, and newborn birth weight

8. Describe in detail how RECIPIENT will secure and protect the Limited Data Set including but not limited to a description of the security of any databases to be used and how the Limited Data Set will be transmitted, if applicable, and stored: Data will be stored on a secure network at

UTHealth Cizik School ofNursing

C. OBLIGATIONS AND ACTIVITIES OF RECIPIENT

1. RECIPIENT agrees to the following:

   a) To not Use or further Disclose the Limited Data Set for any purpose other than as permitted by this

      Data Use Agreement or as Required by Law;

   b) To use appropriate data security measures and other safeguards to prevent inappropriate Use or

      Disclosure of the Limited Data Set other than as provided by this Agreement;

   c) To notify BAYLOR, in writing, of any Use or Disclosure of the Limited Data Set not provided for by this Agreement of which RECIPIENT becomes aware, including without limitation, any Disclosure of PHI to an unauthorized employee, agent or subcontractor of the RECIPIENT, within ten (10) days of its discovery;

   d) To ensure that any agent and/or subcontractor of RECIPIENT to whom it provides the Limited Data Set agrees, in writing, to the same standards, restrictions and conditions that apply through this Agreement to the RECIPIENT.

   e) To not identify the information contained in the Limited Data Set or contact the Individual/s.

   f) To not create, receive, maintain, transmit, Use or Disclose the Limited Data Set outside of the

      United States.

2. This Data Use Agreement does not authorize the RECIPIENT to Use or Disclose the Limited Data Set for the Permitted Data Use in a manner that would violate the requirements of the HIPAA Rules if done by BAYLOR.

3. RECIPIENT will indemnify, defend and hold harmless BAYLOR and any of BAYLOR'S affiliates, and their respective trustees, officers, directors, employees and agents ("Indemnitees") from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by RECIPIENT or any subcontractor, agent or person under RECIPIENT'S control.

4. RECIPIENT understands that violations of the terms of this Agreement by RECIPIENT may be considered violations of the federal HIPAA Rules.

D. TRANSFER OF DATA

After execution of this Agreement, BAYLOR shall deliver the Limited Data Set and any additional data that are not direct identifiers as provided in Section B.7. to the RECIPIENT in the following secure manner: Recipient will be extracting data from Baylor Clinical Trial Management System as she is an approved user with a current password to the system.

RECIPIENT: Name: Dr. Diane Wardell
Title:
UTHealth Cizik School ofNursing
Address: _____
E-mail address: Diane.Wardell@uth.tmc.edu
Phone: 713-500-2056, SON-589
Other: _____

With a copy to: Name : Jodi H Behr
Title: PhD Candidate!UTHealth Cizik School ofNursing;
Research Assistant Baylor
College of Medicine Ob/Gyn Department
Address: _
_____
E-mail address: Jodi.h.behr@uth.tmc.edu; Jodi.behr@bcm.edu
Phone: 502-759-1333
Other: _____

E. TERM AND TERMINATION

1. This Agreement shall terminate when all of the Limited Data Set, including copies or replicas, provided by BAYLOR to RECIPIENT for the Permitted Data Use is destroyed, as evidenced by a Certificate of Destruction, or securely returned to BAYLOR. If it is not feasible to return or destroy the Limited Data Set, appropriate data protection and safeguards are extended to the Limited Data Set in accordance with the requirements of the HIPAA Rules and this Agreement for as long as the Limited Data Set remains in possession by the RECIPIENT.

2. Destruction of the Limited Data Set must be in accordance with industry standards and processes for ensuring that reconstruction, re-use, and/or re-disclosure of the Limited Data Set is prevented after destruction using a method effective for the media in which the Limited Data Set is contained.

3. Either Party may terminate this Agreement for a material breach by the other Party, if such breach is not cured to the satisfaction of the non-breaching Party within thirty (30) days after the non-breaching Party gives written notice of the breach to the breaching Party

F. MISCELLANEOUS

1. A reference in this Agreement to a section in the HIPAA Rules means the section as amended or as renumbered.

2. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA Rules.

3. The respective obligations of RECIPIENT under Section C of this Agreement shall survive termination of this Agreement.

4. Any ambiguity in this Agreement shall be resolved to permit BAYLOR to comply with the HIPAA Rules.

5. There are no intended third party beneficiaries to this Agreement. Without in any way limiting the foregoing, it is the Parties' specific intent that nothing contained in this Agreement gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose PHI is Used or Disclosed pursuant to this Agreement.

6. Nothing in this Agreement shall be construed to create: (i) a partnership, joint venture, or other joint business relationship between the Parties or any of their affiliates; (ii) any fiduciary duty owed by one Party to another Party or any of its affiliates; or (iii) an agency or employment relationship between the Parties or any of their affiliates.

7. Failure or delay on the part of either Party to exercise any right, power, privilege or remedy hereunder shall not constitute a waiver thereof. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

8. The persons signing below have the right and authority to execute this Agreement and no further approvals are necessary to create a binding agreement.

9. The provisions of this Agreement shall be severable and, if any provision of this Agreement shall be held or declared to be illegal, invalid or unenforceable, the remainder of this Agreement shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

10. The descriptive headings of the articles, sections, subsections, exhibits and schedules of this Agreement are inserted for convenience only, do not constitute a part of this Agreement, and shall not affect in any way the meaning or interpretation of this Agreement.

11. In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern. Without limiting the foregoing, no provision of any other agreement or understanding between the parties limiting the liability of RECIPIENT to BAYLOR shall apply to the breach of any covenant in this Agreement by RECIPIENT.

12. This Agreement shall be construed in accordance with and governed by the laws of the State of Texas or jurisdiction of BAYLOR without regard to applicable conflict of laws principles. Any suit, action or proceeding against either Party with respect to this Agreement shall be brought in the state or federal courts located in Harris County, Texas, and the other Party hereby submits to the non-exclusive jurisdiction of such courts for the purpose of any such suit, action or proceeding.

13. Any notices pertaining to this Agreement shall be given in writing and shall be deemed duly given when personally delivered to a Party or a Party's authorized representative as listed below or sent by means of a reputable overnight carrier, or sent by means of certified mail, return receipt requested,

postage prepaid. A notice sent by certified mail shall be deemed giYcn on the date of receipt or refusal o(retelpl All notices shall be addressed to the appropriate Pany us follows:

lfto BAYLOR
Baylor College of Medicine Chief Compliance Officer One Baylor PlRZB MSBCM265
Houston, Texas 77030   _____

_____
_____

I4. This Agreement is binding upon and inures to the benefit of the Parties hereto and their respective successors lllld permitted assigns. However, neither Pany may BSSilltl any of its rights or delegale any of its obligatims under this Agreement without the prior wrinen consent of the other Party, which OO!lSCl\t sllaiii\OI be **onably** withheld or delayed. Notwithstanding any provisions to the oontruy, however, BAYLOR retains the right to assign or delegate any of its rights or obligations hereunder to any of illl wholly owned subsidiaries, affiliates or sucussor companies. Assignments lllldc in violation of this provision tR null and void.

15. This Agreement, together with all exhibits, schedules, riders, lUid amendments, if applicable, which arc IUlly completed and signed by authorized persons on behalf of both Parties from time to time while this Agreement is in effca, oonstitulell the entire Agreement between the Parties hcn:to with respect to the subjeet mancr 🖝 and supersedes all previous writlen or oral undeBW dings. agrc:cments, negotiations, commitmmts, and any other writing and communication by or between the Panics with respect to the subject mlllller hetco[In tile event of lllly inconsistencies between any provisions of this AgR>cmentin BllY provisions of the exhibits, sc:hcdulcs. riders, and Amendment, the provisions of this Ag.rtc.11enl shall COlllJ'Ol••

16. An electronic c:opy or fBCSimilc of a signature hereto will be binding upon the signatory as if it were an original **si**   **_**

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the Effective Date set forth aboYe.

BAYLOR COLLEGE OF MEDICINE,
By: _____   _____
(Authorized Signature)   (Authorized Signature)
Print name: _____   _____
Title: _____   Essor, DIRECTOR
Date: _____   I I 9   PhD PROGRAM

Read and Understood By: Principle Investigator signature
Name: Dian Wardell PhD   NHNP-BC
Signature: Diane Wardell PhD
Date: 9/15/14

Read and Understood By: Recipient project leader
Name: Jodi H. Behr
Signature: _____

Page 6 of 7   _____

es shall be addressed to the appropriate Pany us follows:

Date: _____

Stamped Approval Space

Appendix C

CPHS Approval

UTHealth™

The University of Texas
Health Science Center at Houston

Dr. Jodi Behr
Cizik School of Nursing

August 06, 2019

<u>HSC-SN-19-0662</u> - *HIV-adapted Centering Pregnancy ® Program Outcomes for Women Living with HIV and their Newborns*

The above named project is determined to qualify for exempt status according to 45 CFR 46.101(b)

CATEGORY #4 : *Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.*

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via iRIS to the Committee for the Protection of Human Subjects for review.

INFORMED CONSENT DETERMINATION:
Waiver of Consent Granted

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. <u>Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.</u>

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):
Exempt from HIPAA: No identifiers are extracted

STUDY CLOSURES: Upon completion of your project, submission of a study closure report is required. The study closure report should be submitted once all data has been collected and analyzed.

Should you have any questions, please contact the Office of Research Support Committees at 713-500-7943.

Appendix D

Data Management & Codebook

Data Management and Codebook

1. Introduction

   The purpose of this document is to provide a step-by-step guide and serve as a

   reference for the data collection process.

2. Assessing eligibility criteria

   A master list of subjects that were provided care through Harris Health and Baylor

   College of Medicine will be obtained from Judy Levison, MD, MPH. The master

   list will contain names and medical record numbers. If inclusion criteria are met

   and no

   exclusion criteria apply, the name and the medical record number will be used to

   access the CTMS system record for the subject.

   Once the subject is included, a study identification number will be assigned in the

   principal investigator's database. A four-digit identifier will be assigned to each

   subject. The first two digits will be the year the subject started prenatal care and

   the last two

   digits will be a consecutive running list of numbers.

3. Study Personnel

   Study personnel will enter the following codes found in the Variable Codebook

   into the data worksheet.

Variable	Definition	Units of Variables	Coding for Variable in SPSS	Data Source in BCM CTMS
Age	Age of mother at first prenatal care visit	Years	Numerical value	Demographics screen
Race	Race of mother	None	1 Caucasian 2 Black 3 Hispanic 4 Asian/Pacific Islander 5 Native American 6 Other	Demographics
Infections	Presence of infection(s) other than HIV	None	0 No presence of other infection 1 Presence of other infection	Pregnancy Complications
Mother's smoking status	Mother's smoking status during pregnancy	None	0 Did not smoke during pregnancy 1 Did smoke during pregnancy	Substance abuse screen
Mother's other substance abuse	Mother's use of other substances by self-reported information	None	0 Did not use other substances during pregnancy 1 Did use other substances during pregnancy	Substance abuse screen
Previous preterm birth	A birth that occurred prior to 37 weeks gestation	None	0 Non previous preterm birth 1 Previous preterm birth	Pregnancy detail screen
Single/Multiple Birth	A single or multiple newborn	None	0 Single birth 1 multiple birth	Newborn screen
Congenital anomaly of the newborn	A congenital anomaly	None	0 No congenital anomaly 1 congenital anomaly	Pregnancy Complications
Fetal demise	A pregnancy that resulted in	None	0 No fetal demise	Pregnancy Complications

	a fetal demise		1 Fetal demise	
Miscarriage	A pregnancy that ended in miscarriage	None	0 No miscarriage 1 Miscarriage	Pregnancy Complications
Type of prenatal care	Care provided to the mother during pregnancy: Two different models provided One on one care or group prenatal care	None	0 Traditional one-on-one care 1 group prenatal care (Centering)	Visits screen
Adequacy of prenatal care: To calculate the index score the following data is needed:	Index score is derived from Adequacy of Prenatal Care Index.	None	1 Inadequate 2 Intermediate 3 Adequate 4 Adequate Plus	Estimated gestational age at entry into program: Pregnancy details screen
1.Gestational month prenatal care began at Harris Health (MPCBBC)	The month of the pregnancy that prenatal care began at Harris Health	Months	NA	Pregnancy details screen
2.Number of visits (NPCVBC)	Number of prenatal care visits at Harris Health	Visits	NA	Number of visits screens
3. Gestational age (GAGEBC)	Newborn gestational age	Weeks of gestation at birth	NA	Baby Outcome Screen
Maternal plasma HIV RNA levels	Number of HIV plasma RNA cells in maternal blood in last specimen collected prior to delivery	None	0 Detectable maternal HIV RNA levels 1 Undetectable maternal plasma HIV RNA levels	Lab screen
Newborn gestational age	Gestational age of newborn at delivery in weeks & days	Weeks & days	Numerical value	Baby outcome screen
Newborn birth weight	Birth weight of newborn	Kilograms	Numerical value	Baby outcome screen

CURRICULUM VITAE
Jodi Herron Behr, PhD, APRN, RNC-NIC, ACCNS-P

EDUCATION:

The University of Texas Health Science Center at Houston, Houston, TX	2020	PhD	Nursing
University of Missouri, Columbia, MO	2014	Post-Master's Certificate	Pediatric Clinical Nurse Specialist
Indiana University, Indianapolis, IN	2006	MSN	Nursing
Indiana University, Indianapolis, IN	1999	JD	Law
Purdue University West Lafayette, IN	1994	BSN	Nursing

PROFESSIONAL POSITIONS:

Baylor College of Medicine
Houston, TX
      Research Assistant   3/2017 - Present

HealthTrust Workforce Solutions
Houston, TX
      Registry NICU Staff Nurse   8/2017 - 8/2018

HCA Healthcare Houston West
Houston, TX
      Maternal-Child Nurse Supervisor   12/2016 - 8/2017

Memorial Hermann
Houston, TX
      Mother-Baby & NICU Nurse Manager   06/2016 – 10/2016

Norton Healthcare
Louisville, KY
  System Nurse Educator –
  Nursing Research & Evidence-based
   Practice   07/2015 - 06/2016

  NICU Clinical Nurse Specialist   05/2007 - 07/2015

  NICU Level III Nurse Manager   10/2005 - 05/2007

  PICU Assistant Nurse Manager   07/2005 - 10/2005

St. Vincent Hospital
Indianapolis, IN
  NICU Staff Nurse & Pediatric
  Float Nurse   01/2002 - 07/2005

Locke Reynolds LLP   01/2001 - 01/2002
Indianapolis, IN
  Associate Attorney

Humana Inc.   05/1999 – 01/2001
Louisville, KY
  Medical Malpractice Claims Manager

State of Indiana   05/1998 – 05/1999
Indianapolis, IN
  Office of Medicaid Program Coordinator

Indiana University   12/1997 – 05/1998
Indianapolis, IN
  Health Policy Research Assistant

Smart, Kessler, & Torres   08/1996 – 12/1997
Greenwood, IN
  Law
  Clerk

Home Hospital	03/1995 – 08/1996
Lafayette, IN	

    NICU Staff Nurse

Pediatric Nursing Specialists	10/1994 – 03/1995
Indianapolis, IN	

    Home care nurse for technology dependent children

Riley Hospital for Children	06/1994 – 03/1995
Indianapolis, IN	

    Staff Nurse – Infant ICU

PROFESSIONAL MEMBERSHIPS:

Academy of Neonatal Nurses	2002 - Present
American Association of Critical Care Nurses	2011 - Present
American Nurses Association	2014 - Present
National Association of Clinical Nurse Specialists	2008 - Present
National Association of Neonatal Nurses	2002 - Present
Sigma Theta Tau International Nursing Honor Society	1994 - Present

PUBLICATIONS:

Behr, J. H., Wardell, D., Rozmus, C., & Casarez, R. L. (2020). Prevention strategies for neonatal skin injury in the neonatal intensive care unit (accepted for publication)

Flynn, G.A.H., Polivka, B., & Behr, J. H. (2018). Smartphone use by nurses in acute care settings. *Computers, Informatics, Nursing: CIN, 36,* 120-126.

Ray, M. & Behr, J. (2017). National attention on opioid use and abuse: NACNS in the forefront. *Clinical Nurse Specialist: The International Journal for Advanced Nursing Practice, 31,* 115-117.

Polivka, B., Anderson, J., Greenwall, A., Louderback, J, & Behr, J. H. (2016). Comparison of outcomes of extended dwell peripheral intravenous catheters and peripherally inserted central catheters in children. *Journal of the Association for Vascular Access*, *21*, 158-164.

Morris, L., Behr, J. H., & Smith, S. L. (2015). Hydrocolloid to prevent nares breakdown in preterm infants. *MCN, The Journal of Maternal Child Nursing*. *40*, 39-43

Stewart, D. L. & Behr, J. H**.** (2012). Pain and stress in the neonate. *Journal of the*
Kentucky Medical Association, *110*, 5-11

PRESENTATIONS:

Poster Sessions

The Parent Involvement Continuum: The Importance of Achieving Parental Presence, Participation, and Engagement in the NICU, National Association of Neonatal Nurses Annual Conference, Poster Presentation, 07/2019

Predictors of Suicide and Weapon Carrying Among High School Students, The University of Texas Health Science Center at Houston Cizik School of Nursing Research Day, 04/2018

The Use of a Double Barrier Hydrocolloid Dressing to Prevent Skin Breakdown in Very Low Birth Weight Neonates (VLBWs) on High Flow Nasal Cannula, National Association of Neonatal Nurses Annual Conference & Research! Louisville Nursing Symposium, Poster Presentation, 10/2013

An Evidence-based Approach to Preventing Hypothermia in Very Low Birth Weight Babies, Poster Presentation, Research! Louisville Nursing Symposium, 09/2012

Promoting Evidence-Based Skin Care Practices through Skin Care Rounds, National Association of Neonatal Nurses Annual Conference, Poster Presentation, October 2011

Teaching Central Line Practices in a 97-Bed Level IIIC NICU, National Association of Neonatal Nurses Annual Conference & Research! Louisville Nursing Symposium, Poster Presentation, 10/2010

Achieving Staff Compliance with Pulse Oximetry Alarm Limits and Saturation Goals for Neonates 32 Weeks and Less, National Association of Neonatal Nurses Annual Conference & Research! Louisville Nursing Symposium, Poster Presentation, 10/ 2010

Promoting Evidence-Based Practice Through a Virtual Journal Club, National Association of Neonatal Nurses Annual Conference & Research! Louisville Nursing Symposium, Poster Presentation, 10/2010

Collaboration Within the CA-BSI Collaborative: National Association of Children's Hospitals and Related Institutions Annual Conference, Poster Presentation, 10/2008

Podium & Invitation Presentations

HIV-adapted CenteringPregnancy® Program Outcomes for Women Living with HIV and their Newborns, Robert Wood Johnson Future of Nursing Scholar Summer Institute,
07/2018 & 07/2019

The Use of Smartphones by Nurses in the Clinical Setting, Norton Healthcare Chief Nursing Officers Meeting, 03/2016

Norton Healthcare Professional Nursing Practice, Norton Healthcare Institute for Nursing, 07/2015- 06/2016

Evidence-based Practice Workshop, Norton Healthcare Institute for Nursing, 09/2015

Neonatal and Pediatric Pain: Babies and Kids Are Different, Kosair Children's Hospital
Nursing Grand Rounds, 07/2015

The Johns Hopkins Evidence-Based Practice Model, Norton Healthcare Nurses Are Leaders Nursing Symposium, 05/2014

The Johns Hopkins Evidence-Based Practice Model, Norton Healthcare Institute for Nursing Evidence-Based Practice Mentor Workshop, 04/2014

Clinical Practice Guidelines, Norton Healthcare Institute for Nursing Evidence-Based
Practice Mentor Workshop, 04/2014

NIRS and Nursing Care: Can Using Near-Infrared Spectroscopy Enhance Nursing Care in the NICU? National Association of Neonatal Nurses Annual Conference, Specialty Session Presentation, 10/2013

New Innovations in the Care of the Neonate, University of Louisville School of Medicine
Pediatric Grand Rounds, 04/2013

Updates on Skin Care in the Neonatal Intensive Care Unit, Kosair Children's Hospital
Nursing Grand Rounds, 08/2013

Lessons Learned through the IRB Journey, Podium Presentation, Research! Louisville
Nursing Symposium, 12/2012

The OWLs (Oxygen with Love) Have It: Association of Women's Health, Obstetric, and
Neonatal Nurses Annual Conference, Specialty Session Presentation, 09/2010

AWARDS & RECOGNITION

2017 – 2020	Robert Wood Johnson Foundation Future of Nursing Scholar
2016 Internship	Nursing Organization Alliance Nurse in Washington
	Scholarship Recipient
2014	Norton Healthcare Evidence-Based Practice Nurse of the Year
1993	Purdue University's Helen R. Johnson Senior Nursing Undergraduate Scholarship