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Walden University

College of Health Sciences

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Carole Ann Moleti

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Walden University 2015

Abstract

CenteringPregnancy™ Implementation and its Effect on Preterm Birth and Low Birthweight

by

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MPH, Columbia University, 1987

MS, Columbia University, 1986

BS, Herbert H. Lehman College, 1979

Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Nursing Practice

Walden University

February 2015

Abstract

Preterm birth (PTB) and low birthweight (LBW) babies are the source of a large burden of infant, neonatal, and childhood morbidity. The purpose of this project was to expand the use of the CenteringPregnancyTM Group Prenatal Care Model as an evidence-based intervention for management of both medical and psychosocial risk in low-income, ethnic and racial minorities in New York City. The standardized model developed by Schindler Rising decreases the incidence of preterm birth and low birthweight and increases the rate of breastfeeding. A CenteringPregnancyTM program implementation plan, customized to meet the needs of a multisite urban hospital system, was coordinated with the Centering Healthcare Institute to ensure method fidelity while allowing for an individual site's needs based upon patient demographics and provider mix. Program evaluation showed that the logic models supported implementation and expansion of Centering Groups at 2 federally qualified health centers, with adequate progress toward site approval, method fidelity scores, and favorable patient and staff satisfaction ratings using the CenteringCountsTM data collection system. After a total of 4 Centering group cohorts with 26 women, 7 at high medical risk, 4 delivered preterm (11.5%), 2.3% less than the institutional average PTB rate of 13.8%. One out of 26 women delivered a LBW infant. Twenty-two of 24 women (92%) initiated breastfeeding compared to the institutional average of 89%. To foster a change in policy toward Centering as the default option for prenatal care, ongoing evaluation is required to assess the reduction of and fiscal impact on preterm and low birthweight rates to offset the cost of implementation.

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Dedication

This project was undertaken for one reason: the women of The Bronx. Caring for them, despite all the complexities and difficulties, has brought me the greatest joy and fulfillment imaginable. Their smiles, hugs, tears, and trust have kept me going through those long sleepless nights and hectic days.

My thoughts often reach out to great-grandmother Jennie Bruno, who delivered babies for the women of The Bronx in the early 1900s when mothers and babies routinely died. And to my grandfather, Alexander Bruno, who passed her talent, her legacy, and her instruments to me. To my husband John, my sons Nicholas and Adam, and my daughter Maya who put up with the crazy schedules and phone calls in the middle of the night. And to Michael and my parents who encouraged me from the very beginning to accept the call, along with the challenges answering it would bring.

Acknowledgments

This project is the culmination of more than 2 decades of work that began with the kind offer of a public health internship from Nancy DeVore, CNM, MS. The years that ensued in the midwifery practice at Jacobi Hospital were some of the happiest of my career, with treasured memories and enduring friendships. The influence of mentors like Nancy and Margaret Comerford Freda, EdD, RN, CHES, with whom I worked with at Einstein's Program to Reduce Obstetrical Problems and Prematurity (PROPP), has come full circle and back to the basics with CenteringPregnancyTM, the intervention that just might be the answer we've been looking for all these years.

Thanks go out to my longtime midwifery partner Susan Bellinson, CNM, MS for her willingness to help with this project, and Peter Bernstein, MD, MPH for his enthusiasm and support of the research process. Sharon Schindler Rising, CNM, MS, FACM and the entire team at Centering Healthcare Institute as well as at Montefiore's Comprehensive Family Care Center and Family Health Center welcomed and supported the planning and implementation of the Centering expansion that preceded data collection and analysis. Special mention is due Rebecca Mahn who, despite the rigors and time constraints of medical school, has remained deeply involved and committed to CenteringPregnancyTM as the twenty-first century's answer to stubborn problems and disparities that affect women and children. I am immensely grateful for all the teamwork, dedication, and support needed to do this work, which can be so difficult and complex.

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Section 1: Overview of the Evidence-Based Practice Project

Preterm birth (PTB) and low birthweight (LBW) babies are the source of a large burden of infant, neonatal, and childhood morbidity. Annually, the cost to the U.S. health care system of babies born too early or two small rose from an estimated \$5.8 billion in 2001 (Russell et al., 2007) to \$26.2 billion in 2005 (Centering Healthcare Institute [CHI] 2013). The major portion of costs incurred was for babies who were not extremely premature (Russell et al., 2007). Darling and Atav (2012) estimated that the rate of LBW babies (<2500 grams) increased from 7.7% in 1996 to 8.2% in 2009, which reflected the increasing trend toward elective inductions and late preterm birth. This led to a major public education campaign by The March of Dimes directed toward women and families to discourage elective inductions (March of Dimes, 2013). Despite some progress, rates of PTB and LBW in many states and localities remain higher than Healthy People 2020 targets (U.S. Department of Health and Human Services, 2011).

CenteringPregnancyTM Group Prenatal Care (Rising, 1998), currently in use with low medical risk women, has a beneficial effect on self-efficacy and self-esteem, leading to greater self-care competence, as described by Orem (1980). Centering has been shown to decrease the rate of preterm birth and low birthweight infants; increase the numbers of women breastfeeding at hospital discharge; increase self-efficacy; and lower the rates of depression, stress, and maladaptive behaviors (CHI, 2013). This effect might be more pronounced in women at both high medical and psychosocial risk who experience the additional stressors of pregnancy complications (Picklesimer et al., 2012).

Through a systematic review of the literature, Lathrop (2013) compared group prenatal care to traditional one provider, one patient prenatal care. Despite several studies with conflicting or inconclusive findings attributed to a lack of randomization and/or small sample size, group prenatal care participants have higher rates of breastfeeding initiation and satisfaction with care. Outcomes were significantly improved in high-risk populations, particularly adolescents and those from racial and ethnic minorities (Lathrop, 2013). Evidence from randomized controlled trials and larger prospective, correlational, and retrospective cohort studies found that group prenatal care participants have lower rates of preterm birth, higher birthweights in babies born preterm, adequate weight gain, increased contact hours of prenatal care visits, and more knowledge and better preparation for labor and delivery (Lathrop, 2013).

Meta-analyses of the effectiveness of various prenatal care and education programs (Gagnon & Sandall, 2011; Hodnett, Fredericks, & Weston, 2010), though inconclusive, point toward a need identify the efficacy of standardized educational programs and specific interventions for patients at high psychosocial risk. Designing effective prenatal care and education requires attention to individual health literacy, learning styles, cultural, and ethnic preferences. Centering was designed to meet the needs of women at psychosocial risk (CHI, 2013) and, while effective, the mechanism by which CenteringPregnancy™ effects its benefits has been postulated but not sufficiently investigated (Sheeder, Yorga, & Kabir-Greher, 2012).

Problem Statement

The incidence and prevalence of preterm birth and low birthweight in The Bronx, New York City exceeds regional state, national, and local averages despite years of borough-wide, targeted educational programs such as the Program to Reduce Obstetrical Problems and Prematurity (PROPP) to mitigate risk factors and foster timely intervention (Freda, Damus, Anderson, Brustman, & Merkatz, 1990). The lack of a defined, effective intervention dictates a need to implement an evidence-based model to address the needs of this vulnerable population. Use of the plan-do-check-act (PCDA) model (Deming as cited in Kelly, 2011) guided the planning, implementation, and expansion of CenteringPregnancyTM Group Prenatal Care and an evaluation of quality improvement, satisfaction, and financial impact in this marginalized socially at risk population.

Purpose Statement

The purpose of this evidence-based practice project was to develop a process and outcome model for program implementation in a large, multisite health system and to evaluate CenteringPregnancyTM Group Prenatal Care Model (Rising, 1998) as an intervention for management of both medical and psychosocial risk in low-income, ethnic and racial minorities in The Bronx, New York City. The Centering Healthcare Institute documented a decrease in the rates of preterm birth, maternal depression, and stress scores and an increase in breastfeeding initiation when used in the general population of pregnant women (CHI, 2013). Use of CenteringCountsTM, the data collection system developed by CHI (Munroe, 2013), standardizes site reports and data collection and validates prenatal care adequacy by trimester of prenatal care entry and number of visits (Kotelchuck, 1994). It monitors method fidelity based upon adherence to the 13 essential

elements. CenteringCounts[™] also tracks the progress from baseline institutional rates of key indicators of maternal and neonatal health, including preterm birth, low birthweight, and initiation of breastfeeding toward targeted benchmarks. These data were used to track progress for the target population of racial and ethnic minority women at high psychosocial risk in both low medical and high medical risk pregnancies.

The project included clinical, quality improvement, and financial arms with ongoing evaluation of outcomes using the CenteringCountsTM data collection and analysis system (Munroe, 2013). The clinical arm included use of CenteringPregnancyTM Group Prenatal care to address educational and self-care deficits and empower women and families to make informed choices about the burgeoning and inappropriate use of emergency services and technology. The goal was to decrease stress related and iatrogenic effects on the mother and her fetus/newborn to ensure safer, more cost effective care and a smoother adaptation to parenthood (CHI, 2013, 2014; Moleti, 2009; Picklesimer et al., 2012). The quality improvement arm validated the role that the doctor of nursing practice (DNP) can play in program planning, design, implementation, and evaluation, as well as on interdisciplinary teams providing evidence-based care. The financial arm estimated the impact of preterm birth and low birthweight reduction, as measured by the marker of neonatal intensive care unit (NICU) admission, using the current cost estimate based upon the total number of deliveries for the institution, the Bronx wide percentage of preterm births, and NICU admissions.

Four Montefiore Medical Center and Montefiore Medical Group (MMC/MMG) sites were previously certified by CHI, leaving behind a group of trained nurses,

midwives, and physicians. There were vestigial Centering programs at two of the original sites, Comprehensive Family Care Center (CFCC) and Family Health Center (FHC). The ultimate goal of the implementation was to begin the process of making CenteringPregnancy™ Group Prenatal Care the opt out model at all MMC/MMG sites (see Table 1). Upon conclusion of this project, the two practicum sites, CFCC and FHC, were preparing for the CHI site approval process in early 2015. Use of the process and outcome logic models for both existing and new Centering programs will enable roll out of the opt out model to other sites in the MMC/MMG, using additional PDCA cycles, over the next 2-5 years.

The evaluation obtained preliminary evidence regarding the impact of Centering implementation and expansion on women at high medical and psychosocial risk on rates of low birthweight, preterm delivery, and initiation of breastfeeding.

Project Goals and Objectives

- 1. Develop an evidence-based, institution-wide process and outcomeoriented model for the implementation and expansion of the CenteringPregnancyTM Group Prenatal Care Model to the target population of pregnant women at high medical and psychosocial risk.
- Develop evidence-based practice guidelines in concert with Centering

 Health Care Institute's model and methodologies to operationalize

 CenteringPregnancy™ groups for the target population of pregnant

 women enrolling for prenatal care in two urban, federally qualified health

 centers (FCHCs), all of whom are at high medical and psychosocial risk.

- 3. Develop a practice implementation plan for both current and new sites within MMC/MMG with a focus on CenteringPregnancy TM method fidelity to the 13 essential elements (CHI, 2014) and sustainability.
- 4. Collect data and calculate rates and percentages for the rates of low birthweight, preterm delivery, and breastfeeding initiation, method fidelity, patient and staff satisfaction measures, and financial impact assessment using the CenteringCountsTM data collection system (Munroe, 2013).

Significance and Relevance to Practice

PTB and LBW babies are the source of a large burden of infant, neonatal, and childhood morbidity. The monetary cost to the health system, as well as emotional, psychosocial, and educational costs, impact caregivers, families, and communities.

National Benchmarks

PTB is a nationwide problem. Martin and Osterman (2013) reported that the U.S. preterm birth rate (<37 weeks completed weeks of gestation) decreased from 12.8% in 2006 to 12% in 2010. The preterm birth rate for Black infants in the United States was lower than ever in 2010, but it was still about 60% higher than the rate for White infants (Martin & Osterman, 2013). Non-Hispanic, Black infants had a rate of preterm births of 17.1% in 2010, a decrease from 18.5% in 2006, according to birth certificate data (Martin & Osterman, 2013). Non-Hispanic Whites (10.8%) and Asian/Pacific Islanders (10.7%) fell below the average. Hispanics (11.8%) and American Indian/Alaska Natives (13.6%) hover just over or below the national figure (Martin & Osterman, 2013). Each preterm

birth costs an average of \$51,600.00 per infant (Darling & Atav, 2012). The rates are well above Healthy People 2020 targets (See Table 1), with persistent racial disparities. The emotional and social costs augment the economic burden to the U.S. health care system.

Preterm Birth in the Study Population

New York State partners with individual cities and counties in funding initiatives to address PTB. The Bronx has rates of preterm birth at 12.4% (March of Dimes, 2013), well above the Healthy People 2020 and March of Dimes benchmarks (U.S. Department of Health and Human Services, 2011). Blacks have the highest rate of preterm birth at 15.4% (March of Dimes, 2013). The main practicum site, CFCC, whose population is 33% Black and 45% Hispanic, reported a preterm birth rate slightly above the boroughwide rate of 12.8% in 2012, likely reflecting population demographics and the very high medical and psychosocial risk status of women in this perinatal referral center. Despite the most cutting edge medical and perinatal interventions, the rate of PTB rose to 14.7% in 2013 (C. Lau, personal communication, July 8, 2014). The cost of this increase, using NICU admission as the proxy measurement, was nearly 1 million dollars in direct neonatal care costs alone (Darling & Atay, 2012).

Low Birthweight Babies in New York State, New York City, and The Bronx

The March of Dimes funds state and local health initiatives and public awareness campaigns to address LBW. Aggregate data from 2008-2010 also reported disparities in the New York State (NYS) rate of LBW babies (<2500grams regardless of gestational age at birth), with Whites at 6.8%, Blacks at 12.8 % and non-Black Hispanics at 7.8%. The overall NYS rate is 8.2% (March of Dimes, 2013). The Bronx has an overall rate of

low birthweight of 9.9% as compared with New York City as a whole at 8.7% (March of Dimes, 2013). This translates into 2,190 Bronx babies in 2010, for a cost of \$111,690,000 (Darling & Atav, 2012; March of Dimes, 2013, Russell et al., 2007). Citywide, the number of low birthweight infants totaled 10,483, with direct neonatal intensive care costs alone of \$540,922,800 (March of Dimes, 2013). The additional emotional, financial, and social costs of caring for children with chronic conditions as sequellae of prematurity places a heavy burden on families, schools, and communities.

Despite the Hispanic paradox, a phenomenon, described by Fuentes-Afflick, Hessol, and Perez-Stable (1999), which explains positive health outcomes in Hispanic immigrants living in poverty, Puerto Rican women are second only to Black women for the risk of LBW and more likely to deliver at 32-36 weeks than non Hispanic Whites (Tandon, Colon, Vega, Murphy, & Alonso, 2012; Steiner et al., 2009). Puerto Ricans make up 9% of the Hispanic population nationwide (Motel & Patten, 2014). The Bronx has the highest proportion of Puerto Ricans in the United States, and this group comprises 6% of the Hispanic population in the borough (Motel & Patten, 2014). This demographic may contribute to the higher rates of LBW in the catchment area of the institution.

Quality Improvement Targets for Preterm Birth and Low Birthweight

Reduction of the rates of PTB and LBW are current national priorities. Healthy People 2020 objectives call for a reduction in the rate of preterm birth to 11.4% and low birthweight to 7.8 % (U.S. Department of Health and Human Services 2011). The March of Dimes (2013) has set even more stringent benchmarks for its signature campaign to reduce preterm birth rates to 9.6%. Their efforts are combatting late preterm birth due to

iatrogenic and preventable causes as well as early elective deliveries that lack evidencebased medical indications (See Table 1).

Definition of Terms

Psychosocial risk: Psychosocial risk include susceptibility to adverse health outcomes secondary to decreased access to medical and dental care, nutritious food, physical/geographical barriers, poverty, inadequate educational services, language/cultural barriers, substance use/abuse, and substandard housing/homelessness (Moleti, 1990). In addition to physical harm, psychosocial risk includes the adverse effect of stress on relationships, mental health, and emotional well-being.

Key indictors: Each Centering site's current rates of preterm birth (<37 weeks gestation), low birthweight babies <2500 grams), the percentage of women who are breastfeeding, the cesarean section rate, and the number of women who return for postpartum visits (CHI, 2014).

Medical high risk: Pregnant woman with either a medical or pregnancy-related condition that impacts upon her health status or that of the fetus/newborn, requiring perinatal or other specialist involvement in management of pregnancy, labor, delivery, postpartum, or neonatal period (Moleti, 1990).

Preterm birth: A live birth before 37 completed weeks of gestation as calculated from the first day of the last menstrual period or by first trimester sonographic findings (World Health Organization, 2013).

Low birthweight: A newborn of any gestational age with a birthweight below 2500 grams or 5 pounds and 8 ounces (March of Dimes, 2014).

Breastfeeding: This study conforms to the definition used by Centering

Healthcare Institute in their data collection tool, CenteringCounts TM, meaning the mother

was breastfeeding her infant on hospital discharge (Munroe, 2013).

Low income: A household income of up to 138% of the federal poverty level, adjusted for family size, according to federal and expanded New York State Medicaid eligibility guidelines established by the Patient Protection and Affordable Care Act of 2010 (Obamacare Facts, 2014).

Frameworks

CenteringPregnancy™ is a nurse-midwife designed intervention, targeted to low income and racial and ethnic minority women that appears to correct self-care deficits (Orem, 1980) in low income, ethnic and racial minority pregnant women at high psychosocial risk. Moleti (1990) postulated that nursing interventions in women at both medical and psychosocial risk, if begun on a positive, facilitative rather than punitive note, with attention to the individual's particular needs, would be more effective in restoring the patient's ability to avoid, adapt, and cope with crises (see Figure 4). Tenets of social cognitive theory (Bandura, 1971) and applications of middle range nursing theories by Rew (2003) and Perry (2004) may explain the mechanisms by which Centering exerts its benefits.

Change models to engage all stakeholders and assure program sustainability included Lewin's field analysis (as cited in Kelly, 2011) and disruptive design (Christensen, 2013). The PCDA quality improvement methodology (Deming, as cited in Kelly, 2011), in use at MMC/MMC, was used to structure the project planning,

implementation, and evaluation. The interplay between models will be explored in further detail in Section 2.

Assumptions

This project is based on the use of the standardized, validated Centering

PregnancyTM Group Prenatal Care Model. The program consists of 10, 2-hour group

sessions beginning at 12-16 weeks gestation plus the 4-6 week postpartum session, which

conforms to the standard schedule of prenatal/postnatal visits. All care is provided in the

group space, including a patient self-assessment sheet that enables women to set personal,

physical, emotional, and behavioral goals related to the session content. All group

facilitators must have received training in the conduct of the Centering method to insure

fidelity and validity the method (CHI, 2014).

At each visit, there is an individual physical assessment by the provider, then discussion and education on session content related to the current stage of pregnancy. Facilitation during conduct of the group models networking and problem solving skills, which fosters empowerment and self-efficacy. The development of these skills leads to healthier behavioral choices during the pre and postnatal period and beyond (CHI, 2014). Therefore, the following assumptions are made:

- Providers are licensed and credentialed to provide prenatal care and are trained and certified in facilitation of Centering groups by CHI.
- If facilitators adhere to the Centering curriculum and the 13 essential elements (see Table 2), all members of the group in a peer-professional

- relationship will engage in an open, honest discussion that promotes networking, problem solving, and healthier behaviors.
- All CenteringCounts[™] data will be entered accurately and as completely as possible.

Scope and Limitations

The Centering Healthcare Institute's timeline for full method implementation is 3-5 years. During the first 12 months, the site prepares for site approval. At the end of that period, a full year of data from CenteringCounts[™] is sent to CHI. Site approval visits will be scheduled at about 16 months from initial implementation. The DNP project ended in December 2014, 3 months shy of the 12-month mark for CenteringCounts[™] implementation. Ongoing data collection on women enrolled in Centering groups at two federally qualified health centers (FQHCs), FHC and CFCC, will continue to track the first year's progress toward quality improvement targets and method fidelity. The majority of women in both CFCC and FHC will not be enrolled in Centering, and the data for women not enrolled in group care will continue to be collected in aggregate by both sites in the normal process of quality management.

This is a quality improvement project, and data collection was limited to data collected by the institution during the normal course of CenteringPregnancy™ program planning, design, implementation, and evaluation (with CenteringCounts™). Upon termination of the DNP project, additional outcomes research commenced to collect both quantitative data and qualitative data on women's lived experience and how that is impacted upon by participation in Centering. Data on preterm birth, birthweight, and

initiation of breastfeeding for estimated date of confinement (EDC) cohorts not enrolled in Centering will be extracted and used for comparison to CenteringCounts[™] data during the post project period. These data will enrich the preliminary findings of the DNP project and illuminate the mechanisms by which Centering exerts its beneficial effects, but were not within the scope of this project.

Special efforts were made to include women whose primary language is Spanish in Centering Groups. The sociocultural experience of these Latinas may be different than those who are acculturated enough to be conversant in English. CenteringPregnancyTM materials are available in Spanish but not in other languages spoken in the target population, such as Bengali, Albanian, and Khmer. Women whose primary language is other than English or Spanish were excluded from participation.

Implications for Social Change in Practice

Prenatal care has been conducted in the same fashion since the early 1900s. After an advent in the late 1950s, the momentum for increased parent involvement and decision making during the childbearing year did not increase until much later, with childbirth education in the 1970s and breastfeeding support in the 1980s (Wertz & Wertz, 1989). Recent advances and reliance on technology have rolled back the consumer movement in maternity care, with rising rates of induction of labor, elective and repeat cesarean section, and almost universal epidural anesthesia, all of which contribute to increased costs and iatrogenic complications (Moleti, 2009). Nursing and midwifery roles in obstetrical care were reduced in scope due to increased used of technology and the move away from "natural childbirth." Maternity Center Association (MCA) and many other

birth centers closed, and midwives now struggle to maintain normalcy, patient involvement, and patient empowerment in the childbearing process (Childbirth Connections, 2013). In 1998, about 3 years after MCA closed, Schindler Rising developed the CenteringPregnancyTM Group Prenatal Care model, largely based upon the midwifery care model pioneered by Watson Lubic, at Maternity Center Association. Both were named as "edge runners" by the American Academy of Nursing and featured in a Clinical Director's Network research initiative investigating innovative programs designed to foster evidence-based practice in maternity and newborn care (Mason, 2013).

Summary

CenteringPregnancy™ Group Prenatal Care decreases the rates of preterm delivery (Ickovics, 2011; Picklesimer et al., 2012), a significant source of emotional and physical pain and disability to affected families and children. In addition, Centering addresses health disparities in racial and ethnic minorities (Tandon et al., 2012) and decreases levels of maternal stress and increased self-efficacy amongst Centering participants (Ickovics et al., 2011). Reduction of adverse outcomes has the potential for significant cost savings to the U.S. health care system as well.

The focus of the DNP project was to expand the use of Centering at two FQHCs at MMC/MMG and obtain preliminary evidence that the groups would be well accepted by both patients and providers, be cost effective, and would have an impact on the high rates of preterm birth and low birthweight and low rates of breastfeeding in a population of racial and ethnic minority women at high medical and psychosocial risk. At the conclusion of the project, both sites were running two concurrent Centering Groups.

CenteringCounts[™] was being used for ongoing evaluation of outcomes as required by CHI. Both sites, FHC and CFCC, were preparing for the site approval process culminating in a visit by CHI in Spring 2015. It is my intent, working with the preceptor, Dr. Peter Bernstein, to obtain funding and continue the expansion of Centering to other sites in the medical center over the next 3 to 5 years as well as to conduct more detailed qualitative and quantitative outcomes research on Centering's impact on key indicators of maternal child health and the resulting fiscal impact. This will be described in Section 5.

Section 2: Review of Scholarly Evidence

Implementation of a CenteringPregnancy™ program is a time and resource intensive process necessitating a change in the way prenatal care is delivered. This affects all stakeholders, patients, staff, administrators, and community-based partners. Centering, though midwifery designed, is delivered by multidisciplinary teams and is not based on one single theoretical framework. CHI espouses disruptive design (CHI, 2013; Christensen, 2013) as a method of program initiation and expansion. Though CenteringPregnancy™ lowers the rate of PTB and LBW and ameliorates health disparities, its mechanism of action as an intervention remains unknown. It is postulated that the enhanced education and psychosocial support offered to Centering participants reduces stress levels and barriers to prenatal care attendance.

Search Strategies

Search of the CINAHL database using keywords *psychosocial support*, *self-care*, and *pregnancy*, with cross-referenced additions, yielded 72 results. Using keywords *psychosocial support* and *pregnancy* yielded one result on the Cochrane and one on the DARE databases. *Self-care* alone in the search of systematic databases yielded no results, a pertinent negative indicating that randomized controlled trials and meta-analyses failed to identify Orem's concepts in their theoretical base. Relevant references in the papers were explored.

Search of the CINHAL database using the keyword *Centering Pregnancy* yielded 22 results, including two systematic reviews and four randomized controlled trials, all of which were reviewed and relevant bibliographic sources explored. CHI-provided training

materials and literature were also incorporated into the review. Program evaluation and planning texts by Hodges and Videto (2011) and Kettner, Moroney, and Martin (2013) offered summaries of methodologies and change theories, as well as formative and summative program evaluation. Relevant articles in both bibliographies were explored. A search of the CINHAL and Business and Management databases yielded only four models that offered structure change strategies suitable to this type of project and the institution.

Review of the Literature

CenteringPregnancyTM Group Prenatal Care as an intervention shows promise for improving psychosocial and birth outcomes, especially for adolescent women (Ford et al., 2002; Hoyer, Jacobson, Ford, & Walsh 1994), as well as racial and ethnic minorities who are traditionally more medically and psychosocially vulnerable and underserved (Ickovics et al., 2007; Ickovics et al., 2011). Leahy-Warren (2005) found that nurse modeling of mothering behaviors had a positive impact on perceived social support and self-care competency. Ickovics et al. (2003) found a 33% reduction in preterm birth. In a RCT using intention-to-treat models, Ickovics et al. (2011) found no significant differences in psychosocial function; yet, high-stress women randomly assigned to group care reported significantly increased self-esteem, decreased stress, and social conflict in the third trimester of pregnancy; social conflict and depression were significantly lower 1-year postpartum. This indicates that women who participate in Centering find the support they need to better cope with the stressors of pregnancy, changes in family

dynamics, and the physical, emotional, and social changes that occur during transition to motherhood and parenting.

PTB disproportionally affects women of color. The impact of Centering on racial and ethnic disparities was addressed by Picklesimer et al., 2012. There was no significant difference in the preterm birth rate for non-Hispanic Blacks (7.5) and Whites (6.5%; p =.63). For traditional care participants, the disparities in preterm birth rates persisted with non-Hispanic, African American women at 16.1% and Whites at 13.7% (p=.01). Centering participants had infants with higher birthweights (3245 +/- 579 grams or 7.21 pounds +/- 1.3 pounds) than women in traditional care (3178 =/- 654 grams or 7lbs +/-1.4 l pounds, p=.05) for those in traditional care. Mean gestational age at delivery was 38.8 weeks for women in group care compared with 38.3 in traditional care (p < .001). The adjusted odds ratio for PTB for Centering Participants was 0.53 (95% CI, 0.34-0.81; Picklesimer et al., 2012). Tandon et al. (2012) found a 5% PTB rate in Hispanic women in group care with a 13% rate in those in traditional care. There were no significant differences in low birthweight between the two groups, possibly due to a smaller Centering sample size. Patient self-selection, as well as exclusion of women too high risk due to with medical complications, could impact these rates (Picklesimer et al., 2012). Both could be addressed in future studies using the opt out model for Centering participation recommended by CHI (2014) to increase the sample size or inclusion (with separate analysis) of women with select high-risk conditions.

Substance use and abuse are risk factors for PTB and LBW. Naughton, Prevost, and Sutton (2008), in a meta-analysis of RCT or quasi-randomized system of 15 eligible

trials, found that programs that included structured social support resulted in significantly greater rates of smoking cessation (13% for self-help and 4.9% for regular care). Though there was financial compensation involved in some studies, and significant heterogenicity noted in analysis, Naughton et al. concluded that there is need for theoretical development and exploration of alternative modes of self-help interventions.

Social support may help women cope better, decreasing their dependence upon tobacco and other substances for stress relief. Yu, McElroy, Bullock, and Everett (2011) studied specific interventions to decrease cigarette smoking and increase self-esteem in pregnant women and their partners. Increasing social support and self-esteem was linked to greater self-care competence. Renker (1997) studied a convenience sample of 152 pregnant adolescents from Detroit, Michigan using a predictive-correlational design and instruments with known psychometric properties. She found self-care agency accounted for a significantly lower incidence of low birthweight a lower incidence of miscarriage, substance use, and emergency service use. Psychosocial interaction effects between abuse, social support, and self-care agency showed that the social support factor of Shelter and Family Help significantly impacted birthweight by 17% (Renker, 1997). Leahy-Warren (2005) used a framework based upon Bandura's theory of self-efficacy (1995) and identified nurses as the primary source of effective support for new, first-time mothers, as well as the importance of including partners/support persons in the process.

Mechanisms that may explain the improved outcomes in group care participants are multi-factorial. They include better nutrition, less substance use, empowering women to seek medical attention more often and earlier when experiencing problems, and better

compliance with treatment regimens due to a more positive and accessible relationship with care providers (CHI, 2013). An enhanced level of social support, including group support, might ameliorate stress and increase coping. Stress reduction may, in turn, decrease inflammatory mediators that contribute to the cascade of preterm labor (Picklesimer et al., 2012). A synthesis by Arabia (2002) demonstrated a link between stress, social support, and pregnancy outcomes. Merkatz (1989) researched the influence of maternal attachment and capacity for empathy on the perception of social support in pregnant low income, minority women in New York City, identifying assessment of sense of self as important to understand how social support operates and for planning clinical interventions. Johnson and Raternick (2009) described the use of the equivalent plan-do-study-act (PDSA) model for implementation of a group diabetic teaching model, in which each cohort constituted a PDSA cycle, with an overlap of 2 weeks to allow adjustments to be made as needed (the study or check and act) with the goal of a fully functional, sustainable program.

Conceptual Frameworks

Self Care Theory

According to Orem's theory of self-care deficit (or dependent care deficit), people benefit from nursing because they are subject to health-related limitations that render them incapable of continuous self-care. This constitutes the core of Orem's grand nursing theory (Orem, 1980). Orem (1980) conceptualized a reciprocal relationship between self-care, self-care capabilities (self-care agency), therapeutic self-care demand, and nursing capabilities or nursing agency. Moleti (1990) postulated that the inter-related theoretical

frameworks of Maslow's hierarchy of needs (1970), Peplau's conceptualization of levels of anxiety (Hay, 1961; Peplau, 1963), and crisis intervention theory by Aquilera and Messick (1986), fostered a stepwise approach to the management of psychosocial risk. Identifying the stage of each theorist's paradigm the patient was in, plus giving support, information, education, and concrete services to reduce anxiety, meet basic needs, and manage crises, would move the individual to a higher level of function and correct self-care deficits (see Figure 4).

Social Science and Middle Range Nursing Theoretical Frameworks

Middle range nursing as well as social science theories based upon psychosocial support in at risk patients have been tested in numerous studies. Rew (2003) based the theory of taking care of oneself on Orem's self-care concept defined as "the personal care that human beings require each day and may be modified by health, state, and other factors" (Orem, as cited in Rew, year, p. 234). Possible applications of Rew's middle range theory of taking care of oneself (2003) include increasing self-esteem as critical in fostering positive movement toward self-care.

Bandura's social learning theory, based on the concept of reciprocal determinism, sought to explain social influences that affect learning such as groups, culture, and ethnicity (Bandura, as cited in McEwen & Wills, 2011). Environment, cognitive factors, and behavior interact, and "people learn vicariously and unaware from the conglomeration of environmental stimuli or by emulation of those they admire" (Bandura, as cited by McEwen & Wills, 2011, p. 360). Bandura expanded his theory to include social cognition, and the resulting self-efficacy, the belief that one has the ability

to change behaviors and recognition that personal health practices and choices can positively influence health (McEwen & Wills, 2011).

The purpose of social cognitive theory (SCT) is to understand individual and group behavior and to identify methods in which behavior can be modified or changed (Bandura, 2004). Though consequences mediate behavior, SCT contends that cognitive processes enable humans to predict the outcome of behavior before it is performed and make positive health change (Bandura, 2004). Sarker, Fischer, and Schillnger (2007) found that the associations between self-efficacy and self-management were consistent across race/ethnicity and health literacy levels.

Tenets of SCT (Bandura, 1977), as well as Roy's adaptation model (2009), along with the concepts of self-efficacy (Bandura, 1995) and self-care competency (Orem, 1980) could explain the benefits of CenteringPregnancy™ on patient stress and depression as well as compliance with care and avoidance of harmful practices. Perry's Middle Range Theory of Self-Transcendence (2004) describes the bond between the nurse and patient that might explain what enables the beneficial effects of Centering on pregnancy outcomes. The concept of self-transcendence could explain the nurse's motivation and ability to provide psychosocial support to patients at risk in any number of specialties and situations. Previously discussed studies by Renker (1997) and Leahy-Warren (2005) provide evidence further linking these concepts to nursing care provided to pregnant women and new mothers. Development of relationships between these concepts and examination of CenteringPregnancy™ as a clinical application of middle

range nursing theories, including those of Moleti (1990), Perry (2004), and Rew (2003) continued as this project was concluded. A conceptual map is presented in Figure 1.

Change Models

Disruptive Innovation or Disruptive Design

CHI espouses an evidence-based practice model from the business community known as disruptive innovation or disruptive design. Christensen (2013), of the Harvard University School of Business explains disruptive innovation as the mid line trajectory of growth, which is 'good enough' to serve existing mainstream customers' needs, though it may not satisfy the most demanding consumer and over satisfy the less demanding ones. Christensen et al., (2013) take great pains to point out that disruptive innovation is not synonymous with incremental innovations, which are "ineffective in sustaining the growth of breakthrough technologies" (p.17.2). Thus disruptive innovation requires an all or nothing effort. Once the disruptive product gains acceptance in new or low-end markets, the improvement cycle begins. As the pace of technological progress outstrips customers' abilities to use it, the previously not-good-enough technology eventually improves enough to intersect with the needs of more demanding customers (Christensen, 2013).

Field Analysis

Change models suitable for structuring introduction of evidence-based interventions into clinical practice included Lewin's force field analysis (as cited in White and Dudley-Brown, 2012). Lewin's strategy enabled emphasis on positive forces and maneuvering around the negative, but to also identified neutral forces that might be

turned into positive energy. Havelock expanded upon Lewin's basic concepts to create a theory of planned change (Havelock, as cited in White & Dudley-Brown, 2012, p. 52), guides the processes and behaviors to facilitate the change process. Once the culture and context of the environment (field) is understood in terms of facilitative and oppositional elements (Lewin, 1951). Havelock's mnemonic CREATER (as cited in White & Dudley-Brown, p. 53), suggests the following steps:

- Care—attention to the need for change
- Relate—build a relationship
- Examine—diagnose the problem
- Acquire—the relevant resources
- Try—choose the solution
- Extend—disseminate, diffuse, gain acceptance
- Renew—stabilize and sustain capacity

Plan Do Check Act

The PDCA cyclic, systematic approach (Deming, as cited in Kelly, 2012) is the chosen quality improvement tool in use at the Montefiore Medical Center. It provided both the mechanism and framework to conduct this to project, the focus of which was on facilitating evidence-based practice to improve quality and patient care. By utilizing continuous, ongoing performance evaluations and the PDCA model, the institution aims to objectively monitor and evaluate the quality and appropriateness of care that is customer-focused, interdisciplinary, data-driven, outcome-oriented and proactive (Montefiore Medical Center, 2014).

Originating from industrial settings, and also known as the Shewhart cycle, the steps are cyclical in nature (Kelly, 2011). Planning and doing involve identifying a goal and implementing a process to put it into place. Checking involves determining the measure or benchmarks for success. At the act or conclusion portion of the cycle, adjustments are made to the intervention to improve performance, adjust workflows or methodology, or perhaps even decide that the intervention is not suitable and should be eliminated. Thus, a new PDCA cycle may begin to refine the original or a to design a new intervention (Kelly, 2011).

Systems Theory-The Logic Model

Kettner et al., (2013) describe use of the logic models to develop a hypothesis of etiology, which explains the current understanding of cause and effect. This working intervention hypothesis focuses on activities and interventions and the causes with an expectation that, if successful, the program would "have a positive impact on the effects derived from the inputs, process, outputs, outcomes, and impact components of the logic model flow chart" (Kettner et al., 2013, p. 125). Its purpose is to depict the sequence of events, identify resources which can then be matched to needs, design and implement the program for a defined site and population, and measure outcomes (Kettner et al., 2013).

Summary

Centering as an intervention enhances Moleti's theoretical model of caring for patients at both medical and psychosocial risk (1990), which has been published and presented to audiences of nurses, physicians, and other health care providers. Significant gaps in knowledge exist in documenting a pathway by which CenteringPregnancyTM

exerts its benefits, and if those benefits are psychosocial, physical, or a combination.

Tenets of self-care theory (Orem, 1980), SCT (Bandura, 1975, 1977), and transcendence (Perry, 2004) form the basis for middle range nursing theories advanced by Leahy-Warren (2005), Moleti (1990), Renker (1997), and (Rew 2003) to operationalize Centering as an intervention strategy to decrease the rate of preterm birth, low birthweight, and increase breastfeeding initiation in pregnant women.

Better patient outcomes, significant cost savings, as well as increased patient compliance and satisfaction will be possible if the target population of women at high medical and psychosocial risk have ready availability to CenteringPregnancyTM groups. This underscores the need for ongoing research on its mechanism of action as well as efficacy in women at psychosocial high risk as well as for selected medical complications that may contribute to late or inadequate prenatal care attendance, early delivery, low birthweight, and barriers to breastfeeding initiation. This will require further concept analysis as well as replication of previous CenteringPregnancyTM research findings.

Section 3: Project Plan

Summary

The concurrent processes of formative and summative evaluations (Hodges & Videto 2011; Kettner et al., 2013) were implemented at CFCC and FHC, two FQHCs in two a large, urban hospital network. In the early stages, formative evaluation was guided by the CHI model implementation timeline and method fidelity and the 13 essential elements. Summative evaluation was conducted using CenteringCountsTM, a spreadsheetbased data collection tool designed and provided by CHI to member sites. In addition to the ongoing evaluation of outcomes, the instrument addresses fidelity to the method and 13 essential elements, as well as staff and patient satisfaction scores. CenteringCountsTM also tracks each site's progress toward established benchmarks. In order to build a sustainable program, and integration of Centering into all levels of the organizational culture, appropriate change models were used. These included Lewin's (1951) field analysis, disruptive design (Christensen, 2013) and PDCA (Deming, as cited in Kelly, 2011). Systems theory and logic models guided the ongoing formative and summative evaluation process and will permit replication in future expansion efforts (Kettner, 2013; see Figures 2 and 3).

Nature of the Project

Though the project was focused on quality improvement and expansion of Centering at two network FQHCs, the institution entered into negotiations with CHI and funding partners to design an in-house Centering training program for all staff, with the goal of Centering to be the opt out model of prenatal care services in all of its sites

providing prenatal care services. Ongoing evaluation of method fidelity to the 13 essential elements as sites are established is required to maintain the support of CHI for continued use of the method. Evaluation of patient outcomes is measured by preterm birth and low birthweight rates, rates of breastfeeding initiation, and fiscal impact. Fiscal impact, as measured by preterm and low birthweight rates and the impact on NICU admissions, is critical to obtain and maintain both institutional- and community-based funding.

The standardized CenteringPregnancyTM intervention must be properly instituted to assure the validity of the method. One requirement is that an opt out approach is used. This means that all women are screened for medical eligibility and assigned to groups based upon a similar range of due dates unless they elect to return to traditional care (CHI, 2013). This is a major redesign of traditional prenatal care from the one patient one provider visit to the Centering group care concept.

One challenge was to tailor this intervention to women who wanted to participate, but had family commitments, a lack of childcare, time schedule constraints (work or picking up children from school), or medical high-risk conditions requiring multiple weekly visits. More than half of eligible women at both FHC and CFCC contacted during recruitment and appointment reminders gave reasons for opting out of or leaving Centering because the group concept was threatening, they had time or childcare constraints, or they preferred one-on-one care. Some women with selected high medical risk conditions asked to join, or were invited, but many failed to attend more than two sessions, which is considered the minimum number to be considered a Centering

participant for outcomes measurement. Prenatal patient surveys at FHC and CFCC (*N*=104) found that 33% of women would need to bring their children to groups. Spanish speaking women made up 20% (n=24) of the respondents and 99% indicated they would enroll in Centering if offered. Among the 80% of English speaking respondents (*n*=85), 46% would enroll. The target opt in rate set by CHI is 60% of all prenatal patients in 3 to 5 years. The initial opt-in rate for English and Spanish speaking prenatal patients combined was 66%. Significantly, of the 30% of English speaking respondents who would not enroll filled out all the questions, indicating that with more information and encouragement, as well as addressing child care needs, the percentage of English speaking women that would opt in would be even higher.

To foster greater patient engagement, involvement of all levels of staff and training in the 13 essential elements, the benefits of group care, and group facilitation techniques was critical to increase awareness of the program. Centering must overcome staff resistance to this change by continuous and meaningful involvement at the clinical, secretarial, and administrative levels to counter fears that past experience with waning financial, staffing, and administrative support for the program would be repeated. After an inventory of the numbers of CHI-trained facilitators (providers), nursing and support staff, regular meetings were scheduled at both FHC and CFCC to provide updates on the planning and implementation process. Staff with particular interest and experience with Centering were encouraged to volunteer to be assigned to groups as they were being formed and help with patient outreach and recruitment. Others were encouraged to support their coworkers in adjusting workflows and helping to recruit and retain patients.

Social workers and nursing and secretarial staff at CFCC attended a full day of training conducted by the DNP candidate during which they participated in facilitation exercises and a mock Centering Group. Due to real estate issues, only one staff meeting was done at FHC, but all residents in Family and Social Medicine received 1 full day of facilitation training. Due to financial constraints and a lack of funding for facilitator binders, training of OB/GYN residents at CFCC was not conducted.

One nurse at FHC was previously CHI certified and serves as Centering Coordinator during all groups during which the family and social medicine residents participated. One midwife at CFCC was previously CHI certified and the DNP candidate (also CHI certified) supervised and trained a new Centering coordinator who assisted with groups. A nurse-midwifery student assisted the provider at CFCC.

Overview of Project Planning and Implementation

Application of Lewin's (1951) field analysis enabled the identification of strengths and resources, as well as challenges that comprise the positive, negative, and neutral forces to be accentuated, mitigated, or augmented. Using the process and tenets of disruptive design (Christensen, 2013) enabled the effects of planning and intervention process to attract the attention of higher levels of administration and establish a focus for strategic and sustainability planning.

Other challenges during the course of the project began when there was failure of the residency program in obstetrics and gynecology to underwrite the training material costs. Though there was a 2-hour information session about Centering, the lack of funding precluded training the obstetric residents in the use of the method so the number

of groups at CFCC remained limited to those conducted by the single nurse-midwife—far below the level needed for the opt out model to be implemented at CFCC. Staffing at CFCC was disrupted by resignations, retirements, transfers, or illnesses of key staff. This included the only registered nurse supervisor on the unit, the bilingual (English/Spanish) social worker involved in Centering recruitment, the unit administrator responsible for the secretarial staff and schedules, two unit secretaries, and three licensed practical nurses. The exodus of trained staff complicated recruitment for and conduct of the Centering groups.

FHC experienced real estate related problems (sick building syndrome related to pervasive mold) and a delay in a planned move to a new site. This delayed the family practice resident training until July 2014. Planned meetings and surveys with all FHC OB/GYN staff about the benefits of Centering and basic Centering training, were expected to be accomplished as part of the site movement workflow and orientation process, but never occurred due to the difficulty in scheduling meetings in the face of other concerns and distractions. FHC is the smaller of the two sites, and the one with a better established Centering program. It had been hoped that the move would create an urgency to modify and change workflows and train more staff at FHC, but that was precluded pending the resolution of other issues.

Development of the process logic model began with an assessment of readiness based upon administrative and clinician support for the program and both FHC and CFCC. Staff surveys were performed at CFCC to evaluate past knowledge and experience with Centering, concerns and beliefs about the method, and to engage all

levels of staff in the change process from its inception. Staff were asked what role they would like to play in conduct of Centering groups, even if it were to support coworkers' absence from the unit on group days. Patient surveys guided logistics such as preferred time and days of the week and how to gauge how the need for childcare and partner/support person attendance would impact enrollment and space constraints. Finally, patient language preferences were considered but only Spanish and English could be accommodated, though Bengali was requested. Administrators, medical providers, and resident physicians at both FHC and CFCC received information about Centering. Emphasis was placed on along with subsequent exploration of the reasons at each site for selecting Centering PregnancyTM as the intervention as well as the justification for the techniques of facilitation used during. At all meetings and trainings the critical need for adherence to the 13 essential elements (see Table 2) that influence group effectiveness was emphasized (Kellogg Foundation, 2004). Untrained and inexperienced facilitators can default to a didactic model, which is why CHI insists that a certified provider supervises all groups at all times for proper reinforcement.

After needs assessment with the key stakeholders, which include clinical staff, patients, and mid level administration, appointments were scheduled with the physician serving as chief operating officer at MMC as well as the director of the Bronx Community Health Network (BCHN), which oversees the FQHCs. Executive and administrative directors and the director of training for the MMG were contacted and their support enlisted. The Public Relations department was engaged in publicity efforts. This department prepared several articles and news releases about the Centering

expansion. Plans are in place to tape a Centering session and interview participants.

Patients enrolled in Centering are being recruited to sign media release consents.

Short-term goals included securing immediate programmatic funding and supplies as well as staff and systems development. Long term sustainability planning was a focus, with an emphasis on interim funding for expansion after the practicum year concluded. This included planning for major resident and nursing training sessions and ongoing research activities in high risk and selected ethnic populations. A linked activities approach model focused on the specifics of the implementation process that can be adapted to the needs of each site. These included negotiation with CHI on in house staff and resident training to enable adoption of the model at all prenatal care sites in the MMC system over the next 3-5 years. The detailed steps for new site Centering implementation took into account the flexibility needed to adapt to the varied needs of each practice and the demographics of the patients they serve. To alleviate funding concerns, there was ongoing writing for grants that target health disparities and champion innovative systems for care delivery, one of which is CenteringPregnancyTM (Mason, 2013).

Institution wide process and outcome logic models (see Figures 2 and 3) targeted the institutional end-point goal at the request of the project mentoring team to articulate, inform and guide mid level management and strategic planning activities and budgetary considerations. These included setting up a Centering PregnancyTM Research Institute to document the effect of the intervention on the various populations served by Montefiore Medical Center. This articulates with the overall mission of the medical center, and its mandate as a Pioneer Accountable Care Organization (ACO) in providing large scale,

cost effective, comprehensive, culturally appropriate, and patient centered evidence-based care as part of a medical care home (Center for Medicare and Medicaid Services, 2012). Even with a modest 15% reduction in the preterm birth rate, MMC would save seven million dollars in direct neonatal intensive care costs alone.

Change Model Execution

Field Analysis

Positive forces included strengths and resources in both CFCC and FHC that included an experienced, multicultural and multilingual secretarial and nursing staff of LPNs and patient care technicians (PCT's), many of whom had prior CHI training and experience with running Centering Groups. The role of RNs is limited by their small numbers in the ambulatory sites. Increase in the numbers of nurse practitioners and nurse-midwives have been included in a proposal for expansion within the Centering program.

Both sites have had attending physicians and midwives who had facilitated

Centering groups in the past, with one midwife certified by CHI as a trainer. Both site

administrators and medical directors were supportive of the Centering expansion, as were
the higher-level administrators of the Montefiore Medical Group (MMG). The Public

Relations department has been receptive and interested in publicizing implementation.

Centering Healthcare Institute has expressed support for the project and a desire to help
with the expansion at Montefiore. The DNP candidate, a midwife who formerly worked
at CFCC and with the attending physicians in family and social medicine staffing FHC,
had a positive and facilitative working relationship with all levels of staff and
administration. The residency program directors for the departments of obstetrics,

gynecology, and women's health and family and social medicine, as well as the residents, were enthusiastic about their role in Centering The directors of obstetrics and gynecology at FHC and CFCC are both CHI certified Centering providers and are also supportive of the expansion project. Both FHC and CFCC have dynamic and committed Centering Coordinators to recruit and support patient engagement in Centering Groups.

Neutral forces included large numbers of staff in the health centers that had little or no knowledge of Centering and its benefits, which is critical to reassure patients who have concerns about the benefits of Centering attendance. Upper level managers, senior administrators, and BCHN juggle requests for critical financial and managerial support of multiple programs and project implementations. As such, their support of the process was critical to keep the Centering program moving forward while the financial concerns were addressed. Due to budgetary constraints, none were able to offer programmatic funding for Centering expansion.

Negative forces included the impending retirement of chairman of the department of obstetrics and gynecology, which stalled discussion of expansion or major modifications to any programs, including residency training. The senior management team declined the project preceptor's request for programmatic budgetary funding of the Centering program as part of the ACO model implementation of Maternity Care Homes. The cost estimate provided by CHI for training on a scale large enough to allow a major expansion was between \$30-40,000.00, well above the discretionary funding available to site directors. Part of the 3 to 5 year goal of expansion to all sites, includes the process of obtaining programmatic and grant funding will continue after the initial year.

Plan Do Check Act

Similar to the methodology used by Johnson and Raternick (2009), each site's PDCA cycle focused on program implementation and development of the evaluation plan for the program's first year progress toward benchmarks and adherence to the 13 essential elements of Centering (method fidelity). Use of CenteringCountsTM guided each site through the process of setting their benchmarks and targets, as well as continuous tracking of patient attendance, satisfaction, and outcome data after delivery. Provider debriefings after each Centering group session, guided by the CenteringCountsTM worksheets, examine ongoing efforts toward CHI site approval and method fidelity scores.

Utilizing a quality improvement approach and a series of PDCA cycles (Deming, as cited in Kelly, 2011), the multifaceted impact of implementation of the CenteringPregnancy™ Group Prenatal Care program (Rising, 1998) at two FQHCs in a large, urban multi-hospital system was undertaken. By focusing on quality issues and an area (preterm birth rates) where the institution is performing far worse than local and state benchmarks, the project was able to attract the attention of high level administrators and community partners that oversee the FQHCs involved. Cost containment tied to quality and coordination of care, as well as innovative systems of care to vulnerable populations is critical to the institution, a Pioneer ACO (CMS, 2012). The current focus for ACOs is on chronic medical conditions, and due to great financial success during the first two years (Evans, 2014), the time to address maternity care may be at hand.

The PDCA methodology was used to facilitate a working relationship with clinical level staff on the project to enlist their critical involvement in program development, maintenance and recruitment, as well as to maintain buy-in and focus on the ongoing quality improvement process. Health educators and family health workers performed outreach to advise the target population of the availability of Centering and its benefits. Recruitment efforts are ongoing and both sites are currently running two group cycles, with additional group cycle implementations planned every 4-6 weeks.

At the conclusion of the DNP project, the staff was able to clearly articulate the steps in the PDCA process and remain committed to its maintenance and making necessary changes as the program expands. Administration and community partners attended initial presentations on the project, have been kept informed of progress, and received a detailed snapshot of relevant findings at the conclusion of the practicum.

Funding was provided by the individual sites for the pilot programs during the first PDCA cycle, and it is hoped that demonstration of quality improvement will advance the program to the formal phase of institutional policy development. Upon completion of this DNP project, a second PDCA cycle commenced to implement the logic models developed for expansion of Centering to other sites and begin a more in depth research study. This second cycle will continue the process with an emphasis on sustainability and to determine Centering's continued impact on the identified quality measures and fiscal parameters. The 15-15 midwifery expansion proposal for years 3-5 is presented in Section 5.

Once the patients in the initial four group cycles gave birth and outcome data was analyzed, a preliminary report was prepared to present to administration. In the spring of 2015, the final outcome data will be analyzed and administrators and community partners to enlist support to fund ongoing expansion. This will complete the formative process, which developed logic models for implementation and the summative evaluation process, which examines program impact (Kettner et al., 2013).

Disruptive Innovation

For this project, the concepts of disruptive innovation were translated into use of the opt out model (successful at FHC), as well as a focus on the involvement of lower levels of the organization: clinical, secretarial and site and unit level managers. This created momentum for change and movement at the upper levels of the organization, as well as with stakeholders (funding sources and patients), to create impetus for change (Christensen et. al., 2013). Silva et al. (2011) advocate the use of disruptive innovation in creation of medical care homes linked with health information technology (HIT) and telehealth platforms to "transition from a passive patient that is told what to do to a fully engaged and active partner in his/her care" (p. 298). This mirrors CHI's strategy to redefine the conduct of prenatal care from business as usual to a new model (CHI, 2014).

Systems Theory-The Logic Model

The logic models coordinated site-specific Centering implementation activities with the CHI timeline and requirements. The intervention (implementation of Centering) addressed the problems of PTB, LBW, and medical and psychosocial risk factors, with an expectation that, if successful, the program would have a positive impact on the

benchmarks of maternal and fetal well being (Kettner et al., 2007). This formed the basis for the program hypothesis (Centering will improve outcomes and satisfaction) derived from the inputs, process, outputs, outcomes, and impact components of the logic model flow chart (Kettner et al., 2013). These models can be used, when space and funding allows, as Centering is expanded to other sites in the MMC/MMG system.

Summary

PDCA created the mechanism and disruptive innovation the momentum for expansion of CenteringPregnancyTM at two sites in the MMG, FHC and CFCC. The PDCA logic chart created both a process and impact map (see Figure 2) during planning to ensure development based upon sound logic and theory, but also served as the basis for the evaluation plan (Hodges & Videto, 2011). The process and impact logic chart (see Figure 3) enabled the team to determine whether the program has been implemented in the desired order, to identify barriers, and explore how it is expected to work by linking the underlying theoretical constructs expressed as the 13 essential elements of the CenteringPregnancyTM method (see Table 1).

By focusing on the areas of the organization within my sphere of influence (disruptive design) and positive forces (Field Analysis) the project proceeded despite the challenges and setbacks. All staff was charged with the responsibility to inform, educate, and direct appropriate patients into Centering PregnancyTM Group Prenatal Care and are able to do so. Outcome data from the research study, expected to be complete in May of 2015, will provide justification to expand both Centering and midwifery practice through out the medical center in order to help meet the institution's mandate as an ACO to

implement evidence-based strategies such as maternity and patient entered medical homes. This strategy will meet the needs of vulnerable populations by using innovative interventions for better care, better health and lower cost (CMS 2012). Meetings will occur with BCHN and with senior level managers to move Centering to the systematic agenda and create a program based budget for the institution to supplement outside grant funding sources.

Population and Sampling

For this project, participants in Centering groups in two FQHCs designated as medically underserved were identified and cohorted by EDC. Method fidelity data required by CHI (Munroe, 2013) were entered into the CenteringCountsTM database and rates of low birthweight, preterm birth and breastfeeding initiation as well as prenatal care adequacy were calculated.

Pregnant women registering for prenatal services in two FQHCs who currently conduct Centering Pregnancy™ Group Prenatal Care were the source of the participants. These FQHCs are satellites of (MMC/MMG), a voluntary, urban hospital system in New York City, which provides care to many areas designated as medically underserved. The institution provides care with funding from a number of city, state and federal programs, grants, philanthropic organizations, education and research activities, as well as private and Medicare and Medicaid insurance reimbursement contracts.

MMC conducted 7000 deliveries in two inpatient sites in 2012 (U.S. News and World Report, 2012). The institution serves as a tertiary care perinatal referral center for Bronx County, New York City, as well as southern Westchester County, New York and

southern Connecticut. MMC is the University Hospital System of the Albert Einstein College of Medicine. Use of these two sites, one a high-risk referral center and the other a family practice site, comprise approximately 23% of the institution's deliveries. Use of both sites resulted in a wider population of both high and low medical risk patients, though all are categorized as high psychosocial risk. It was estimated that in the course of the first year of the project CFCC would enroll 25 women into a Centering group and FHC would enroll a similar number.

Proportionally, FHC had a larger percentage of women in Centering (25% of each EDC cohort) than CFCC (2% of each EDC cohort) since their program was better established. CFCC's designation as a high-risk referral center complicated enrollment because of the time constraints for women needed to make separate high-risk clinic visits. Lack of childcare and work and school schedules were another significant barrier. These enrollment percentages are expected to increase in the second and third years as the programs become better known and accepted. As more staff is trained, groups can be added at additional days and times. The use of hospital volunteers for childcare is being explored. Finally, a greater number and variety of providers will enable scheduling groups for women who speak primarily Spanish and Bengali.

Data Collection

Instrument

CenteringCountsTM

CenteringCountsTM is a proprietary data collection system produced by Centering Healthcare Institute designed to promote the triple of aim of better care, better health, and lower cost (Munroe, 2013). The data is held in three Microsoft Excel pre programmed spreadsheets. The first worksheet assists the site in establishing current rates and percentages on key indicators, choosing benchmarks, and setting targets. The second is programmed for ongoing collection of data for all groups at the individual site. This tracks attendance, prenatal care adequacy and outcome data, which feeds into additional pages which aggregate the data and calculate procedure and outcome measures. The third is a method fidelity checklist, staff and administration support and satisfaction scoring sheets, and progress toward site approval or re-approval.

Developed by CHI and provided free of cost to approved sites, the de-identified data compiled and automatically analyzed must be submitted on a yearly basis to maintain site approval to utilize the CenteringPregnancyTM method (Munroe, 2013). CenteringCountsTM ensures fidelity to the method by tying the documentation to the monthly self-assessment sheets and post group debriefing on how the facilitation and health assessment as well as the group process flowed. Completion of the worksheets after each session, instead of after the final postpartum group, ensures that the data is fresh and accurate.

Protection of Human Subjects

In consideration of the special risk groups, which include pregnant women, there was little anticipated risk to participants regardless of whether or not they choose Centering, which is voluntary. Standards of prenatal care conform to clinical practice guidelines for the institution, regardless of whether the participant opts in or out of CenteringPregnancyTM Group Prenatal Care. CenteringCountsTM tracks pregnancy

outcome data collected as a matter of course by each site for internal quality improvement monitoring. The Walden University Institutional Review Board approved the use of CenteringCountsTM data for the evaluation of the program design implementation during the DNP practicum and completion of the final DNP paper. (see Appendix. B).

To maintain momentum and foster sustainability, the Institutional Review Board at the Einstein Montefiore Institute for Clinical and Translational Research (ICTR) has approved a study protocol and documents, with Peter Bernstein, MD, MPH as principal investigator. This will expand and continue the data collection and subsequent analysis now that the DNP project is complete (see Section 5).

Quantitative Assessment

Customary, de-identified quality assurance pregnancy and outcome data were entered into CenteringCounts[™] for all women in Centering Care. The data included parity, estimated date of confinement (EDC), number of Centering and other prenatal visits, actual date and type of delivery, birthweight, gestational age at delivery, and breastfeeding initiation.

Project Evaluation and Dissemination

Process evaluation documented factors related to the organization and program itself for the purpose of improving the effectiveness of the intervention. The logic models were linked to the CHI site development and approval process with a focus on fidelity, completeness, and exposure (see Table 2). This provided support needed to maintain the

program as well as determine if theories or models were appropriately applied (Hodges & Videto 2011).

Adherence to the 13 essential elements were translated into scores on CenteringCounts[™] that tracked progress and adherence to standards for site approval. Formative evaluation during implementation and operation of the program to monitor its progress and effectiveness (Kettner, et al 2013) was critically important to Centering implementation. Each site has a different provider mix, unique space and staffing configurations and prenatal populations, which vary in size, medical and psychosocial risk profiles, and language, and cultural needs. Balancing variations to accommodate individual practice environments and styles with fidelity requires ongoing examination of the effect on the group process and patient and provider perception of effectiveness. Site approval, as well as patient satisfaction and outcomes are jeopardized when major departures from standardized Centering methods are made (CHI, 2013).

CenteringCountsTM utilizes a system for ongoing formative evaluation for providers after each group session. This post group checklist allowed for flexibility during planning and implementation and at the same time reminded providers to be cognizant of the 13 essential elements on an ongoing basis. This self-evaluation was critical for development of the facilitation skills, which enabled the intervention to be successfully integrated with individual site needs in mind while maintaining validity and reliability.

Summary

The quality improvement, clinical, and financial impact arms of the project began with a PDCA cycle in September, 2013 at the high-risk perinatal referral center staffed by resident and attending physicians and nurse midwives under the Department of Obstetrics and Gynecology and Women's Health at CFCC. A short time later it was expanded to include a smaller family practice site FHC, staffed by residents and attending physicians by the Department of Family and Social Medicine. Focus on quality improvement and use of Field Analysis (Lewin, 1951) and Disruptive Design (Christensen, 2013) involved all levels of staff, patients, and administrators, in ongoing meetings and staff development.

A presentation was made in March 2014 to community stakeholders through the Bronx Community Health Network (BCHN) who oversees all of the institution's FQHCs. Outreach to the community was initiated by nurses, social workers, health educators, and family health workers who attended the staff Centering training sessions in November, December, and July 2014. Staff and provider training and support as Centering groups were organized and rolled out. These activities were coordinated with the Centering Implementation Timeline recommended by Centering Healthcare Institute. Table 2 presents considerations for the conduct of groups to assure adherence to the 13 essential elements (CHI, 2014).

Outcomes, including the numbers and percentages of women enrolled in Centering, gestational age at delivery, birthweight, trimester of entry to care and number of prenatal visits were tracked since January 2014 using CenteringCountsTM.

Collaboration between the Centering Healthcare Institute and Montefiore Medical Center by use of the CenteringCountsTM data collection tool ensured fidelity to the method and validity of the intervention, as well as collaborative, ongoing analysis of the program's outcomes and impact. The financial impact of Centering implementation's effect on birthweight, gestational age at delivery and NICU admission, cannot be fully assessed until after one year of this project's CenteringCountsTM data. An expanded research protocol was implemented at CFCC and FHC to include assessment not only of the outcomes assessed during this project for Centering participants but also those for traditional care EDC cohort controls, with evaluation of maternal depression and stress scores. Qualitative assessments of women's lived experiences of sources of support during pregnancy will enrich the findings. In addition, ongoing evaluation of outcomes via CenteringCountsTM will continue, including the fiscal impact of any institution wide decrease in preterm birth, low birthweight, and NICU admission. The institution could save in excess of seven million dollars in direct NICU costs alone with a modest 15% reduction in preterm and low birthweight rates in this population at high medical and psychosocial risk.

The long term goal of this project's formative and summative evaluation process remains to roll out CenteringPregnancyTM Group Prenatal Care to all prenatal care sites in the Montefiore Medical Group. Creating Patient Centered Medical Homes and Maternity Care Homes is part of the mandate of an Accountable Care Organization (CMS 2012) in providing innovated, evidence based interventions to improve outcomes in vulnerable populations. The 15-15 proposal initiative calls for a 15% reduction in the rate of preterm

birth by expansion of the CenteringPregnancyTM program plus creation of an in house "birth center" run by 15 full time equivalent midwives for 15% of low medical risk women. It is estimated that savings from a fully implemented Centering program would save the institution \$7 million in direct neonatal intensive care unit costs alone (Darling & Atav 2012). In addition to creating a seamless transition from antepartum to intrapartum and post partum/newborn care, an in hospital "birthing center" for lower risk women could potentially save the institution an additional \$1.2 million by decreasing inductions, cesarean sections, and use of technology not necessary in normal births that lead to iatrogenic complications and longer length of stays for both mothers and babies (Howell, et al., 2014; Moleti, 2009) (see Table 4).

Ongoing negotiations with CHI, community organizations, and private foundations seek to consolidate all staff and facilitator Centering training in the institution. The Learning Network administers a variety of educational programs, manages credentialing of faculty, scheduling, CME/CEUs, and conflict of interest issues. Particularly important to CHI is the attention paid to the curriculum ensuring that house trainers will adhere to the 13 essential elements and maintain the fidelity to the Centering Model. Program implementation cost savings by consolidating in house training for all sites in at MMC will cut training cost, enabling more sites to apply the logic models for new sites (see Figure 3) This is key to the expansion throughout the medical group sites and continuing competency maintenance of group facilitators and trainers.

The planning and budgetary processes will involve the medical center, CHI, community partners, and payers in implementation of what is expected to be an

intervention well suited to meeting the needs of its diverse and challenging population with a cost effective, evidence-based approach to complex and difficult to manage problems. Presentation of the findings of this project and the planning and evaluation scheme demonstrated and enhanced the role of the DNP prepared nurse in evidence-based practice design for the institution. Ongoing research under an institution-wide Centering research protocol, in which I am involved as Centering Champion, continues to enable program expansion and ongoing evaluation of outcomes.

Section 4: Summary of Outcomes, Findings, and Implications

The project included clinical and quality improvement arms. The clinical arm implemented and expanded the use of CenteringPregnancy™ Group Prenatal care to address educational and self-care deficits and empower women and families to make informed choices about the burgeoning and inappropriate use of emergency services and technology. The quality improvement arm validated the role the that DNP-prepared nurse can play in program planning, design, implementation and evaluation, as well as on interdisciplinary teams providing evidence-based care.

Summary of Outcomes

Centering was implemented and expanded at two FQHCs, and was well accepted by participants and staff. At the conclusion of the first PDCA cycle, staff at both sites identified changes that needed to be made to increase recruitment and conduct of the groups to improve workflows. Ongoing study will determine the impact that Centering has on preterm birth and low birthweight reduction, as measured by the marker of NICU admission, using the current cost estimate based upon the total number of deliveries for the institution, the borough-wide percentage of preterm births, and NICU admissions. Significant cost savings, combined with better patient outcomes and staff and patient satisfaction, will demonstrate the program's impact and foster administrative and budgetary support for expansion to other prenatal care sites in the medical center.

Goal 1was to develop an evidence-based process and outcome-oriented model for the implementation and expansion of the CenteringPregnancyTM Group Prenatal Care Model to the target population of pregnant women at high medical and psychosocial risk.

Utilizing the process and outcome logic models developed (see Figures 2 and 3) the summative evaluation (Kettner et al., 2013) of the program using CenteringCounts[™] analyses determined that CFCC met all the essential elements for method fidelity and thus for site approval. FHC, because of soon-to-be-remedied deficiencies in the Centering space and materials, in addition to attendance of children at groups, did not meet critical method fidelity criteria, and thus the site was not deemed ready for the site approval process. The staff satisfaction element scored at level 3, no better than routine care. Evaluation included the time required for preparation for Centering groups, set up, refreshments and charting, which were similar at both FHC and CFCC. Lack of space dedicated only to Centering would remedy this, but is not a reality at either site due to space constraints.

Goal 2 was to develop evidence-based practice guidelines in concert with Centering Health Care Institute's model and methodologies to operationalize services for the target population of pregnant women enrolling for prenatal care in two urban, FCHCs, all of whom are at high medical and/or psychosocial risk. CFCC had budgetary problems and challenges due to high turnover of nursing staff and social service staff. A lack of funding precluded OB resident training and involvement in Centering, but a nurse-midwifery student did participate in the group 2 cycles at CFCC. FHC's program included training of family practice residents who are now participating in facilitating groups. The Centering space concerns will be remedied when the site moves to its new quarters in early 2015.

Limited training funds at CFCC prevented expansion to more than two simultaneous EDC cohorts by one provider. This precluded using the opt out model, but funding for training materials was approved near the conclusion of the DNP practicum. This will enable the training to go forward and the numbers of simultaneous and specialty groups (languages, targeted high risk conditions, and teens) to increase. At FHC, the opt out model was in place and the numbers of simultaneous groups rose from two to three, with two providers, including a group for Spanish speaking women.

At both CFCC and FHC, groups were below full capacity, reflecting a need for more targeted and systematic recruitment and retention efforts, especially involvement by all center staff that have contact with pregnant women. Both sites were admitting women with high medical risk conditions, and those preliminary outcomes were favorable though the time constraints of multiple clinic visits were cited by some patients as a reason for drop out or irregular group attendance.

Goal 3 was to develop a practice implementation plan for current and new sites within MMC/MMG with a focus on sustainability. Fidelity to the 13 essential elements of the CenteringPregnancyTM method is considered the most important factor in ensuring the growth and expansion of the program (CHI, 2014). At the conclusion of the project, the process and logic impact models were incorporated into grant applications which would provide funding to implement the Centering program at three additional FQHCs at MMC/MMG as well as expand the programs at FHC and CFCC. This would include significant funds to set up and begin in house training critical to the Years 2 to Year 5 expansion process.

Goal 4 was to collect data and calculate rates and percentages for the rates of low birthweight, preterm delivery, breastfeeding initiation, method fidelity, patient and staff satisfaction measures, and financial impact assessment using the CenteringCountsTM data collection system (Munroe, 2013). All women at both sites were considered psychosocially at risk. Out of the participants who completed or were enrolled in a Centering group at the conclusion of the practicum, seven out of 26 had at least one major medical or obstetrical risk factor as well. A snapshot of patient outcomes, based upon 26 participants from four Centering groups cohorted by estimated date of confinement (EDC) who delivered before November 1, 2014, indicated that the high medical risk women fared better than low risk participants when measured by numbers of full-term deliveries and birth weights. Only one of the seven women with medical or obstetrical risk factors delivered preterm. Two of the remaining 19 low medical/obstetrical risk women delivered preterm. One of the 7 with a high-risk obstetrical risk factor who delivered full term had a LBW baby. Ninety-five of all Centering participants for whom data were available were breastfeeding on hospital discharge. It was estimated that one NICU admission at a cost of \$51,600.00 was averted in this population (n=26) of Centering participants. Further analysis, rates, and percentages are presented in the site specific and cumulative summaries and analyses.

I submitted a grant to the American Nurses Credentialing Center/Sigma Theta

Tau Evidence-Based Practice Implementation. The grant was not awarded, but will be
submitted to other sources. This extension of the DNP project will enable implementation

of a qualitative and quantitative study of the effects of Centering on key indicators of maternal and neonatal health to build upon the interim outcome findings.

Interim CenteringCountsTM Data from CFCC

Patient satisfaction scores at CFCC were universally in the Level 4 (better than routine care) and 5 (much better than routine care) range indicating high levels of satisfaction with Centering. Staff satisfaction scores from six staff members at CFCC ranged from 3 (the same as routine care) to 5 (much better than routine care), with an average score of 4.4 or 85% satisfaction. Staff sites indicated the amount of set up of the room and refreshments for groups and the effect of group schedules on the nursing staff workflows for patient preparation, laboratory testing, and sign out as reasons for the scores of 3. Staff were reminded of the PDCA cycle concept and guided through the process of developing solutions to the identified problems.

Two nursing staff members at CFCC, an LPN and PCT, agreed to work with the Centering groups to streamline group preparation, collection of laboratory specimens, and check out for patients needing nursing attention (flu vaccines, Rhogam shots, etc.).

CenteringCounts[™] provides an objective checklist to calculate administrative support scores. The administrative support score at CFCC was 60%. Points were lost for lack of senior management involvement in Centering planning and having line item or petty cash funding that was inadequate for staff and resident training. This limited expansion of the numbers of groups and implementation of the opt out model.

Staffing shortages over the course of the project limited the ability of staff to engage in recruitment and retention, as well as conduct of the groups. CFCC is not using

the opt out model, with only 2% of eligible women enrolled. Until training is funded and there are more providers and facilitators running groups, they will not be able to meet the goal of 60% of women enrolled in Centering within 3-5 years. CFCC's group space score was 100% adequate. The method fidelity checklist completed by one provider and cofacilitator met all critical standards with a score of 13, indicating that the site is on target for site approval between March-May of 2015.

At the conclusion of the DNP project, CFCC had nineteen women who completed a group cycle or were currently enrolled in Centering. Outcome data were entered into CenteringCountsTM for 15 who delivered by November 1, 2014 (Groups 1 and 2). Three women had at least one major medical high risk factor (gestational diabetes, placental abnormalities, oligohydramnios, autoimmune disease, or history of preterm birth/short cervices). Patient outcomes were available for all. One woman, who was medically high risk, attended only one group. There are currently 5 women enrolled in Group 3, one is at high medical risk (due dates in December, 2014 and January, 2015). Group 4 is being formed with a target list of ten women (due dates in April and May, 2015).

Interim CenteringCounts[™] Data from FHC

The administrative support score at FHC was 90%, with points lost for senior management not being involved in Centering planning. Real estate issues disrupted planned meetings with staff at FHC though a one hour meeting was held with OB/GYN staff nurses to inform them of the project. The site is planning a move, which will alter workflows as well as improve the Centering space.

For FHC the group space score was 65%, reflecting deficiencies in the group space (size of room, privacy, materials, and signage). The method fidelity checklist completed for one provider and one facilitator indicated that children attended some group meetings. These are critical deficiencies which resulted in a failing score. It was recommended that this be reassessed after the move to new quarters when the group space will be larger to meet space and privacy requirements and will be set up to the proper standards with posters and signage. Childcare must be arranged. The CHI site approval process should not be scheduled until after the move.

FHC was using the opt out model and was on target to increase the numbers of women in Centering to 60% within 3-5 years. Feedback from this interim report, as well as their ongoing CenteringCountsTM data collection and method fidelity checklists will guide and inform the process of remediating deficiencies in group space and conduct of the groups. FHC did not provide patient evaluations for analysis due to a hard drive crash and loss of data. Staff satisfaction scores at FHC were based on four respondents and ranged from 3-5, with an average score of 4.5 or 90%.

At conclusion of the DNP project, FHC had 25 women who completed a group cycle or were currently enrolled in Centering. Outcome data was entered into CenteringCounts[™] for eleven who delivered by November 1, 2014. Two participants were lost to follow up with no birthdate or birthweight recorded. Breastfeeding data were incomplete due to the loss of self-reported patient outcome and evaluation data. A new group has completed the second session and a group for Spanish speaking completed the first session. Due dates range from December 2014 to March 2015. Four women had at

least one major medical high risk factor including placental abnormalities, endocrine, and psychiatric problems.

Summary of Interim Patient Outcome Data From CenteringCounts $^{\mathsf{TM}}$ CFCC

Two women delivered preterm at CFCC due to pregnancy induced hypertension at 35.3 weeks and 36.5 weeks. None of the three women with major medical risk factors delivered preterm. One woman with a medical high-risk condition (placental problem) delivered a low birthweight baby (one ounce shy of the average for gestational age cut off of 5 pounds, 8 ounces) at term (37 weeks). None of the babies from CFCC were admitted to NICU, including one neonate who weighed 4 pounds, 5 ounces born at 35.3 weeks. One woman recruited to attend Centering, but who opted out of group, with no high risk factors, delivered a preterm baby at 35 weeks, also due to pre eclampsia, weighing 3 pounds, 8 ounces who spent seven days in the NICU.

FHC

The total number of Centering participants in two group cycles who attended two or more sessions at FHC was eleven. One woman delivered preterm due to a placental problem. The baby was born at 34 weeks with a birth weight of 5 pounds, 3 ounces and spent one day in the NICU. All other patients for whom data were available, including three other women with high risk factors, delivered at term with average for gestational age babies with no other NICU admissions

Analysis of Interim Patient Outcomes for FHC and CFCC

CenteringCountsTM is designed to record one year of data for accurate calculation of rates of preterm birth, low birthweight, breastfeeding initiation, NICU admission, and the resulting fiscal impact. Due to the small sample size for whom outcomes are known, even after combining data for two sites (n=26), as well as accounting for missing data (primarily breastfeeding status and patient evaluations), assessment of progress toward targets is limited. By March 2015, about the time of site approval visits, one full year of outcome data will have been recorded.

As such, the richness of the analysis comes from in depth case reviews. Prenatal care was adequate for all Centering participants based upon trimester of entry to care and numbers of visits (Kotelchuck, 1994). The low medical risk woman who opted out of Centering, delivered preterm at 35 weeks, whose baby weighed 3 pounds, 8 ounces and spent seven days in the NICU only attended 6 prenatal visits, which is not considered adequate (Kotelchuck, 1994). It may be that the extra attention and outreach provided by Centering Coordinators and providers to group participants encourages earlier and more regular prenatal care attendance and facilitates earlier intervention for problems that could contribute to lower birthweights and other adverse outcomes.

Medical and/or obstetrical high-risk status was not a predictor of PTB or LBW in this sample of Centering participants, with the majority (5 out of 6 high medical/obstetrical risk women) delivering average for gestational age (AGA) babies at term with no NICU admissions. There were three cesarean sections for placental problems (high obstetrical risk). Two of these resulted in deliveries of preterm infants.

The third cesarean resulted in birth of the single low birthweight infant. One woman who had planned a repeat cesarean had a successful vaginal birth after cesarean (VBAC), despite her obstetrical high-risk status of oligohyramnios. All of the medical high-risk women were breastfeeding at hospital discharge.

Case analysis was done for two women, matched for nulliparity, low medical risk status, EDC, and gestational age at preterm delivery due to the same pregnancy complication (pregnancy induced hypertension). The baby of the Centering participant, born at 35.3 weeks weighed 4 pounds, 5 ounces and was cared for in the normal newborn nursery with an average length of stay (3 days). The traditional care participant's infant, born at 35 weeks due to pregnancy induced hypertension, weighed 3 pounds, 8 ounces and spent seven days in the NICU.

Additional case analysis of two Centering participants having second babies, with similar placental problems, demonstrated one full term (37 weeks) elective cesarean section with a baby one ounce away from being AGA at 5 pounds, 7 ounces who went to the normal newborn nursery. The other was 34 weeks, had an emergent preterm cesarean section. The baby weighed 5 pounds, 3 ounces, and spent one day in the NICU. This case analysis supports the finding by Picklesimer et al. (2012) of higher birthweights in infants Centering participants that might contribute to less NICU admission.

That only one obstetrically high-risk mother delivered preterm may reflect the additional support and surveillance. Group visits augmented traditional high-risk clinic attendance that focused on management of the high-risk condition only. One preterm baby born to a low risk Centering mother weighed 7 ounces (318 grams) more than one

born to traditional care participant matched for parity and EDC. A critical factor might have been the better prenatal care adequacy (16 visits including 4 Centering vs. 6 visits with 0 Centering), earlier identification of a problem, or amelioration of a stress related condition leading to a preterm birth in an otherwise uncomplicated pregnancy. The cost "savings" estimate of \$51,600.00 from this one case of NICU avoidance would fully fund the full Centering training program for the expansion and further outcomes research.

The preterm birth rate for the 26 women who completed the four group cycles, two from each site, was 11.5 %. The current institutional rate ranges from 12.8 to 14.7% with an average of 13.8%. One woman out of 26 delivered a LBW (not preterm) baby who did not go to NICU. The institutional rate of LBW in infants born after thirty-seven completed weeks has not yet been determined. Twenty-two out of 24 women (92%) for whom infant feeding data was available were breastfeeding at hospital discharge. The institutional average is 89%.

The 2.3% reduction in preterm birth (PTB) would result in presumably a proportional decrease in NICU admission. If extrapolated to 7000 deliveries at the current average PTB rate of 13.8% (n=966), this 2.3% reduction would put the PTB rate slightly below the Healthy People 2020 target of 11.7% (U.S. Department of Health and Human Services, 2011). Accounting for 133 babies, the cost savings would be over \$6.8 million in direct NICU costs alone.

Implications

Policy

CenteringPregnancyTM has been endorsed by individuals and organizations deeply

engaged in the implementation of health care reform efforts on national, state, and local levels. These include Lu of the Center Health Resources Systems Administration (HRSA) Fineberg, of the Institute of Medicine, Laube, past president of ACOG, and leaders of numerous policy, quality and maternal child health care advocacy organizations (CHI, 2013).

The March of Dimes, The Kellogg Foundation, and The Center for Medicare and Medicaid Services have endorsed and funded the expansion of CenteringPregnancy™ to improve the health and well being of mothers and babies (CHI, 2014). Rising, the founder of Centering HealthCare Institute, has been cited as a nursing "edge runner" by the research initiative investigating innovative programs designed to foster evidence-based practice in maternity and newborn care nursing (Mason, 2013). This advances the role of nurses fully participating in development to advance not only health policy but also in implementation of innovative programs to improve the health of vulnerable populations, a mandate of the ACO. The Institute of Medicine Report on the Future of Nursing (2010) recommended that nurses practice to the full extent of their training and experience and that they be full partners with physicians and other health professionals in health care redesign. This project met those objectives and the process of transition and expansion will continue to do the same as I continue work as the Centering Champion for the organization.

Practice

This project paves the way for my continued presence at the bedside and working alongside nursing staff as a hands-on manager in the clinical care units. This will entail

supporting the staff as they participate in the PDCA process to improve the care provided to patients as well as their own clinical skills. As part of the community at large, the Centering implementation has opened up a wider role in program design and in long term and strategic planning. An expanded role in the education of medical students, nursing students, advanced practice nursing students, resident physicians and allied health care staff will involve not only Centering training, but in other areas of maternal-child health as well. As part of the next phase of Centering expansion during the second PDCA cycle, the opportunity to partner with CHI and become a certified Centering trainer has been offered. In addition, certification as a CenteringParenting™ provider will provide the opportunity to establish a teen friendly Centering program that will engage women under 21 in the Centering experience during their pregnancies and the first year of their babies' lives. This expansion will draw from the MMG sites in the high schools and those that serve teenagers and young women to one of the two former practicum sites at CFCC and FHC.

Research

With a fully functional Centering program in place, outcomes evaluation is already in progress. This will expand to include the research protocol developed along with the practicum preceptor, which commenced upon the conclusion of the DNP project. The first phase will compare CenteringCountsTM outcome data for EDC cohort controls, matched for parity and risk status, who opted out of Centering and remained in traditional care. The first year CenteringCounts quality assurance data, when complete in March 2015, will contribute to the database of outcomes at CHI as well as permit extrapolation

of the fiscal and quality improvement effects of expansion of the program to other sites in the medical center.

Social Change

A fundamental change in the way prenatal care is delivered to maximize patient involvement and critical decision making about technology is a hallmark of the Centering program. The triple aim of better health, better care, and lower cost can be achieved for the most vulnerable populations by an educational, empowering intervention that has been demonstrated to reduce health disparities and some of the most stubborn complications including preterm birth and low birthweight (CHI, 2013)

According to IOM report on the future of nursing (2010), nurses should be full partners with physicians and other health care professionals in redesigning health care in the United States. This dictates that nurses should participate in and lead decision-making and be involved in the health care reform process. The related recommendation is that nurses should practice to the full extent of their education and training in the programs that they are redesigning.

Nurse practitioners and nurse-midwives in the institution are underutilized in the obstetrical services. The 15-15 proposal, calls for a increase of the midwifery staff to 15 full time equivalents to run Centering programs throughout MMC/MMG and deliver low risk women in a "birth center" environment (see Table 4). In addition to an anticipated 15% reduction in preterm birth from Centering, low technology care in labor has been shown to be effective in reducing costs (Howell, Palmer, Benatar, & Garrett, 2014).

Project Strengths and Limitations

Strengths of this project include the involvement of clinical level staff in the change and quality improvement process—a personal gain for them as they are able to utilize the knowledge to impact other programs and ensure better care for patients. The logic models developed not only provide the agency blueprint for program expansion, they assist with the coordination of CHI's site implementation and approval processes and will speed the process of site approval by ensuring Centering is set up with the required attention to the 13 essential elements. It has paved the way for an in house training program and for ongoing Centering outcomes research.

Site benchmarks and targets have been set by which to measure outcomes of the program (see Table 2), and a transition plan was put into place at the beginning of the practicum to ensure that the Centering implementation process would continue from year 2 through year 5 with the final goal of all MMG sites providing prenatal services to be offering CenteringPregnancyTM Group Prenatal care to at least 60% of eligible women. Patient and staff satisfaction with Centering is high, the groups continue to form and cycles are being completed, and plans are in place for more detailed evaluation of patient outcomes using a research protocol for both quantitative and qualitative analysis. The institutional policy and budgetary matters reflected in the administrative support scores are being addressed. Funding sources for training of new staff to roll out more groups within existing sites are being sought to ensure sustainability and growth of the program over the next 3 to 5 years.

The limitations of the project include the small amount of clinical outcome data,

given the 5 month lead time to begin the program, as well as the need to wait six months from inception to four weeks after after delivery. The nature of the project as a quality improvement endeavor, and its implementation within the time constraints of an academic program, precluded measurement of outcomes until after a full year of CenteringCountsTM data collection.

There is no control group consisting of women in traditional care with which to compare preliminary outcomes. The numbers of women who completed a full Centering group cycle are too small and the demographic data too sparse to be generalizable. Age, race, country of birth, and ethnicity data are not recorded in CenteringCountsTM so the racial and ethnic make up of the patients and the effect on racial and ethnic disparities in this sample cannot be assessed.

Recommendations for Future Work

Plans have already been put into place for expanded outcomes evaluation, with Montefiore/Einstein institute for Clinical and Translational Research (ICTR) Institutional Review Board approval, to analyze both qualitative and quantitative data to better try and elucidate the methods by which Centering effects its benefits. Ongoing evaluation of outcomes will continue with CenteringCountsTM but will be expanded on to include measurement of maternal stress, self-esteem and depression scores. This project will be discussed in Section 5.

Moving the Centering budget from the petty cash funding to a program budget would provide funding for selected MMG sites to adopt Centering using the logic models and with the support of CHI and existing site facilitators. Outreach to payers and private

foundations has been ongoing with a new grant application efforts underway.

Streamlining the training process to be conducted in-house jointly with CHI will enable more MMC/MMG staff to become certified as Centering facilitators and enable the roll out of more groups at both existing and new sites.

Analysis of Self

The past two and a half years of doctoral education has expanded my sphere of interest and influence, by encouraging engagement in higher level academic and managerial activities and strategic planning. New knowledge about the policy and change process has turned frustration with the slow pace of improvements into an analytical and strategic one, with a focus on incremental gains and sidestepping challenges in order to maintain forward motion.

As Scholar

I submitted a grant application to the American Nurses Credentialing

Center/Sigma Theta Tau for funds to foster involvement over the next two years in

research utilizing the developed protocol, including qualitative and quantitative study of

CenteringPregnancy™, along with Peter Bernstein, MD, MPH .as the principal

investigator. Though not awarded, additional funding is being sought to commence more

robust research as the implementation project concluded and the expansion portion

began. This includes preparation of a major grant application for the Allen Foundation,

which funds training programs for health professionals preparing to offer innovative

approaches to nutrition education.

As Practitioner

Plans are underway for me, as part of the expansion plan, to initiate a Centering program for teenagers that would enable young mothers and their partners and parents to enroll in the eleven session CenteringPregnancyTM program and a follow-up CenteringParentingTM program that would follow the mother-baby dyads for the first year of life. Teens would be recruited from all MMG sites, including the 14 New York City High Schools served by the Montefiore School Health Program (MSHP). Depending upon geographic location and patient preference for delivery sites, students would be referred for intake appointments at either FHC, in the West Bronx, CFCC, in the East Bronx, or the Center for Children and Families (SBCCF), in the South Bronx, to enroll in the Centering. Colleagues from FHC, the SBCCF, and CFCC will join me in offering this innovation. This combination of programs is exceptionally well suited to teenagers and their families that need extra parenting education and support to continue their education. It complements the work of other community organizations such as the Nurse-Family Partnership that offers support to first time mothers, a large proportion of which are teenagers and could use these programs as referral sources for their clients.

As Project Developer

Sustainability planning continues as the one-year anniversary of Centering's expansion approaches in January 2015. Terminal project presentations to the directors of the MMG sites CFCC and FHC reported the quality improvement and financial impact of the Centering intervention. Presentations to members of the departments of obstetrics, gynecology and women's health, and family and social medicine over the next year will highlight the evidence-based practice significance of Centering versus traditional prenatal

care models. Follow up presentations after the one year anniversary to the Bronx Community Health Network (BCHN), which oversees the institution's (FQHCs), will provide information on the value of this evidence-based model in addressing the high rate of preterm birth and low birthweight in the community, as well as on persistent health disparities.

The 15-15 proposal, incorporating the expansion of midwifery services and low technology labor, delivery and post partum care by midwives and family practitioners will be addressed with the new chair of the department of obstetrics and gynecology as well as the president and CEO and chief operating officer at MMC.

What Does This Project Mean for Future Professional Development?

As the organization's Centering Champion, I will organize and conduct CHI site approvals, ongoing Centering training, resident and medical student education. The continued involvement introduces nursing, nurse practitioner, and nurse-midwifery students to both clinical care and evidence-based concepts and fosters their career development.

As part of MMC/MMG's collaboration with CHI, plans are underway for a study of large multi-site in house training models using the logic models developed for this project. Outcomes of the clinical, quality improvement educational and financial outcomes of this project will be adapted to PowerPoint and poster presentations for in house training, workshops, and speaking engagements with consumers including the New York City Chapter of the March of Dimes and CHI.

In order to be able to conduct large-scale trainings, I will enter the Centering Health Care Institute's trainers training program in January, which involves an advanced workshop as well as facilitation of national training programs as part of the advanced certification process. Already a level 2 CenteringPregnancyTM Provider, I will become a certified Centering trainer and level 1 CenteringParentingTM provider. This extension of lifelong learning enables continued use of the process and outcome logic models developed during the practicum and ongoing participation in the process of meeting the 3 to 5 year goal of all prenatal sites in the MMG having an active Centering program.

Summary and Conclusions

Berwick (2003) emphasized that local adaptation of any program, which often involves simplification, is nearly a universal property of successful dissemination. In a successful diffusion process, the original innovation itself mutates into many different but related innovations. The logic models succeeded in creating a roadmap for implementation that maintains CHI endorsement and method fidelity and validity while at the same time acknowledging the individual needs and demographics of each site.

Change is difficult in complex organizations (Kelly, 2011) but use of the selected change models and frameworks, including PDCA, field analysis (Lewin, 1951), and disruptive design (Christensen, 2013) moved the project forward over the course of one year by focusing on clinical and frontline staff and supporting previously CHI trained providers in the program expansion at their sites. They are now independent and new groups are being formed and started with the support of local administration. All staff is working to adjust the recruitment and engagement of patients and group day workflows

to meet the dynamic changes and challenges at each site. My role continues to be one of consultation and support as needed, with plans for ongoing involvement in clinical care and conduct of Centering groups and CHI endorsed and sponsored training of staff and providers in all prenatal care sites within Montefiore Medical Center/Montefiore Medical Group.

Interim analysis of patient outcomes from four completed Centering group cycles at two FQHCs demonstrates that CenteringPregnancy™ Group Prenatal Care has the potential to impact the high rate of preterm birth, low birthweight, and health disparities in a population of women at both medical and psychosocial risk. Preliminary data indicate a potential for significant cost savings using neonatal intensive care unit admission as a proxy measurement. Breastfeeding initiation rates in the first four group cohorts were higher than the institutional average.

Competition for funding in a climate of cost containment is an ongoing reality. Documentation of the beneficial effects of CenteringPregnancyTM to all stakeholders, particularly its impact on the stubborn problems of preterm birth, low birthweight, and health disparities would document the need and justify the expense of expansion. Grants are being sought. On the policy level, proposals for expansion of Centering are being advanced by the candidate, the practicum preceptor, and other administrative colleagues in the Montefiore Medical Group during institution wide planning meetings and practicum outcome dissemination presentations with senior management as well as with the Bronx Community Health Network.

The 15-15 proposal fits into a recommendation by New York State Medicaid to utilize midwives in a birth center environment for lower risk women, which has been shown to dramatically decrease the cost of intrapartum and postpartum care (Howell et al., 2014). As such, enhanced Medicaid funding might be available for ongoing expansion of CenteringPregnancyTM that would facilitate seamless transitions to both intrapartum care and CenteringParentingTM as well as creation of Maternity Care Homes (MCOs) under the Montefiore Pioneer ACO mandate. Cassell (2014), of the National Quality Forum, has indicated that maternity care will be focus for ACOs in 2015.

The 15-15 proposal calls for a 15% reduction in the rate of preterm birth by expansion of the CenteringPregnancy™ program plus creation of an in house "birth center" run by 15 full time equivalent midwives for 15% of low medical risk women. Thus, outpatient care would articulate with inpatient services and create a seamless continuum of care within the framework of a PCMH/MCH model. It is estimated that savings from a fully implemented Centering program would save the institution \$7 million in direct neonatal intensive care unit costs alone (Darling & Atav, 2012). An in hospital "birthing center" for lower risk women could potentially save the institution an additional \$1.2 million by decreasing inductions, cesarean sections, and use of technology not necessary in normal births that lead to iatrogenic complications and longer length of stays for both mothers and babies (see Table 4).

Section 5: Scholarly Product: Research Proposal

The Effect of CenteringPregnancy TM on Key Indicators of Maternal Child Health in Women at Medical and Psychosocial Risk

Principal Investigator: Carole Ann Moleti, MS, MPH, CNM, FNP-BC Co-Investigators: Peter Bernstein, MD, MPH
Dana Schonberg, MD, MPH
Hillel Cohen, DrPH, MPH
Rebecca Mahn, BS

Overview

CenteringPregnancy™ Group Prenatal Care (Rising1998) has been demonstrated to be an evidence-based intervention to address the inter related problems of high rates of preterm birth, low birthweight, stress, and depression in racial and ethnic minority women at high medical and psychosocial risk (Centering Health Care Institute, 2013a). Using a summative and formative evaluation process (Kettner, Moroney, & Martin, 2013), logic models were developed to expand the use of the Centering model in two prenatal care sites in a large urban hospital network. The project evaluation plan utilized the required CenteringCounts™ data collection tool provided by Centering Healthcare Institute (2013b) to track patient outcomes, staff and patient satisfaction, and method fidelity. Pilot testing during the evaluation phase of the project demonstrated that these models were an effective way to roll out Centering groups in the remainder of prenatal care sites the ambulatory network.

Nearing conclusion of the first Plan-Do-Check-Act (PDCA) cycle,

Comprehensive Family Care Center (CFCC) and Family Health Center (FHC) were

running three Centering group cycles each. Method fidelity for both sites, as determined

on CenteringCountsTM, demonstrated positive movement along the path to site approval,

as measured by attention to The 13 essential elements of Centering. Staff evaluations ranged from 65%-100% satisfied, with an average score of 85%. Narrative commentary identified the need for greater administrative support to ensure proper staffing, funding for ongoing training, space, supplies, and equipment.

Preliminary data from CenteringCountsTM maternal-newborn health outcomes for four EDC cohorts that completed an eleven session Centering group cycle, though limited by lack of demographic data and small numbers (n=26), yielded three preterm infants (gestational ages 34.3-36.6 weeks). Only one infant was born to a mother with an obstetrical risk factor (a placental problem) that spent one day in the neonatal intensive care unit (NICU). Another woman with the same obstetrical risk factor (a placental problem) delivered at term and the baby was one ounce less (5 pound and 7 ounces) than the 5 pound, 8 ounce cutoff to be considered average for gestational age. The infant did not require NICU admission. Thus, six out of the seven women considered medically high risk delivered at term with no adverse neonatal outcomes. The two low medical/obstetrical risk mothers who delivered prematurely did so because of pregnancy induced hypertension. Thus, seventeen of nineteen low medical risk women delivered full term. None of the babies born to low medical/obstetrical risk women went to the NICU. Twenty-one out of twenty-two women (92%) for whom infant feeding data were available were breastfeeding on hospital discharge. The institutional rate is 89%.

The preterm birth rate was 11.5% for this sample. The institution's preterm birth rate ranged from 12.8% in 2012 to 14.7% in 2013, with an average of 13.8%. The 2.3% reduction in preterm birth would result in presumably a proportional decrease in NICU

admission. If extrapolated to 7000 deliveries at the current average PTB rate of 13.8% (n=966), this 2.3% reduction to 11.1% would put the PTB rate below the Healthy People 2020 target of 11.7%. Accounting for 133 babies, the cost saving of would be over \$6.8 million in direct NICU costs alone.

The requested grant funding would facilitate the beginning of a second PDCA cycle and provide continued champion support to CFCC and FHC through the CHI site approval process in Spring 2015. It would also enable expansion of CenteringPregnancyTM to three additional Montefiore Medical Center/Montefiore Medical Group (MMC/MMG) sites over the two-year period of the grant, beginning December 2014.

In addition to the use of CenteringCountsTM, a quantitative assessment of maternal stress and depression will be added to the evaluation plan, using the Prenatal Psychosocial Profile [PPP] (Curry, Christian, & Campbell, 1998) and the Edinburgh Postnatal Depression Scale [EPDS] (Cox, Holden, & Sagovsky, 1987). A qualitative assessment using focus groups for both pregnant and post partum women in both Centering and traditional prenatal care will explore patients' sources of support, and whether that differs in women who participate in Centering and those who attend customary prenatal care visits.

Background, Purpose, and Nature of the Study

Background

A standardized methodology for implementation of CenteringPregnancy™ Group

Prenatal Care (Rising, 1998) has been developed to roll out the method as an intervention

in an urban, inner city population of racial and ethnic minority pregnant women at high medical and psychosocial risk in a large, multicenter health system in The Bronx, New York City. The goal is to continue the process of Centering Health Care Institute (CHI) approval for two existing sites, Comprehensive Family Care Center (CFCC) and Family Health Center (FHC) that provide care for a population of pregnant women at high medical and psychosocial risk. During the two-year period of the proposed grant, evaluation of outcomes for the first PDCA cycle, to include six groups of Centering participants cohorted by estimated date of confinement (EDC) will be initiated at commencement of funding in December 2014. Another PDCA cycle will be continue the expansion process, with an identical evaluation of outcomes, to three additional sites beginning in February 2015 (see Table1). The Centering program evaluation will be expanded to include a prospective cohort study, with both qualitative and quantitative measurements of maternal stress and depression.

CHI requires official training for facilitators, coordinators, and clinical teams at new sites before the expansion can commence. By special arrangement, the principal investigator, a nurse-midwife at Montefiore Medical Center, was permitted to offer abbreviated Centering training to resident and attending physicians, clerical staff, nurses and health educators, who would then be able to work with officially CHI trained physicians and midwives as preceptors. This agreement included an understanding that CenteringCounts[™] data would be used to measure of method fidelity and that these data would be sent to CHI at the end of the first PDCA cycle in January 2015. Site approval visits will be conducted in Spring 2015. The goal of the second PDCA, in addition to

rolling out three new sites, Wakefield, Williamsbridge, and Family Care Center (FCC), is to offer in-house official training for all staff at greatly reduced cost, designating the principal investigator as instruction and method initiation champion.

Nature of the Study

This proposed evidence-based practice process and outcome study would commence in December 2014. Institutional support includes Peter Bernstein, MD, MPH, director of medical research programs for the Department of Obstetrics, Gynecology, and Women's Health. Dana Schonberg, MD, MPH from the Department of Family and Social Medicine will serve as a research associate for qualitative methodologies. Hillel Cohen, DrPH, MPH will offer biostatistics support. Rebecca Mahn, BA, a medical student at the Albert Einstein College of Medicine, will serve as a research assistant. In summary, the investigator will use the funds provided to further test the logic models developed for use in the institution for their ability to maintain method fidelity during the expansion process. Outcomes will be evaluated using a prospective cohort convenience sample of women who enroll in Centering (the intervention group) with a control group of those in traditional prenatal care.

Evidence-Based Significance of the Proposed Study

The problems of preterm birth (PTB) and low birthweight (LBW) babies are the source of a large burden of infant, neonatal, and childhood morbidity. The annual cost of babies born too early or too small to the United States health care system rose from an estimated \$5.8 billion in 2001 (Russell et al., 2007) to \$26.2 billion in 2005 (CHI, 2013a). The major portion of costs was for babies who were not extremely premature

(Darling & Atav, 2012; Russell et al., 2007). Using March of Dimes data, it is estimated that the rate of low birthweight babies (<2500 grams) increased from 7.7% in 1996 to 8.2% in 2009 (March of Dimes, 2013).

Research suggests that CenteringPregnancyTM Group Prenatal Care (CHI, 2013b) has a beneficial effect on self-efficacy and self-esteem, leading to greater self care competence as described by Orem (1980). Centering has been shown to decrease the rate of preterm birth and low birthweight infants, increase the numbers of women breastfeeding at hospital discharge, increase self-efficacy, and lower the rates of depression, stress, and maladaptive behaviors (CHI, 2013b). This effect might be more pronounced in women at both high medical as well as psychosocial risk who experience the additional stressors of pregnancy complications.

Through a systematic review of the literature, Lathrop (2013) compared group prenatal care to traditional one provider, one patient prenatal care. Lathrop found evidence from randomized controlled trials and larger prospective, correlational, and retrospective cohort studies that group prenatal care participants have lower rates of preterm birth, higher birthweights in babies born preterm, and a beneficial effect on adequate weight gain, increased contact hours of prenatal care visits, with more knowledge and better preparation for labor and delivery. Despite several studies with conflicting or inconclusive findings attributed to lack of randomization and/or small sample size, group prenatal care participants have higher rates of breastfeeding initiation and satisfaction with care. Outcomes were significantly improved in high-risk

populations, particularly adolescents and those from racial and ethnic minorities (Lathrop, 2013).

Meta-analyses of the effectiveness of various prenatal care and education programs (Gagnon & Sandall, 2011; Hodnett, Fredericks, & Weston, 2010), though inconclusive, point toward a need identify the efficacy of standardized educational programs and specific interventions for patients at high psychosocial risk. The mechanism by which CenteringPregnancyTM exerts its benefits has been postulated but not sufficiently investigated (Sheeder, Yorga, & Kabir-Greher, 2012).

Preterm Birth Data

National Benchmarks

Martin and Osterman (2013) reported the US preterm birth rate (<37 weeks completed gestation) decreased from 12.8% in 2006 to 12% in 2010. The preterm birth rate for Black infants in the United States was lower than ever in 2010, but it was still about 60% higher than the rate for White infants (Martin & Osterman, 2013). Non-Hispanic Black infants had a rate of preterm births of 17.1% in 2010, a decrease from 18.5% in 2006, according to birth certificate data (Martin & Osterman, 2013). Non-Hispanic Whites (10.8%) and Asian/Pacific Islanders (10.7%) fell below the average. Hispanics (11.8%) and American Indian/Alaska Natives (13.6%) hover just over or below the national figure (Martin & Osterman, 2013).

Despite the Hispanic paradox, a phenomenon, described by Fuentes-Afflick, Hessol, and Perez-Stable (1999), which explains positive health outcomes in Hispanic immigrants living in poverty, Puerto Rican women are second only to Black women for

the risk of LBW and more likely to deliver at 32-36 weeks than non Hispanic Whites (Stein et al., 2009; Tandon et al., 2012).

Each preterm birth costs an average of \$51,600.00 per infant (Darling & Atav, 2012). Assuming a modest 15% decrease in preterm birth with the Centering intervention, the cost savings to the institution would be almost 7 million dollars in direct neonatal care costs in one year, not counting the cost of persistent infant and childhood morbidity.

Low Birthweight Babies in New York State, New York City, and The Bronx

Aggregate data from 2008-2010 compiled by the March of Dimes (2013), also reports disparities in the New York State rate of low birthweight (LBW) babies (<2500 grams regardless of gestational age at birth), with Whites at 6.8%, Blacks at 12.8 % and non-Black Hispanics 7.8%. The overall NYS rate is 8.2%. The Bronx has an overall rate of low birthweight of 9.9% as compared with New York City as a whole at 8.7%. This translates into 2190 Bronx babies in 2010, for a cost of \$111,690,000 (Darling & Atav, 2012; March of Dimes, 2013, Russell et al., 2007). Citywide, the number of low birthweight infants totaled, 10,483 with direct neonatal intensive care costs alone of \$540,922,800 million (March of Dimes, 2013). Low birthweight data at CFCC is currently not reported separately from preterm birth rate data. This LBW benchmark will be established during the two-year period of this study by identifying the numbers of babies born after 37 completed weeks of gestation who weighed less than 51bs 8oz.

Quality Improvement Targets for Preterm Birth and Low Birthweight

Healthy People 2020 objectives call for a reduction in the rate of PTB to 11.4% and LBW to 7.8 % (U.S. Department of Health and Human Services, 2011). The March of Dimes (2013) has set even more stringent targets for its signature campaign to reduce PTB rates to 9.6%, by targeting late preterm birth due to iatrogenic and preventable causes such as early elective deliveries that lack evidence-based medical indications (CHI, 2013b).

Project Questions

- Will low income, racial and ethnic minority women at high medical and psychosocial risk who receive support and education using the Centering PregnancyTM Group Prenatal Care Model give birth to fewer preterm and low birthweight infants than those receiving traditional prenatal care services?
- Will low income, racial and ethnic minority women at high medical and psychosocial risk who receive support and education using the Centering PregnancyTM Group Prenatal Care Model experience less stress and post partum depression and exhibit greater self esteem/self efficacy as measured by the Prenatal Psychosocial Profile (PPP) Scale and Edinburg Postnatal Depression Scale (EPDS) scores during the second and third trimesters as well as at the post partum visit than a cohort of women receiving traditional prenatal/postnatal care services?
- Will low income, racial and ethnic minority women at high medical and psychosocial risk who receive support and education using the Centering

- Pregnancy[™] Prenatal Care Model be breastfeeding on hospital discharge than a cohort of women receiving traditional prenatal care services?
- What is the experience of low income racial and ethnic minority women at
 high medical and psychosocial risk who participate in Centering
 PregnancyTM Group Prenatal Care in seeking and finding sources of
 preganancy, delivery and post partum education and support?
- What is the experience of low income racial and ethnic minority women at
 high medical and psychosocial risk who opt out and choose to remain in
 traditional prenatal care services in seeking and finding sources of
 pregnancy, delivery and post partum education and support?

Specific Aims/Hypotheses

This study will add to the body of evidence that suggests that

CenteringPregnancyTM as the opt out model of prenatal care has a positive impact on key indicators of maternal and neonatal well-being.

- H 1: Low income, racial and ethnic minority participants at high psychosocial risk in CenteringPregnancy™ Group Prenatal Care will exhibit decreased anxiety and stress scores measured by the Prenatal Psychosocial Profile (PPP), less preterm birth, low birthweight, and post-partum depression measured by the Edinburgh Postnatal Depression Scale (EPDS) as compared with an EDC cohort receiving traditional prenatal care services.
- H 2: Low income, racial and ethnic minority participants with both medical and psychosocial high risk conditions in CenteringPregnancyTM Group Prenatal Care will

exhibit decreased anxiety stress scores measured by the PPP, self reported substance use, preterm birth, low birthweight, and post-partum depression measured by the EPDS as compared with an EDC cohort receiving traditional high-risk prenatal care services.

H3: Cost benefit analysis will show that expenses and administrative costs of care of women and neonates/infants with the CenteringPregnancy™ Group Prenatal Care Model will be offset by decrease in the rates of low birthweight, preterm delivery, and neonatal intensive care unit admission.

Theoretical/Conceptual Frameworks

Orem's Self-Care Theory (1980), tenets of social cognitive theory (Bandura, 1997), and self-efficacy (Bandura, 1995) form the basis for the concepts of empowerment and social support--the foundation upon which the CenteringPregnancy™ Group Prenatal Care Model (Rising 1998) is based Rew's middle range theory of taking care of oneself (2003) found increasing self-esteem is critical in fostering positive movement toward self-care. Perry's middle range theory of self-transcendence (2004) describes the bond between the nurse and patient that might enable the beneficial effects of Centering on pregnancy outcomes (see Figure 1).

Literature Review

Search of the CINAHL database using keywords psychosocial support, self-care and pregnancy, with cross-referenced additions, yielded seventy-two results. Using keywords psychosocial support and pregnancy yielded one result on Cochrane and one on the DARE databases. Self-care alone on the search of systematic databases yielded no results, a pertinent negative indicating that randomized controlled trials and meta-

analyses failed to identify Orem's concepts in their theoretical base. Relevant references in the papers were explored.

Search of the CINHAL database using the keyword Centering Pregnancy yielded 22 results, including two systematic reviews and four randomized controlled trials, all of which were reviewed and relevant bibliographic sources explored. CHI provided training materials and literature were also incorporated into the review. Program evaluation and planning texts by Hodges and Videto (2011) and Kettner, Moroney and Martin (2013) offered summaries of methodologies and change theories, as well as formative and summative program evaluation. Relevant articles in both bibliographies were explored. A search of the CINHAL and Business and Management databases yielded only four models that together offered structure change strategies suitable to this type of project and the institution

Moleti (1990) postulated that the inter related theoretical frameworks of Maslow's hierarchy of needs (1970), Peplau's conceptualization of levels of anxiety (1963) and crisis intervention theory by Aquilera and Messick (1986), fostered a stepwise approach to the management of psychosocial risk to reduce anxiety, meet basic needs and manage crises, moving the individual to a higher level of function (see Figure. 4). Yu, McElory, Bullock, and Everett (2011) used grounded theory research concepts (Hunter, Murphy, & Grealish, et al., 2011) and the Prenatal Psychosocial Scale (Curry, et al., 1998) to study specific interventions to decrease cigarette smoking and increase self-esteem and in pregnant women and linked increasing social support and self-esteem to greater self-care competence. Renker (1997) found self-care agency accounted for a significantly lower

incidence of low birth weight, a lower incidence of miscarriage, substance use, and emergency service use. Psychosocial interaction effects between abuse, social support, and self-care agency showed that the social support factor of shelter and family help significantly impacted birthweight by 17% (Renker, 1997). Leahy-Warren (2005) used a framework based upon Bandura's theory of self-efficacy (1995) and identified nurses as the primary source of effective support and that nurse modeling of mothering behaviors had a positive impact on perceived social support and self-care.

Ickovics et al. (2011) found highly stressed women randomly assigned to group care reported significantly increased self-esteem, decreased stress, depression, and social conflict in the third trimester of pregnancy through the first year postpartum when compared to women in traditional prenatal care. Social conflict and depression were significantly lower 1-year postpartum, with improved psychosocial outcomes for high-stress women enrolled in Centering.

Ickovics et al. (2007) and Ickovics et al. (2003) found a 33% reduction in preterm birth in Centering participants. Picklesimer et al. (2012) report a decrease in preterm delivery, though exclusion of women with medical complications might be contributing factors to improved outcomes. Other factors include empowering women to seek medical attention earlier when experiencing problems, better compliance with treatment regimens, healthier behavior choice, and a more positive, accessible relationship with care providers. An enhanced level of social support, including group support, might ameliorate stress and increase coping. Stress reduction may, in turn, decrease

inflammatory mediators that contribute to the cascade of preterm labor (Picklesimer et al., 2012).

Methods

Effecting change of care models from traditional prenatal services to Centering in complex organizations requires an incremental approach (Kelly, 2011). The Plan-Do-Check-Act [PDCA] Model (Deming, as cited in Kelly, 2011), the chosen quality improvement methodology at the Montefiore Medical Center (MMC), is used in the Centering implementation and expansion process. Disruptive design (Christensen, 2013) focuses practice change efforts at the lowest level of the organization with involvement of all staff in a series of PDCA cycles linked to EDC cohorts entering groups as well as participants who elect to remain in traditional prenatal care services.

Research Design

This is a quantitative study with qualitative components for triangulation. Using a prospective cohort design and a non-probability sampling strategy will ensure that selected racial and ethnic groups will be represented (Polit & Beck, as cited in Fawcett & Garity, 2009, p. 143) and improve generalizability. Deviant case sampling of data on women with medical high-risk conditions avoids confounding by analysis of women with a higher incidence of adverse pregnancy and neonatal outcomes separately from those who are not considered medically or obstetrically at risk (Polit & Beck, as cited in Fawcett & Garity, 2009, p. 140).

Subjects and Setting

Pregnant women enrolled in two federally qualified health centers (CFCC and FHC) who currently conduct CenteringPregnancy™ Group Prenatal Care will be the source of the study population. These two agencies are satellites of MMC, a voluntary, urban hospital system in New York City, which provides care to many areas designated as medically underserved women. The majority of patients are considered low income, with a household income of up to 138% of the federal poverty level, adjusted for family size, according to Federal and expanded New York State Medicaid eligibility guidelines (Obamacare Facts, 2014). MMC conducted 7000 deliveries in two inpatient sites in 2012. The institution serves as a tertiary care perinatal referral center for Bronx County, New York City, as well as southern Westchester County, New York and southern Connecticut.

Instruments

CenteringCounts™ is a proprietary data collection system produced by Centering Healthcare Institute designed to promote the triple of aim of better care, better health, and lower cost (Munroe, 2013). The data are held in three Microsoft Excel pre programmed spreadsheets. The first worksheet assists the site in establishing current rates and percentages on key indicators, choosing benchmarks, and setting targets. The second is programmed for ongoing collection of data for all groups at the individual site. This tracks attendance, prenatal care adequacy and outcome data, which feeds into additional pages which aggregate the data and calculate procedure and outcome measures. The third is a method fidelity checklist that includes staff and administration support and satisfaction scoring sheets. Progress toward site approval or re-approval is tracked based upon those measures in addition to fidelity to The 13 essential elements.

Developed by CHI and provided free of cost to approved sites, the de-identified data compiled and automatically analyzed must be submitted on a yearly basis to maintain site approval to utilize the CenteringPregnancyTM method (Munroe, 2013). CenteringCountsTM ensures fidelity to the method by tying the documentation to the monthly self-assessment sheets. Providers debrief after each group by reviewing the facilitation process and health assessments as well as the group process. Completion of the worksheets after each session, instead of after the final postpartum group, ensures that the data are fresh and accurate. In addition, corrections can be made during the group cycle if there is lack of adherence to the 13 essential elements.

The instruments to measure depression and stress include the Edinburg Postnatal Depression Scale [EPDS] (Cox et al., 1987) and the Prenatal Psychosocial Profile [PPP] (Curry, Burton, & Fields, 1998). The EPDS was confirmed to have good user acceptability when administered as a postnatal questionnaire with satisfactory sensitivity (79%) and specificity (85%) (Cox, Chapman, Murray, & Jones, 1996).

For the PPP, construct validity of the stress scale was supported by theoretically predicted negative correlations with self-esteem, partner support, and support from others (N = 91) (Curry, Campbell, & Christian 1994). Convergent validity of the stress scale was demonstrated by a correlation of .71 with the Difficult Life Circumstances Scale. Adequate levels of internal consistency were found (Curry et al., 1994).

Procedure

The CenteringPregnancy™ Group Prenatal Care Model, developed by Rising (1998) is a structured pre and postnatal care program that includes the family and the

nurse/physician in a peer patient/professional group setting. There are eleven, two-hour group sessions beginning at 16 weeks gestation and ending with the 4-6 week post partum session, which conform to the standard schedule of prenatal visits. All care is provided in the group space, including a patient self-assessment (physical and behavioral related to the class content), individual physical assessment by the provider, then discussion and education, which models networking, problem solving skills, and healthy behaviors during the pre and postnatal period and beyond. This replaces individual prenatal visits (unless indicated or requested) and eliminates the need for separate visits or programs on nutrition, breastfeeding, childbirth preparation, and newborn/infant care and development. The content is pre-determined but fluid, depending upon the needs of the group. All group facilitators must receive training and supervision in the conduct of the Centering method to insure fidelity to the program and internal/external validity of research findings (CHI, 2013a).

Women in both traditional care (controls) and Centering Care (intervention group) who agree to participate will complete the PPP at intake, during the second trimester and again at 36 -38 week gestation. The EPDS will be administered to all participants in both Centering and traditional care at 4-6 weeks postpartum. The PPP will be completed during control and intervention focus groups conducted antenatally. Focus group participants (control and intervention groups) will complete the EPDS between four and eight weeks after delivery.

Estimation of sample adequacy for the quantitative portion set the goal of admitting 25 women into both the control and experimental groups (H. Cohen, personal

communication, November 19, 2013). For the qualitative portion, four focus groups will be conducted, two antenatally and two post-partum, at each study site. One antenatal and one postnatal focus group will be conducted for Centering participants and one antenatal and one postpartum focus group will be conducted for traditional care recipients.

Qualitative assessment for both Centering and traditional care participants will explore patients' sources of support and education and how those preferences influence enrollment or opt out of Centering care.

Plan for Data Management/Analysis

Quantitative Analysis

All data will be collected, coded, cleaned, and entered into SPSS version 21.

Descriptive statistics will be used to examine the demographic and socioeconomic data on patient information sheets, summarize, and characterize relationships between the control and experimental group. Descriptive statistics will also be used to assess data elements such as age and parity, ethnicity and income, marital status, and country of birth. Inferential statistics will be used to test the hypothesis that Centering participation will be associated with higher birthweight and gestational age at delivery. These outcome variables will be analyzed as continuous and also categorized into high, normal, and low as defined by established standard measurements in weeks of pregnancy and kilograms. Measures of central tendency and testing for significance using the mean, standard deviation, and variance will be calculated. Bivariate and multivariate methods including multiple analyses of variance and multiple linear regression will test relationships be used to adjust for potential when analyzing the outcomes as continuous variables and logistic

regression models when analyzing the outcomes as dichotomous variables (H. Cohen, Personal communication, November 19, 2013).

Qualitative Analysis

After completion of either the PPA or EPDS (depending upon whether or not they have delivered) open ended questions will be posed to allow for themes to develop during discussion. Participants will be informed told that the purpose of the meeting is to find out more about women's sources of information about pregnancy and birth, post partum care, and infant care and feeding. Six to eight women in the ninety minute focus groups will be asked to answer questions based about why they did or did not chose Centering care. Then they will be asked to describe their sources of support and satisfaction with that support. They will be asked to describe their information, education and support needs during the pregnancy. Finally, they will be asked to describe how prenatal care visits met their needs, addressed their concerns, and prepared them for labor, delivery, the postpartum period and for infant care.

The transcribed interviews will be coded and analyzed for themes using the grounded theory approach for qualitative data analysis. Early data will be analyzed and used to modify the interview guide for future interviews so that emerging themes can be explored in greater detail. Data will be coded line-by-line and organized into a conceptual framework, which will allow for themes to emerge.

The coding scheme will be developed by members of the research team through an iterative process. Once the scheme is developed, raters will independently code a portion of the data and compare coding to ensure coherence and validity of the coding

scheme. Discrepancies will be resolved through discussion and consensus. Participants will have the opportunity to validate the analysis of their transcribed data.

Limitations

Limitations of the study include the potential for drop out leading to gaps in data collection and reduced sample size. The PPP is not validated for non-English speaking participants (Curry et al., 1998), which limit generalizability of some quantitative data to Spanish speaking populations. Focus groups in Spanish will offer additional insights into the needs of this subpopulation. Future studies can build upon the findings using a larger Spanish speaking population and instruments validated for use in languages other than English.

Participants will not be randomized into groups. Historically, most women that enter the Centering Program are free of major medical risk factors, resulting in a healthier population, and selection bias. The lower rates of low birthweight and prematurity in Centering participants may reflect better overall mental, physical and psychosocial health rather than the effect of the intervention itself. The inclusion of high medical/obstetrical risk participants will examine this in greater depth.

Human Subjects Protection

The study has been approved by the Institutional Review Board at the Institute for Clinical and Translational Research (ICTR) at the Albert Einstein College of Medicine and Montefiore Medical Center. In consideration of the special risk groups, which include pregnant women, there is little anticipated risk to participants regardless of whether they participate in Centering, which is voluntary. Enrollment in Centering will

not obligate the participant to enter the study. Standards of care will conform to clinical practice guidelines for the institution, regardless of whether the participant opts in or out to CenteringPregnancyTM Group Prenatal Care.

Written informed consent will be obtained indicating that participation in the study is voluntary and may be terminated at any time. Intrapartum, neonatal and post partum care will be identical for both the control and experimental groups as will care for women who choose to not participate in the study. At any data collection point if a woman or newborn is found to be in acute crisis or at a safety risk due to a EDPS score > 9 or other psychosocial issue, they will be escorted to a credentialed staff care provider, social worker, or to the emergency department.

Data will be collected in a private location and all identifying information removed from survey instruments and audio recordings. The instruments, recordings, and SPSS data sets will be secured and password protected. All participants will receive a token of appreciation for their time in the form of gift cards distributed after each survey completion (\$10.00) and after each focus group (\$25.00).

Study Timeline

December 2014-September 2016

Additional staff will be trained in the Centering method enabling expansion at existing sites and roll out to three new sites in the Montefiore Medical Group. New EDC cohorts in both the control and intervention groups will be identified and data collection will commence at the prescribed intervals. Focus groups will be conducted antenatally and postpartum. Data collection for additional cohorts will continue until all women

reach their 6-week postpartum visit. Additional focus groups will be scheduled if time and funding allow to reach target enrollment and saturation. Centering Health Care Institute will be invited to Centering sites for the site approval process in the spring of 2015.

November-December 2016

Data entry and analysis will be completed, the research report will be written, and the project will be concluded. The final paper outlining results and dissemination of Centering research findings will be submitted for publication in peer-reviewed journals.

Proposed Project Budget

All values are in U.S. Dollars.

Categories	Amount Requested	Total Budget Amounts
Personnel (Requests for Investigator salaries may be included. Include hourly rate for personnel.)	0	0
Secretarial staff	0	0
Typing Costs (must be those directly related to the research. Typing of dissertations will not be funded.)	0	0
Research Assistants	500	500
Consultants (Limit to \$50 per hour)	0	0
Supplies	5500	8140
Computer Costs (software only)	1000	1000
Travel Expenses (data collection only)	0	0
Other	13000	40600
TOTAL	20000	50240

Justification:

Personnel costs are not included as research activities and related support and administration will be provided by staff assigned to and directly involved in the Centering Program who are compensated as part of their employment by Montefiore Medical Center.

Biostatistics support is being provided by the Department of Obstetrics and Gynecology and Women's Health and the Institute for Clinical and Translational Research at Einstein/Montefiore under contractual agreements for no cost.

Research assistants (2) for both individual interviews and focus groups will be compensated for time and travel by a \$250.00 stipend.

Computer Costs include licensing for SPSS and NVivo Software for Qualitative Data Analysis at \$1000.00

Other Expenses

Training total= \$40,600.00

Official CHI training (off site) for the Centering Coordinator and Health Educator at the Comprehensive Family Care Center Site at \$1200.00 each for a total of \$2400.00. This is a requirement for official CHI site approval, Spring 2015. Family Health Center already has a formally trained Centering Coordinator.

On-site Centering Training for provider and nursing staff would enable a CHI team, along with the Centering Coordinators and the PI, to offer an institution wide Level I training weekend for staff across Montefiore Medical Center's sites that offer prenatal care services. This will enable trained providers and facilitators to begin the startup and site approval process using the standardized logic models at their individual health centers. \$10,000.00 would defray but not cover the entire cost, which for an institution this size approaches \$35,000.00.

CHI site approval visits are required at Comprehensive Family Care Center and Family Health Center after conclusion of the first PDCA cycle (Spring 2015) to assess adherence to the 13 essential elements, assuring validity and reliability of the intervention. The cost per site is \$1600.00 for a total of \$3200.00.

Supplies total = \$8140.00

Centering work books for each participant (10 per group) at \$22.00 each for a total of \$220.00 per group. One group would begin per month to accommodate each EDC cohort (10) for at total **cost of \$2640.00.**

Centering Space Supplies include updated demonstration equipment, charts, and media for each site at \$2000.00

Study and Group Recruitment Literature and Incentives \$1500.00

Participant Refreshments (per site) \$2000.00

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Table 1

Project Goals and Objectives

Goals	Year One	Years Two-Five	Objective	
Expand availability of CenteringPregnancy TM groups at MMC	Two sites in year	Establish Centering at 3 sites per year	All sites with Centering as default opt out model	
Systematize implementation with basic logic model	Negotiate contract with CHI and pilot LOGIC model	Use PDCA cycles to modify model to meet site and population needs	Sustainability plans for training and funding in place	
Decrease rates of preterm birth (<37 weeks)	Baseline at 12.8- 14.7% overall African Americans 15.4%* Hispanics 11.8%*	Reduce rates and eliminate disparities	Achieve at or below target of 11.4%*** for all women	
Decrease the number of women delivering low birthweight babies (<2500 grams)	Baseline national rate 8.2%** African Americans 12.8%** Hispanics 7.8%**	Establish baseline institutional rate	Achieve at or below target of 7.8% ***for all women	
Increase the numbers of women who initiate breastfeeding	Baseline national rate 74.6%***	Baseline MMC rate 86.8-89%**** (North/East)	Maintain target of 81.9%***	

^{**}March of Dimes, 2009-2011 *Martin & Osterman, 2010 ***Healthy People 2020 ****NYCDOH 2009

Table 2 $\textit{The Thirteen Essential Elements of Centering Pregnancy}^{\text{TM}}$

	T	T	
Element	Examples	Purpose	Considerations Music and barriers such
Health assessment occurs within the group space	Women have 3-5 minutes with the provider for physical assessment	Builds a sense of community and camaraderie among group members	as screens and plants provide privacy. May be an issue for individuals
Participants are involved in self-care activities	pants are Women take and record Instituted in self-care their own weight and own		Nurse helps until patients until patient is comfortable.
A facilitative leadership style is used	Questions are answered by the group, not facilitators	Reinforces inner strength and knowledge	Facilitators use guiding techniques and group games
The group is conducted in a circle Each session has an	No empty chairs, all equidistant Self assessment sheets	Circles symbolize unity and community Content is geared to	There should be no barriers, no hierarchy SAS is a springboard for
overall plan	are geared to content	needs at each stage	discussion
Attention is given to the core content, although emphasis may vary	Some groups decide focus more or less time on a topic	Every group's learning needs and style is different.	Content must be covered by end of the series
There is stability of group leadership	Facilitators are committed for ten sessions	Group dynamics are disturbed when leadership changes	No casual observers or students without group permission
Group conduct honors the contribution of each member	All are encouraged to share at each session	Emphasizes each individual's value	Numerous props and games are used
The composition of the group is stable, not rigid	Support persons may change or be absent	Flexibility fosters problem solving skills	No members should start after session 2
Group size is optimal to promote the process	Eight to ten women and support persons are welcome	Groups that are too large or too small limit facilitation	No children due to HIPPA. Reinforces "mom" time
Involvement of support people is optional	Single mothers are welcome	Those without support will obtain it from the group	Generally about half the women are alone during group
Opportunity for socializing with the group is provided	During gathering there is time to share and "catch up"	Food, music, and community foster a relaxed environment	Generally done while assessments are in progress
There is ongoing evaluation of outcomes	Providers debrief to discuss group processes and needs	Content must be made up. Data collection is ongoing	CenteringCounts [™] collects data and assesses processes

Adapted from CHI, 2014; Hodges & Videto, 2011

Table 3 Interim Outcomes of Centering Participants

	CFCC	FHC	Total	Context
Patients	15	11*	26	*2 incomplete or lost to follow up
High Medical Risk	3	4	7	27%
PTB (<37weeks)	2	1**	11.5%	13.7% Institutional 12.4% Bronx***
LBW <37 weeks <2500 grams) Breastfeeding	1**	0	.04%	8.2% State baseline**** Institutional
on Discharge	15/15	7/9	92%	Average 88%

Data from CenteringCountsTM based upon three groups per site, patients delivered by 11/1/14.

^{***} Denotes high medical risk
Martin & Osterman, 2013 *March of Dimes, 2013

Table 4 Estimated Savings from the 15-15 Midwifery Initiative

Parameters	Cost/Savings Basis	Target	Savings/expense	
15% less preterm birth (PTB) 15% midwifery	\$15,600 per PTB*	Cut PTB rate from 12.8%** to 10.8%	\$7 million	
deliveries (Total deliveries=7000)	\$1164.00 per birth***	1050 births per year/88 month	\$1.2 million	
Salaries/fringe (Includes CHI training)	\$125k per midwife (15)	24/7 coverage w/ OB backup Cost savings	(\$1.9 million) \$6.3 million	

Notes: From:

*Darling and Atav 2012 **Martin and Osterman 2013 ***Howell, Palmer, Benatar, & Garrett 2014

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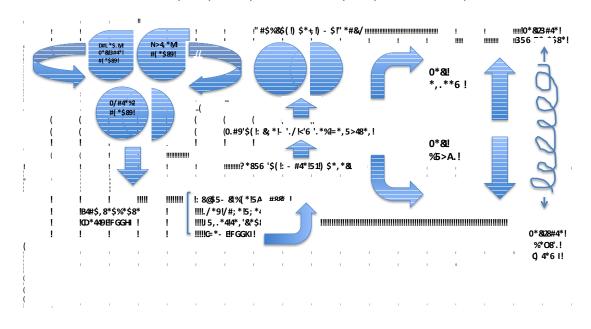


Figure 1. Nursing theory synthesis using constructs by Perry, 2004, Rew, 2003, & Orem,

1980

Centering Pregnancy™ Planning and Process Logic Model (Existing Sites)

Innuto	Outputs		\mathbb{H}	Outcomes Impact			
Inputs	Ч	Activities	Participation	14	Short (First six months)	Medium(Year One)	Long (Years 2-5)
-Centering		-Begin PDCA cycle	-Administration,	Ì	-Roll out one group	-Centering opt out	- Level 1 and Level II training in house
Coordinator and		and set benchmarks	Attendings, NPs,	ı	per EDC cohort	model	
Redesign Team			CNMs, residents &	ı		Benchmark	-PTB/LBW/BF, ER
- CHI trained		-Complete tasks on Centering Timeline**	Centering Coordinator		-Target enrollment level established-8-10	enrollment level evaluate	use, # PP appt rates meets HP 2020
providers		71 26 / 1 11	A11.1 1 C . CC 0	ı	women per group	D II .	targets
-Health educators,		-Identify/schedule group time slots	-All levels of staff &	ı	Elivety sites smaller	-Program and Impact Budgetary Process	-Disparities
PCMH coaches,		group time slots	Centering Coordinator		-Evaluate site quality metrics and targets for	initiated	eliminated
		-Develop line item	Centering Coordinator	ı	PTB. LBW, BF, ER	-Evaluation of	-60% of prenatal
-Space, equipment and supplies, training		budget for supplies, food -equipment,	-Administration, CHI		use, # pp appts, health disparities	outcomes for the first year and adjustment of	patients in Centering
needs		training	-Administration,	ı	and parameter	targets show	-Retraining, new
		Secure funding	BCHN, CHI,	ı	-Maximize visibility of	improving outcomes	training as needed
-Staff: RN/LPN, PCT,		-Begin sustainability	Community Partners,	ı	the program	and patient/staff	o o
secretarial		grant and program	Payers, Grants	ı		satisfaction	-Years 2-5 Program
		budget		ı	Data reporting and	-Continue visibility	Budget in Place
-Partners and Funding		-Practice	-CHI, Redesign team,	ı	practice fidelity	and maintain	
sources-BCHN,		management**	Centering	ı	assured as expansion is	enrollment	
March of Dimes, CHI		- Centering Counts TM	Coordinator, Providers		in process	-Site Re-Approval	-Eligible patients aware and able to
-Publicity and Public		-Websites, local media	110114610			with work toward	access Centering
Relations, Outreach		publication, outreach	-Public relations, local	ı		institutional	All sites under cluster
			media and			membership or	or institutional
-Patients:		-Patient surveys	publications, all staff,	ı		clusters	membership plan
			BCHN	Ι,			1 1
					External Factors		
Assumptions			-PNC access continues to evolve due to health care reform.				
CenteringPregnancy™ reduces the rates of PTB, LBW, maternal stress,				-ACOs, regional perinatal networks, community partners, and a variety			
& health disparities.**				of funding sources are seeking to expand patient centered, evidence-			
CHI fidelity and validity will be maintained by CenteringCounts [™]			eringCounts TM		based maternity care.		
		Timeline			- Bronx women are at ris	k for poor pregnancy out	comes/disparities.

^{**}CHI data and CHI Implementation Timeline

Figure 2. Plan-Do-Check-Act logic model for sites with existing Centering Programs http://www.uwex.edu/ces/pdande/evaluation/evallogicmodelworksheets.html

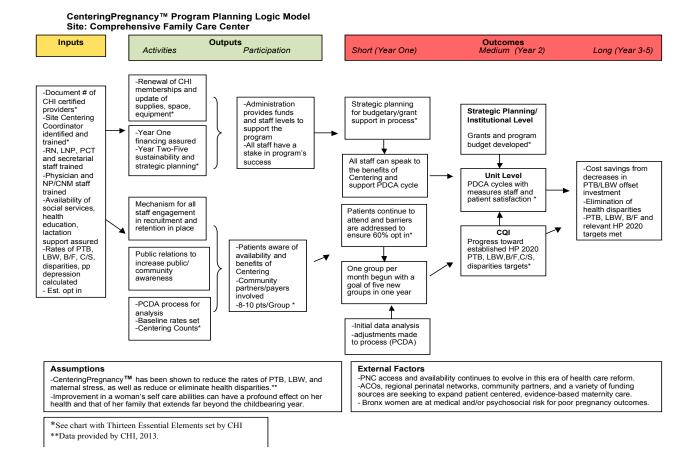


Figure 3. Process and impact evaluation logic model (adaptable for new and existing sites) http://www.uwex.edu/ces/pdande/evaluation/evallogicmodelworksheets.html

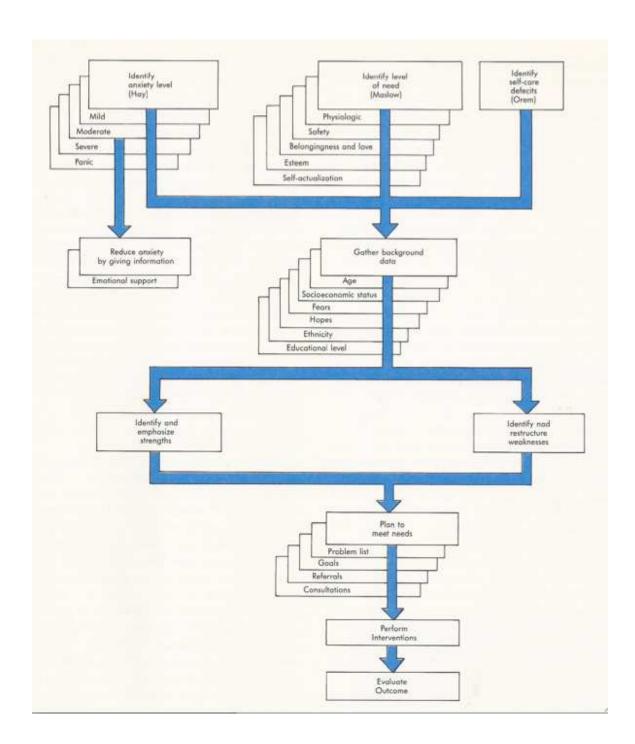


Figure 4. Paradigm for Management of Psychosocial Risk (Moleti 1990, adapted from Hay 1961; Maslow 1951; Orem 1980)

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Appendix A: Curriculum Vitae

Carole Ann Moleti, CNM, FNP-BC, MS, MPH

EDUCATION

WALDEN UNIVERSITY

Doctor of Nursing Practice February 2015

COLUMBIA UNIVERSITY NEW YORK, NEW YORK

Master of Science, (Nurse-Midwifery) School of Nursing, October 1986

Master of Public Health (Health Administration/Population and Family Health)
School of Public Health (Master of Public Health
January 1987

HERBERT H. LEHMAN COLLEGE of the CITY UNIVERSITY OF NEW YORK BRONX, NEW YORK Bachelor of Science (Nursing),
Sumna cum laude, June 1979

PROFESSIONAL EXPERIENCE

MONTEFIORE MEDICAL GROUP/MONTEFIORE SCHOOL HEALTH PROGRAM

Family Nurse Practitioner_July 2008-present

- -Primary care services to male and female adolescents in a NYC public high school population
- -Reproductive health services including IUD and Nexplanon insertion
- -Acute and emergency care evaluation and treatment
- -Chronic disease supervision

NORTH SHORE/LONG ISLAND JEWISH HEALTH SYSTEM Nurse-Midwife (per diem)-2009-present Well-woman gynecology, family planning, antepartum, post partum, intrapatrum care of women in a medically under served population.

MONTEFIORE MEDICAL CENTER, BRONX, NEW YORK WEILER HOSPITAL OF THE ALBERT EINSTEIN COLLEGE OF MEDICINE

COMPREHENSIVE FAMILY CARE CENTER AFFILIATION Staff Nurse-Midwife, July1991-July 2008

- -Antepartum, postpartum, well woman primary care and gynecological care services in a medically underserved population.
- -Intrapartum care of women at the Jacobi Medical Center.
- -Newborn circumcision/dorsal penile block
- -Family planning services including Norplant insertion and removal and cervical cap fitting.
- -Active participation on the Quality Improvement committee and in performing various quality improvement audits and surveillance for PCAP and managed care mandated services.
- -Centering Pregnancy Facilitator

JACOBI MEDICAL CENTER AFFILIATION

Staff Nurse-Midwife, January 1987-June1991

- -Antepartum, intrapartum, postpartum, well woman and family planning services to women in the NYC Municipal Hospital System, including newborn circumcision.
- -Co-director, perinatal bereavement steering committee.
- -Active participation in resident teaching conferences and orientation, medical student didactic and clinical teaching and clinical preceptorship of new midwives and midwifery students

JACOBI MEDICAL CENTER, BRONX, NEW YORK

Administrative Internship, September-December 1986

- -480 hours of service under the preceptorship of the Director of the Women's Health Center and the Medical Director of Ambulatory Care.
- -Completion of an evaluation study, summary and recommendations for the childbirth education program.
- -Assisted in data collection and preparation of proposals for integration of family planning services into the existing services.
- -Participation on JMC, NYC and NYS planning committees.

NORTH SHORE BIRTH CENTER, BEVERLY, MASSACHUSETTS

Nurse-Midwifery Clinical Practicum, June-August 1986

-400 hours of full scope midwifery service under the preceptorship of a five CNM group practice in an alternative birth center and its back-up hospital.

PARENT EDUCATOR, BRONX, NEW YORK

Private Practice, 1981-1988

-Lamaze, cesarean birth and prenatal fitness classes, including breast-feeding and parenting skills and issues.

COLUMBIA PRESBYTERIAN MEDICAL CENTER, NEW YORK, NEW YORK

Nursing Care Clinician, August 1983-March 1986

- -Twenty-four hour management of the postpartum/normal newborn nursery unit with a 35 RN, 4 LPN, and 8 paraprofessional staff with a combined operating and personnel budget of two million dollars.
- -Staffing, scheduling, in-service education and performance appraisal.
- -Operating and capital budget preparation and administration.
- -Implementation of family centered care programs and comprehensive patient education programs and services.
- -Policy and procedure development.
- -Contract administration, grievance procedure and disciplinary procedure for NYSNA, District 1199, and the Licensed Practical Nurses' Association.

Assistant Head Nurse, June 1981-December 1981

-Supervision of a Level III labor and delivery area including the cesarean section operating room.

Staff Nurse, July 1979-June 1981

-Antepartum, intrapartum and postpartum care of women in a Level III center, including operating room duties.

DR. MARTIN LUTHER KING JR. HEALTH CENTER, BRONX, NEW YORK

Family Nurse Practitioner, December 1981-July 1983

- -Provision of primary care to families as member of an interdisciplinary team in a medically underserved area.
- -Provision of prenatal care, well woman gynecology and family planning, well childcare, well adult care and collaborative management of medical problems of adults.
- -Participation in community outreach services for adolescent pregnancy prevention.
- -Designed and implemented Lamaze classes tailored to the need of the adolescent and clients with low health literacy.
- -Designed and implemented the Agency policy on the immediate care of rape/incest survivor.

SPECIAL INTERESTS, EXPERIENCE AND SKILLS

- -Fluent in Spanish.
- -Extensive experience and interest in psychosocial and medical high-risk patient care.
- -Extensive experience in patient and professional education program development and provision.
- -Extensive experience in program development, outreach and administration of maternal-child health care programs.
- -Centering Pregnancy Certified Facilitator

FACULTY APPOINTMENTS

Columbia University School of Nursing, Instructor in Clinical Nursing Columbia University School of Public Health, Adjunct Lecturer Pace University, Adjunct Clinical Instructor

PUBLICATIONS

- Beatty, J., Gutkowski, M., Moleti. C.A., & Nassery, L. (1985) Anger Generated by Unmet Expectations. *MCN: The American Journal of Maternal Child Nursing, 10* (5): 324-327.
- Moleti, C.A. (1988). Caring for socially high-risk pregnant women. MCN: The American Journal of Maternal Child Nursing, 13 (1), 24-27.
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- Moleti, C.A. (2004). Perinatal health care issues of Cambodian women. In M.A. Shah (Ed.). *Transcultural Aspects of Perinatal Health Care (pp.47-61)*. National Perinatal Association.
- Moleti, C.A. (2009). Trends and controversies in labor induction. MCN: *The American Journal of Maternal Child Nursing*, *34* (1), 40-47.

PRESENTATIONS

COLUMBIA PRESBYTERIAN MEDICAL CENTER

- -PMS and Menopause: Myths, Maladies, Remedies
- -Sexual Assessment
- -Constitutional Rights of Parents Accused of Abuse and Neglect
- -Shock: Pathophysiology and Management
- -Interdisciplinary Management of the Psychiatric Patient on an Acute Care Unit
- -Preparation of Visiting Nurse Referrals

DR. MARTIN LUTHER KING JR. HEALTH CENTER

-Immediate Care of the Rape and Incest Survivor: Medico-Legal and Counseling Issues

JACOBI MEDICAL CENTER

- -Prenatal Care (ongoing for medical student teaching)
- -The Stages of Labor and Conduct of Normal Spontaneous Vaginal Delivery (ongoing for medical student teaching)
- -Post partum Care (resident teaching conference)
- -Care of Socially High Risk Patients (resident teaching conference)
- -Proper Use of the POPRAS Form (presented by invitation to the Bronx Perinatal Consortium)
- -Perinatal Bereavement (nursing in-services)

COLUMBIA UNIVERSITY SCHOOL OF PUBLIC HEALTH

Nurse-Midwifery: Historical Perspectives and Current Trends in the Health Care of Women

HERBERT H. LEHMAN COLLEGE/CUNY

Maternity Nursing, Basic lecture course consisting of a 14 lecture series including exam development (taught by invitation of the chair of the Department of Nursing, 9/92-12/92)

MATERNAL CHILD NURSING CONVENTION, SAN DIEGO, CALIFORNIA, 1988

- -Postpartum Care of the Pregnant Adolescent
- -Caring for Socially High Risk Pregnant Women
- -Nurse-Midwifery in the United States: An Address to the Japanese Delegation

NEW YORK CITY CHAPTER Of The MARCH OF DIMES,

-Trends and Controversies in Labor Induction (2007)

RESEARCH PROJECTS AND PROPOSALS

- -Parent Education Programs in the Women's Health Center: Evaluation and Recommendations, performed, 1986.
- -Factors Influencing the Development and Recurrence of Urinary Tract Infections in the Gravid Woman, proposal developed 1985
- -The Cost Effectiveness of the Use of Chux in the Newborn Nursery, performed, 1984.
- -The Effect of Centering Pregnancy on Key Indicators of Maternal-Fetal-Neonatal Health at Woman at High Psychosocial Risk-Doctor of Nursing Practice research proposal, 2014.

LICENSES AND CERTIFICATIONS

- -Certified Nurse-Midwife, ACNM, 1986 (NYS license F000233)
- -Family Nurse Practitioner, ANA, 1982, (NYS license F360313)

- -Registered Nurse (NYS license 320674)
- -Certified Childbirth Educator, C/CES, 1980
- -Centering Pregnancy Level II Facilitator, 2013

PROFESSIONAL AFFILIATIONS AND OFFICES HELD

Clinical Privileges, North Shore/LIJ Health System
American College Of Nurse Midwives
American Public Health Association
American Nurses Association
New York State Nurses Association
Delta Zeta Chapter, Sigma Theta Tau, Charter Member and past secretary
Lehman College Nursing Society, Past Vice President

Appendix B: Walden University Institutional Review Board Approval

IRB <IRB@waldenu.edu> Tue, Oct 7, 2014 at 4:29 PM

To: Carole Ann Moleti <caroleann.moleti@waldenu.edu>

Cc: MaryBeth Stepans < MaryBeth.Stepans@waldenu.edu>, dnp < dnp@waldenu.edu>,

IRB <IRB@waldenu.edu>

Dear Ms. Moleti,

This email is to serve as your notification that Walden University has approved BOTH your doctoral study proposal and your application to the Institutional Review Board. As such, you are approved by Walden University to conduct research.

Please contact the Office of Student Research Administration at dnp@waldenu.edu if you have any questions.

Congratulations!

Libby Munson

Research Ethics Support Specialist, Office of Research Ethics and Compliance

Leilani Endicott

IRB Chair, Walden University

Tue, Oct 7, 2014 at 4:29 PM

IRB <IRB@waldenu.edu>

To: Carole Ann Moleti <caroleann.moleti@waldenu.edu>

Cc: MaryBeth Stepans < MaryBeth.Stepans@waldenu.edu>, dnp

<dnp@waldenu.edu>

Dear Ms. Moleti,

This email is to notify you that the Institutional Review Board (IRB) confirms that your study entitled, "The Effect of Centering Pregnancy on Preterm Birth, Low Birthweight, and Breastfeeding Initiation," meets Walden University's ethical standards. Our records indicate that the site's IRB agreed to serve as the IRB of record for this data collection. Since this study will serve as a Walden doctoral capstone, the Walden IRB will oversee your capstone data analysis and results reporting. The IRB approval number for this study is 10-07-14-0372127.

This confirmation is contingent upon your adherence to the exact procedures described in the final version of the documents that have been submitted to IRB@waldenu.edu as of this date. This includes maintaining your current status with the university and the oversight relationship is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, this is suspended.

If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB materials, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden web site:

http://researchcenter.waldenu.edu/Application-and-General-Materials.htm

Researchers are expected to keep detailed records of their research activities (i.e., participant log sheets, completed consent forms, etc.) for the same period of time they retain the original data. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Please note that this letter indicates that the IRB has confirmed your study meets Walden University's ethical standards. You may not begin the doctoral study analysis phase of your doctoral study, however, until you have received the **Notification of Approval to Conduct Research** e-mail. Once you have received this notification by email, you may begin your study's data analysis.

Sincerely,

Libby Munson

Research Ethics Support Specialist

Office of Research Ethics and Compliance

Email: <u>irb@waldenu.edu</u>

Fax: 626-605-0472

Phone: 612-312-1341

Office address for Walden University:

100 Washington Avenue South

Suite 900

Minneapolis, MN 55401