Project Title

Prenatal breast pumping education of mothers and their support person

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RESEARCH PROTOCOL

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Abstract:

Compelling evidence exists that breast milk helps protect premature infants from prematurity-specific morbidities, including feeding intolerance, late onset sepsis, and necrotizing enterocolitis. Unfortunately, mothers of VLBW infants often exhibit delayed lactogenesis stage II (when the milk "comes in") and inadequate breast milk production. Earlier initiation of breast milk expression following delivery is associated with increased lactation success. However, lack of nursing time and lack of hospital personal are significant barriers to the early initiation of milk expression in this population. The proposed study will follow a prospective cohort of racially and economically diverse mothers of premature infants for 3 weeks following delivery to test *1 primary aim and 1 secondary aim*. **Aim 1**: will evaluate the feasibility of antenatal BM pumping education for SPs of mothers of preterm infants. Issues related to recruitment, randomization acceptance of the intervention, and refinement of the education materials and process will be scrutinized. **Aim 2** will estimate variability of outcome measurements and effect sizes needed to calculate the sample size for a subsequent larger, adequately powered, randomized clinical trial. Eligible women and their SP will be randomly assigned to one of two groups. Group 1 will receive a prenatally delivered lactation educational program including video recordings, a demonstration of how the pump works and will have a breast pump available in their room. The volume of breast milk produced, timing of lactation stage II, duration of lactation and stress during initial expression will be measured. In addition, breast milk sodium levels will be analyzed on Day 1-7, Day 14 and 21.

Background:

Each year over ½ million infants, or one out of eight born in the United States, are premature (less than 38 weeks gestation). Prematurity occurs among non-Hispanic African-American babies at a disproportionate rate of 13.6% compared to 7.2% for non-Hispanic White babies and 6.9% for Hispanic babies (CDC, 2010). The majority (70%) of premature births consist of "late preterm" infants delivered between 34 and 37 weeks (term infants are considered 38 weeks and greater). Approximately 12% of premature infants are born between 32 and 33 weeks, 10% between 28 and 31 weeks, and 6% at less than 28 weeks (March of Dimes, 2010). In the not too distant past, infants born earlier than 32 weeks and weighing less than 1500 grams either did not survive or survived for only short periods of time (Seri & Evan, 2008). With advances in health care and technology, the survival of infants as young as 23 weeks, sometimes weighing as little as 500 grams, is becoming more commonplace (Horbar et al., 2008). Unfortunately, many of these very low birth weight (**VLBW**) infants have significant health complications in the immediate post-birth period and in the years to come.

Reducing Complications

One approach for reducing health complications is ensuring that VLBW infants are fed breast milk, either through feeding at the breast or via gastric tube before they are able to feed directly from the breast. Breast milk has been found to decrease some of the short and long-term morbidities associated with prematurity, including feeding intolerance, late onset sepsis, and necrotizing enterocolitis (Ronnestad et al., 2005; Sisk et al., 2007, 2008). Breast milk not only provides nutrition but helps establish immunological and gastrointestinal competence. Furthermore, premature infants who were fed breast milk were found to have better neurodevelopmental outcomes than those who were formula-fed (Vohr et al., 2005). Reducing complications of prematurity shortens length of hospital stay and decreases both immediate monetary and long-term

social/monetary costs associated with developmental delays and special needs (Child Trends Data Bank, 2010).

Lactation and Milk Formation

Synthesis of milk production begins early in pregnancy, with formation of milk components occurring by 22 weeks' gestation (Hartman et al., 2003). The lactation process is dependent upon several hormones, including prolactin, oxytocin, insulin, cortisol, and progesterone. Progesterone, produced by the placenta, assists in alveolar breast development and inhibits milk production during pregnancy (Humphreys et al., 1997). Prolactin, involved in alveolar development during pregnancy (Ostrum, 1990) is necessary for lactogenesis and likely plays a role in the volume of milk produced (Kent, 2007). Stimulation of the breast by either sucking or artificial milk expression temporarily produces an increase in prolactin levels (Johnston & Amico, 1986). Lower baseline (pre-stimulation) levels have been demonstrated in mothers delivering prematurely, suggesting a relationship between premature delivery and decreased lactation hormone levels (Hill et al., 2009). Oxytocin is released during breast stimulation, resulting in milk being ejected into the ducts and cisterns of the breast (Geddes, 2007). Oxytoxin levels in preterm mothers have been shown to be comparable to those of term mothers with adequate breast expression (Chatterton et al., 2000). Additional hormones, including insulin and corticosterioids, are also necessary for the synthesis of breast milk.

Lactation, the onset of milk secretion, can be divided into two stages. Stage I begins during pregnancy and occurs as levels of progesterone, prolactin, and placental lactogen increase (Neville & Morton, 2001). Elevations in the level of these hormones result in expansion of the terminal duct lobular unit and preparation of the breast for milk production. During mid-pregnancy, essential elements, including mRNA and specific enzymes necessary for milk production, begin to increase. Milk droplets in mammary cells also swell in preparation. At this point, milk production does not occur, but the breast is ready to produce milk soon after delivery (Neville & Morton, 2001; Neville, Morton, & Umemora, 2001). Following delivery, small amounts of colostrum are produced and are available for infant consumption (Neville et al., 2001).
Lactogenesis stage II signals the change from production of small quantities of colostrum to copious amounts of breast milk. This stage occurs following delivery due to a dramatic decrease in progesterone and maintenance of prolactin levels (Kuhn, 1983). Initiation of lactogenesis stage II is experienced by the woman in what is referred to as (a) "milk coming in" or feelings of notable fullness in her breasts (Perez-Escamilla & Chapman, 2000) and (b) increases in milk volume to over 100ml/d (Neville et al., 2001). Maternal perception of a sudden feeling of fullness in the breast has been a traditional method of determining the timing of lactogenesis stage II and is correlated with actual timing of this stage (Perez-Escamilla & Chapman, 2000).

Delayed Lactogenesis Stage II

Lactogenesis stage II usually occurs approximately 30-40 hours following the birth of full-term infants (Hurst, 2007), but delay has been known to occur in 22 to 31% of women who deliver at term (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003). Delayed or impaired lactogenesis stage II has been found in up to 82% of women who deliver prematurely (Henderson, Hartman, Newnham, & Simmer, 2009; Cregan et al., 2001). Delayed progression to stage II among women who deliver full-term has been associated with delayed initiation of breastfeeding, gestational diabetes, obesity, cesarean section, prolonged second stage of labor, primiparity, administration of pain medications during labor, breast implantation and reduction mammoplasty (Chen, Nommsen-Rivers, Dewey, & Lonnerdal, 1998; Hildebrandt, 1999; Morton, 1994; Neifert, et al., 1990; Neubauer et al., 1993).

Delayed lactogenesis stage II has both immediate and longer-term negative consequences. If such delays result in an inadequate amount of breast milk for infant consumption, breast milk feedings are replaced with commercially prepared formula, or feedings are withheld until breast milk is available. Both options may be potentially detrimental to the VLBW infant. Since both intestinal and gastric hormone secretion and motility are dependent on enteral feedings, a delay in feeding can potentially decrease future feeding tolerance (Berseth, 1990). Provision of even small amounts of formula is associated with abnormal changes in the microflora of the

intestinal tract, potentially resulting in increased risk of necrotizing enterocolitis (Taylor, Basile, Ebeling, & Wagner, 2009). A delay in lactogenesis stage II is also associated with decreased success in later lactation (Chapman & Perez-Escamilla, 2003; Hurst, 2007).

Insufficient Milk Supply

Breast milk volume is correlated with gestational age; thus, mothers of premature VLBW infants produce significantly less milk than mothers of term infants (Henderson, Hartmen, Newnham, & Simmer, 2009; Hill et al., 2009). Also, milk volume in mothers of VLBW infants often substantially decreases at around 3 to 4 weeks following delivery (Hill, Aldag, Chatterton, & Zimanman, 2005a). This decreased production may be due to decreased exposure to lactation hormones and decreased mammary gland development during a shortened pregnancy. It may also be related to the mothers need to mechanically express her breasts because her infant is unable to feed directly from the breast due to developmental, physiologic and gastrointestinal immaturity. In one study mothers of VLBW premature infants were 2.8 times more likely to have an insufficient milk supply than mothers who delivered at term (Hill, Aldag and Chatterton, 1999). In another study, many were unable to sustain their milk supply, with 51% failing to produce adequate milk volumes at 6 weeks following delivery (Hill et al., 2005b). In mothers of VLBW infants, longer term adequacy of overall milk production is a reflection of the amount of milk produced during the first week following delivery—underscoring the need for early strategies to increase milk production in this population (Hill, Aldag, & Chatateterton, 1999; Hill et al., 2005a).

Optimizing Milk Supply

Rate of milk synthesis is related to the degree the breast is emptied during breastfeeding or milk expression (Daly, Kent, Owens, & Hartmann 1996). In term infants, maintenance of lactation is dependent on suckling frequency and intensity; lactation success has been correlated with a breastfeeding frequency of 10-12 times per day (Chen, Nommsen-Rivers, & Dewey, 1998). A positive association between frequency of milk expression and milk volume in mothers of VLBW infants has also been demonstrated *in several observational studies* with expression frequency of at last 5 times per day associated with increased milk production (Furman et al., 2002). Kangaroo Care (holding of an infant dressed only in a diaper upon a mother's bare chest) has also been shown *in observational studies* to increase milk *volume in mothers of VLBW infants but the frequency or the duration of kangaroo care needed to increased milk volume has not been determined and may not be possible due to the critical status of the infant (Lau et al., 2007). Duration of individual expression sessions have not been shown to influence milk volume in this population. Lactation support may impact lactation success in mothers of VLBW infants; however the majority of studies have focused on the effect of lactation support on breast feeding success rather than milk volume following breast expression (Pinelli et al. 2001; Gonzalez et al. 2003; Merewood et al. 2006). The use of evidenced based interventions and the use of peer support groups are associated with improved lactation success including the amount of breast milk received by infants during their stay in the NICU (Meier et al., 2004). The presence of lactation consultants in the NICU also increases the number of women providing breast milk to their infants (Gonzalesz et al., 2003). However, little information exists regarding the effect of lactation support on milk volume or lactogenesis stage II in mothers of VLBW infants. Maternal stress and depression are associated with decreased breastfeeding success in term infants. Little, however has been reported concerning the impact of stress and depression in milk volume or lactogenesis in the premature infant (Gagliardi et al., 2010; Zanardo et al., 2011). Hill et al., 2006 found no association between milk volume and mood states in preterm infants using the MAACL-R test.*

Earlier initiation of milk expression has been associated with increased milk volume in mothers of VLBW infants (Hill et al., 1999; 2001; Hill & Aldag, 2005; Hill et al., 2005b; Hopkinson, Schanler, & Ganza, 1988). *However, all studies assessing the effect of initiation timing on milk volume have been observational and no randomized controlled trials regarding precise timing of initiation of milk expression on either milk volume or timing of lactogenesis stage two have been reported. Furthermore, previously published studies have focused on initiation of expression very late following delivery of the infant*. Hill and colleagues (2005b) in an observational study found that initiation of milk expression occurred 27.3 $\pm$ 14.9 hours following birth and timing of initial milk expression inversely correlated with milk volume at one week following delivery. With the

same group of mothers, Hill & Aldag (2005) found timing of expression initiation correlated with adequate milk production at the 6th week. Hopkinson, Schanler, & Ganza (1988) also reported a positive correlation between day of milk expression initiation and milk volume at Week 2, with the earliest expression initiation occurring on Day 2 following delivery. *Many NICUs and maternity units recommend mothers begin milk expression within 6 hours following delivery. These recommendations are based upon an observational study finding* a positive association between initiation of milk expression prior to six hours following delivery and prolonged lactation. This study, however, did not measure actual milk volume or time to lactogenesis stage II and did not determine when during this six hour time frame was milk expression most effective (Furman, Minich, & Hack, 2002).

Education

While prenatal education has been shown to increase lactation duration in mothers of premature infant, education of support persons has not been studied nor has the effect on timing of initiation of milk expression, timing of lactogenesis stage II or milk volume has not been studied

Infant Breast Milk Intake

Healthy People 2020 goals include an exclusive breastfeeding rate of 46.2% for the first 3 months of life (Healthy People, 2020). This is rarely attained in term infants and due to an insufficient milk supply, even less likely to occur in mothers of VLBW infants thus depriving them of the essential benefits of breast milk. Milk volume in these mothers also often substantially decreases at around 3 to 4 weeks following delivery resulting in a further decrease in the number of women providing breast milk to their infants (Hill et al., 2005a)

Preliminary Work

In order to improve breastfeeding success, it is strongly recommended that women who deliver term infants begin breastfeeding within 30-60 minutes following delivery. In our pilot work we mimicked normal term parturition, by initiating milk expression in mothers of VLBW infants with a gestational age between 23 and 32 weeks (*n*=20) within 1 hour following delivery (*n*=10) and compared milk volume and timing of lactogenesis stage II with mothers who began milk expression 1-6 hours following delivery (*n*=10). *Only 1 mother who was approached declined to participate in the study. No statistically significant differences were found between the groups for demographic characteristics or behavioral factors including kangaroo care and expression frequency.* Although the study was small (*n*=20), women who began milk expression within 1 hour following delivery produced statistically significant more milk during the first 7 days. *Total milk volume expressed by women who expressed within 1 hour following delivery was over twice that of mothers who began milk expression later. Women who began milk expression in the first hour also produced significantly more milk at* 3 weeks following delivery and also had a statistically significant earlier lactogenesis stage II. *Stress and pain associated with initial milk expression session was also analyzed between groups with no significant differences found between groups. Women in the earlier expression group tended to report less stress and pain* (Parker et al., 2012).

In addition, we compared women who began milk expression within 6 hours versus those who began milk expression after 6 hours following delivery and found those who began milk expression within 6 hours produced more breast milk in the first 7 days following delivery

In a survey of 80 obstetrical nurses from 3 large hospitals in Florida, over 30% stated that a major barrier to assisting mothers of VLBW infants to begin timely breast milk expression following delivery was a lack of time and lack of personnel.

Primary <u>purpose</u> of this pilot study is to determine the feasibility and potential effect of a prenatally delivered lactation education program for expectant mothers of premature infants and their support person (SP) on timing of initiation of milk expression, lactation success, and stress

Specific aims are as follows:

Aim 1: To evaluate the feasibility of antenatal BM pumping education for SPs of mothers of preterm infants. Issues related to recruitment, randomization acceptance of the intervention, and refinement of the education materials and process will be scrutinized. Aim 2: To estimate variability of outcome measurements and effect sizes needed to calculate the sample size for a subsequent larger, adequately powered, randomized clinical trial

Research Plan:

Research Design

A randomized clinical trial will be conducted to determine the effect of a prenatally delivered lactation educational program for expectant mothers of premature infants and their SP on timing of initiation of milk expression and lactation success. Timing of lactogenesis stage II will be documented, volume of breast milk produced will be measured for the first 3 weeks following delivery and duration of lactation will be documented. Stress regarding the initial milk expression session will be measured. Breast milk sodium levels will be measured at Day 1-7, Day 14 and 21

Sample and Setting

80 mothers who have been hospitalized anticipating the delivery of a premature infant will be sampled by convenience from a maternity unit at Shands Teaching Hospital, a Level III tertiary care center. The hospital is part of the University of Florida and includes a Level III (52 bed) NICU. The hospital catchment area encompasses North Central Florida and Southern Georgia, a predominantly rural and semi-rural population. 120 VLBW infants per year are delivered with 95% of these women electing to express breast milk for their infants. This will also include enrollment of 80 support persons as a couplet with mom.

Inclusion criteria for the mothers are: 1) at least 18 years of age, 2) English speaking, 3) stated intent to breastfeed, 4) anticipating the birth of a premature infant < 35 weeks gestation. Exclusion criteria are: 1) known illicit maternal drug use, 2) history of breast reduction or augmentation, 3) positive HIV status, or 4) infant not expected to live over 2 weeks following delivery.

Inclusion criteria for the support person: 1) is expected to be present immediately following delivery, 2) at least 18 years of age, 3) English speaking

Randomization

Informed consent will be obtained from both mother and SP prior to delivery. Following consent, the pair will be randomly assigned to one of two groups. Group 1 will receive a prenatally delivered lactation educational program. Group II will receive standard care.

Procedure

Once the pair is randomly assigned to one of the groups, the PI, or a research assistant will make an appointment and meet with the mother and her support person (the person or persons stated to be with her during labor and the delivery of her infant). During this meeting the mother and her support person will be provided the following educational activities

1. Viewing of a video regarding the benefits of breast milk for premature infants.
2. Viewing of video with instructions regarding how to use a breast pump and instructions regarding milk expression.
3. They will be given the standard written and verbal pumping instructions provided to all mothers who are pumping breast milk for their infants.

4. A hospital grade breast pump and all necessary equipment for milk expression will be provided and will remain in the mother's hospital room. A demonstration of how the pump works and how to set up the pump will be provided.

Mothers will be visited by the research coordinator, PI, or a research assistant prior to her discharge from the hospital ensure they are successfully using the breast pump and to provide additional instruction if needed. Mothers will also have access to lactation services and nurses on the unit. At this visit, mothers and the SP will be questioned regarding stress associated with the initial milk expression (Appendix A). Participants will be asked to indicate their level of stress on a visual analogue scale and will mark their response on a 100mm horizontal line continuum from none to severe. The score was determined by measuring in millimeters from the left hand end of the line to the point where the subject marked. Since single-item measurements are easier to administer, less burdensome to participants and have been shown to be a valid and reliable tool, participants will be asked to answer only one question pertaining to stress. The mother and SP will also be asked to complete a survey regarding the educational experience (Appendix B,C).

Mothers will be provided with a supply of pre-weighed milk vials and labels in which they will place the milk following expression per standard NICU policy. During hospitalization or while visiting their infant in the NICU, mothers will have a hospital grade electric pump available for use. Upon discharge, all mothers will be provided the same hospital grade electric pump for use while their infant is in the NICU and they continue to lactate. Mothers will be asked to bring vials from all pumping sessions to the NICU, regardless of apparent results. While mothers are still hospitalized, the mother or nurse will bring the vials to the NICU following each expression, where they will be deposited in a refrigerator specified for storage of breast milk for all infants in the NICU. Once mothers go home, they will be instructed to store their vials of expressed breast milk in the refrigerator or freezer at home, and to bring vials to the NICU when visiting their infants (standard NICU policy). All breast milk will be weighed by a breast milk technician blinded to the group assignment (Appendix D). Mothers will be reminded 3 times per week—through phone calls*, texts* or during visits to the NICU—to bring in their breast milk when they visit.

Measurement of milk volumes by weight will occur at the initial expression session, for the first 7 days, and on day 14 and 21. (see Table 2 for a list of all instruments*).* If the infant breastfeeds during the 24-hour period, test weighing will be used to calculate breast milk consumed. *Test weighing* or the weighing of infants prior to and following breastfeeding, has been shown to be an accurate method of determining intake during breastfeeding in preterm infants. Prior to each breastfeeding session, infants will be weighed by the nurse assigned for patient care, and weight will include the clothing, diaper and/or blankets infant is wearing. Following completion of the breastfeeding session, the infant will be weighed again, clad in the same clothing as with initial weight. Infants will be weighed on the Baby Weigh scale (Medela, Inc, McHenry, Ill) to the nearest 0.2 g. The Baby Weigh scale is a portable electronic digital scale that is accurate to within 0.2 grams. The scale will be calibrated by the study coordinator prior to initiation of the study and after every 10 measurements, using 0.2mg, 1 mg, 10mg and 50 mg weights. All weights will meet or exceed ASTM (American National Standards Institute) specifications and will be calibrated by a NVLAP (National Institute of Standards and Technology) accredited lab. The difference between the pre and post-feeding weights will be recorded on the Breastfeeding Data Collection Form taped at the infant's bedside and will be added to the total amount the mother expressed during that 24-hour period (Appendix E).

A < 0.5 mL of breast milk will be obtained daily (if the mother is expressing > 5mL of breast milk per day) daily during days 1-7, day 14, day 21 and the sodium level analyzed

Maternal mood can impact breastfeeding success in term infants and it is possible it may also impact BM production and timing of lactogenesis stage II in mothers of VLBW infants. Prior to her discharge from the hospital and 7 days following delivery, mothers will be asked to complete the MAACL-R; a standardized instrument with well-documented psychometric properties that assesses mood states by using positive and negative mood state scales for Anxiety, Depression, Hostility, Positive Affect and Sensation Seeking. It consists of 132 adjectives at or below an 8th grade reading level, takes approximately 3 minutes to complete. This test has been successfully used in lactating mothers of premature infants and was used in our previous

research. The second test will be completed around day 7 and will be provided to mothers prior to discharge Mothers will be phoned by the research coordinator on to remind them to complete the test. Mothers will return the test when they visit their infant and results will be manually scored by the research coordinator.

Table 2. Instruments (Logs)

Variable	Instrument	Measurement
Demographics (Appendix F, G)	Log maintained by Research Assistant	Age, parity, diabetes, pregnancy induced hypertension, mode of delivery, type of anesthesia, experience with breastfeeding, smoking, obesity, antenatal steroids
Lactation Factors (1-3 below)		
1. Onset of lactogenesis stage II	Log maintained by Research Assistant	Date and time of sensation of breast fullness Corresponding breast milk measurement
2. Sodium level in breast milk	Log maintained by Research Assistant	Date/Sodium level in breast milk corresponding to onset of lactogenesis II
2. Milk volume	Log maintained by Research Assistant	Daily total breast milk weight for days 1-7 24 hour sample at Day 14,21
3. Milk volume alternative for breastfed infants	Log maintained by Research Assistant	(Test weighing) - difference in infant's weight before and after feeding as indicator of breast milk intake.
Kangaroo care	Log maintained by RA	Incidence and length of kangaroo care in minutes extracted from medical record
Infant breast milk intake		
1. Weekly percentage of breast milk received by infant during first 3 weeks of life	Log maintained by Project Coordinator	Data extracted from medical record
2. Percentage of breast milk feedings at discharge	Log maintained by Project Coordinator	Data extracted from medical record
Post partum questionnaire	Log maintained by RA	Completed by RA or PI
Indicator of stress	Log maintained by RA	Completed by RA or PI

Beginning 24 hours after delivery and continuing daily, mothers will be questioned (either in person or over the phone) regarding a sudden feeling of fullness in their breasts as an indicator of the onset of lactogenesis II. This has been a traditional method of determining the timing of lactogenesis stage II and has been shown to correlate with actual timing of this stage. (Appendix I) We will confirm the reliability of self-report by determining whether >100mL of milk is produced per a 24-hour period.

The percentage of breast milk the infant receives week 1, day 14, day 21 and the percentage of breast milk the infant is receiving upon discharge (mL/kg/d for the week prior to discharge) will be collected from the medical records. Neonatal nurses and physicians caring for the infants will not be told of the mother's assigned group (Appendix K.L).

Equipment

A simultaneous electric Symphony Plus Breast Pump ® (Medela, Inc.) will be used during hospitalization, and infant visitation and the same pump will be provided to all mothers enrolled in the study for home use while their infant is hospitalized. These are hospital-grade pumps that can be used for simultaneous breast milk expression (both breasts at the same time). Milk will be weighed on a Scout Balance electronic scale, a portable digital scale accurate to within 0.1 grams (Scout Balance, Florham Park, NJ). The scale contains an external calibration mechanism, stabilizes within three seconds, and will be calibrated by the research assistant prior to initiation of the study and after every 10 measurements using 0.1mg, 1mg, 10mg and 50 mg weights. All weights will meet or exceed American National Standards Institute (ASTM) specifications and will

be calibrated by a National Institute of Standards and Technology (NVLAP) accredited lab. The scale will be placed on the same platform at all times and will be wiped clean with a moist cloth and dried between each weighing.

Data Entry and Management

All data will be entered into a REDCap database having integrated data quality and consistency checks (e.g., data-range) as part of the data procedure. REDCap is a secure, web-based application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, projects are designed and created online from a web browser using the Online Designer or by constructing a 'data dictionary' template file in Microsoft Excel, which is uploaded into REDCap. Both surveys and databases can be built using these methods. REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields. The study database created in REDCap will be password-protected and housed on a designated database server, which is protected by a computer firewall. Data quality will be monitored and assured: 1) as reported; and 2) as entered into the database. For the former, all hardcopy forms will be visually inspected before data entry. Furthermore, a manual comparison of randomly selected data hardcopy forms with data output listing generated from the study database will be performed, and consistency checks will be generated by SQL or SAS programs as part of routine data cleaning procedures.

All subjects eligible for eligible for enrollment will be registered and entered into the study database designed by the program assistant. The system includes designated web servers and supporting database servers. Study data will be directly entered into the database via a secure internet connection. The system allows the PI to access data in real-time and to generate reports based on enrollment status, basic demographics, and data summaries. The web-based data system will also allow for the sharing of data in the future. The system will assign a global unique identifier to each enrolled subject that will serve as the unique subject id. Personal Health Information will not be stored in the study database. The study case report forms (CRFs) will be maintained in study specific folders. The CRFs are considered the primary data collection instruments for this study. When CRFs are not actively being processed, they will be secured in locked file cabinets. In addition to the use of passwords and other security measures, all documents containing identifying information are considered confidential materials and are safeguarded to the greatest possible extent. No individually identifying information will be released or discussed with anyone other than study staff.

Possible Discomforts and Risks:

Possible risks include stress regarding the education process and for the support person, it may be stressful to assist the mother in breast milk expression. This will be measured

Possible Benefits:

Mother who with their support person receive antenatal education may have an earlier initiation of milk expression and have increased lactation success.

Conflict of Interest:

There are no conflicts of interest