THE RELATIONSHIP BETWEEN MATERNAL INTRAVENOUS FLUIDS AND BREAST CHANGES IN THE POSTPARTUM PERIOD: A PILOT OBSERVATIONAL STUDY

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Dedicated to
Michael Durbin
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Table of Contents

CHAPTER 3 - Methods

CHAPTER 4 - Findings

CHAPTER 5 - Discussion and Conclusion

List of Tables

Chapter 1

Chapter 3

Chapter 4

List of Figures

Chapter 1

Chapter 4

List of Thesis Appendices

Glossary

Alveoli: the part of the mammary alveolar gland where milk is produced and stored

Cabbage leaf application: applying cabbage leaves to breasts to help relieve engorgement

Caesarean section: surgical birth procedure, removing the baby through an incision made in the abdomen

Capillary: a small blood vessel connecting arterioles to venules

Edema: increased fluid in the interstitial spaces between cells

Engorgement: intense swelling of breasts usually occurring on day 3 or 4 postpartum

Feedback inhibitor of lactation (FIL): is a whey protein present in milk which controls the production rate of milk at a local level, if milk is being removed frequently and efficiently, less of this protein is present in the alveoli sacs and milk production increases, but if milk stasis occurs and levels of this protein increase then milk production decreases

Hydrostatic pressure: pressure exerted by a liquid

Hypotension: low blood pressure

Interstitial: the space in-between cells and outside of vascular space

Interstitial fluid: fluid found in the interstitial space

Intravenous: within a vein

Lactogenesis II: the period of copious milk production triggered by a withdrawal of progesterone

Lactogenesis III: establishment of mature milk

Latching: when a baby correctly attaches mouth around a woman's nipple for the process of breastfeeding

Lymphatic fluid: clear fluid found outside the cells which is collected and transported by the lymph system

Mastitis: inflammation of the breast

Milk ejection reflex: a reflex triggered by oxytocin which causes milk to be released from the alveoli, also known as a letdown

Multiparous: having given birth previously

Nulliparous: has never given birth

Osmotic pressure: the pressure exerted on a membrane by a solution whose particles are too large to pass through causing fluid to be pulled to the higher solute side

Peripartum period: referring to the last month of pregnancy and the first few weeks after the birth, in relation to the mother

Postpartum: the period after birth, in relation to the mother

Pregnancy induced hypertension: High blood pressure caused by pregnancy

Premature birth: Birth occurring prior to 37 completed weeks of gestation

Pumping: to extract milk from the breast using a manual or electric pump

Reverse pressure softening: applying pressure to the areola, at the base of the nipple, to move some of the fluid away from the nipple and deeper into the breast, thereby softening the areola enough to allow the infant to latch deeper

Vascularity: tissue blood supply

Vasodilation: expansion of blood vessels

Weaning: the transition from breastfeeding to either formula feeding or starting solid food

Abstract

Clinical Issue

Health Canada recommends exclusive breastfeeding for the first 6 months post birth and then the addition of complementary foods with breastfeeding extending to a minimum of two years. Breastfeeding initiation rates in Canada are currently at around 87% but, by one month, about 21% of women have stopped breastfeeding. Engorgement and edema in breast tissue can lead to breastfeeding challenges which may contribute to early weaning.

Purpose

The purpose of this pilot research study was to explore the relationship between intravenous (IV) fluids given to mothers during the peripartum period and postpartum breast or nipple swelling in the first ten days postpartum and determine if a larger study was warranted and feasible. The research question for this pilot study was, "What is the relationship between the amount of IV fluids given to labouring women and edema of the breast and areola complex experienced by breastfeeding women in the first 10 days postpartum?"

Methods

It is a prospective, longitudinal, observational cohort pilot study with repeated measures and a within-subjects design. Participants are first time mothers who planned to exclusively breastfeed and gave birth to a single, healthy newborn by means of a spontaneous vaginal birth, Mother and baby were discharged home together with no contraindications to exclusive unrestricted breastfeeding. Descriptive statistics are reported and linear regression analysis is used to model the relationship between IV therapy and postpartum breast edema.

Results

Women who received IV fluids during labour had higher levels of edema postpartum and rated their breasts as firmer as and more tender than women who did not receive IV fluids. Participants who had IV fluids appeared to be less aware of the fullness associated with lactogenesis II, and the pattern of fullness they described appeared to be related to edema noted. Participants who did not have IV fluids appeared to have unrelated patterns of fullness and edema, and therefore appeared more aware of the onset of lactogenesis II. The results support a larger study about the relationships between maternal perinatal IV fluids and breast or nipple changes.

Keywords

Breastfeeding, engorgement, edema, lactogenesis II, IV fluids

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Chapter 1 - Introduction

Women face challenges in the first few weeks following the birth of their first babies. They need to effectively establish breastfeeding to ensure long term success, but they may encounter difficulties related to postpartum breast and nipple swelling that can undermine this process (Mohrbacher & Stock, 2003). For infant health, women need to build a good milk supply and newborns need to latch deeply and transfer as much milk as is required for adequate weight gain and growth. When women experience breast or nipple swelling in the postpartum period, breast milk supply and transfer can be negatively affected (Mohrbacher & Stock, 2003). Newborns may not be able to effectively latch to their mothers' swollen breasts and mothers find it difficult to breastfeed due to pain and nipple injury (Lawrence & Lawrence, 2011).

Nurses are in a unique position to help women who want to breastfeed; especially in the early days post birth. Nurses help mothers while in hospital, and they also have an opportunity to give anticipatory guidance to new mothers about what to expect in the following days and weeks at home. They can provide guidance about problems which may arise and also offer advice on how to treat these issues and when to seek further breastfeeding help. The purpose of this pilot research study was to explore the relationship between intravenous (IV) fluids given to mothers during labour on postpartum breast and nipple swelling and to determine if a larger study is warranted.

Organization of the Thesis

This monograph-based thesis is composed of five chapters. This first chapter introduces the background: clinical issue, problem statement, the purpose and objectives of the study; the research question and hypotheses; and the conceptual framework. The second chapter is the review of the literature. The third chapter describes the study methodology and the methods

used to collect data. Chapter 4 presents the findings of the data collection. The fifth and final chapter encompasses a discussion of the findings and offers conclusions to the study.

Although there is continuous pagination, the manuscript headers are named for the chapters to make it easy for the reader to move from one chapter to another. All citations are included in a single reference list which follows Chapter 5 and precedes the appendices.

Background

Clinical Issue

Current breastfeeding recommendations in Canada are for mothers to exclusively breastfeed their babies for six months and then start introducing healthy foods to their babies while continuing to breastfeed for a minimum of two years (Health Canada, 2013). While breastfeeding is normal physiological behaviour, it is not without challenges which can lead to high rates of weaning. Breastfeeding initiation rates in Canada are currently at 87.3% (Health Canada, 2012) but by one month, 21.4% of women have stopped breastfeeding (Statistics Canada, 2011). Key reasons given for early weaning are sore breasts and painful nipples (Lawrence & Lawrence, 2011; Mangesi & Dowswell, 2010). The Better Outcomes Registry and Network Ontario (BORN Ontario; 2013) *Provincial Overview of Perinatal Health in 2011 - 2012* reports that on hospital discharge 27.6% of breastfed babies have received formula. Formula supplements can lead to early weaning (DiGirolamo, Grummer-Strawn, & Fein, 2008).

Problem Statement

The first few weeks of breastfeeding can be challenging with many mothers experiencing cracked and painful nipples, engorged breasts, plugged ducts, and possibly mastitis (Lawrence & Lawrence, 2011). Postpartum breast engorgement and breast edema are two forms of postpartum breast swelling. Engorgement is defined as overfull breasts due to excess milk and

increased blood supply, whereas edema is the result of increased fluid in the interstitial space (Cirolia, 1996; Newton & Newton, 1951).

Postpartum breast engorgement may contribute to breast and nipple pain, nipple damage, breast infections and may be one of the reasons women stop breastfeeding (Lawrence & Lawrence, 2011; Mangesi & Dowswell, 2010). It may cause difficulties for babies trying to latch due to swollen breast tissue not being supple enough to achieve a deep latch and feed without causing nipple damage (Cotterman, 2004; Miller & Riordan, 2004), it may reduce the amount of milk a baby transfers at breast (Hill & Humenick, 1994), and it may decrease long term milk supply (Lawrence & Lawrence, 2011).

Breast and nipple edema can also interfere with latching due to swelling and firmness of breast and areola tissue (Miller & Riordan, 2004) and can cause ineffective milk transfer during breastfeeding (Cotterman, 2004). Breast edema may also distort nipple shape resulting in breastfeeding being more challenging for mother and baby and lead to nipple damage and pain (Cotterman, 2004). Both engorgement and edema may contribute to the use of formula and early weaning.

While there have been some studies on postpartum engorgement, postpartum breast edema is not well defined or studied. Until postpartum breast swelling is better understood and clinicians learn ways to teach mothers ways to minimize the negative effects of postpartum breast swelling, breastfeeding rates may continue to drop in the first few weeks postpartum and mothers may be less likely to achieve their breastfeeding goals.

Study Purpose and Objectives

The purpose of this pilot study is to explore the relationship between IV fluids given to mothers during the peripartum period and postpartum breast swelling. This pilot study was also

conducted to determine if a larger study is warranted based on the findings and to determine which data collection protocols would be most useful in a larger study. Variables of interest included the amount, timing, and type of administered IV fluid; postpartum breast edema and engorgement; timing of lactogenesis II; and baby's ability to latch. Table 1 depicts the hypothesized relationships among variables.

Table 1

Relationships Among Variables of Interest

Independent variable	Relationship	Dependent variable
Amount of intravenous fluid Timing of intravenous fluid	Related to	Postpartum breast edema Postpartum areola/nipple edema
Amount of intravenous fluid Timing of intravenous fluid	Related to	Delayed lactogenesis II Baby's ability to latch
Postpartum breast edema Postpartum areola/nipple edema	Related to	Delayed lactogenesis II Baby's ability to latch
Postpartum breast edema Postpartum areola/nipple edema	Independent of	Engorgement Lactogenesis II

Conceptual Framework

The literature is unclear when it comes to distinguishing between postpartum breast engorgement and breast edema. Postpartum breast edema may be a new or previously unidentified phenomenon related to more medicalized birth practices. It was uncommon to see edema when studies of engorgement first appeared (e.g., Newton & Newton's [1951] classic study). The negative effects of both engorgement and edema may be the same, although the causes and the signs and symptoms may be different. Distinguishing between edema and engorgement may prove to be a challenge. The two theories for postpartum engorgement may be describing two separate events, which could be seen in the light of the classic question, "which came first, the edema or the engorgement?" Separating the two phenomenon identifies that each

may have their own antecedents, might present differently, and might require different treatments even though they share common characteristics. Moderators which might have an effect on swelling include early breastfeeding, frequent breastfeeding, previous breastfeeding experience, maternal self-efficacy and the overall duration of feeds. Mediators which might contribute to swelling include parity, type of birth, medication given during labour and birthing, choice of anaesthesia, gestational age and timing and type of IV fluids. A schematic diagram of the conceptual framework developed for this study by the researcher illustrating the relationships among variables is presented in Figure 1.

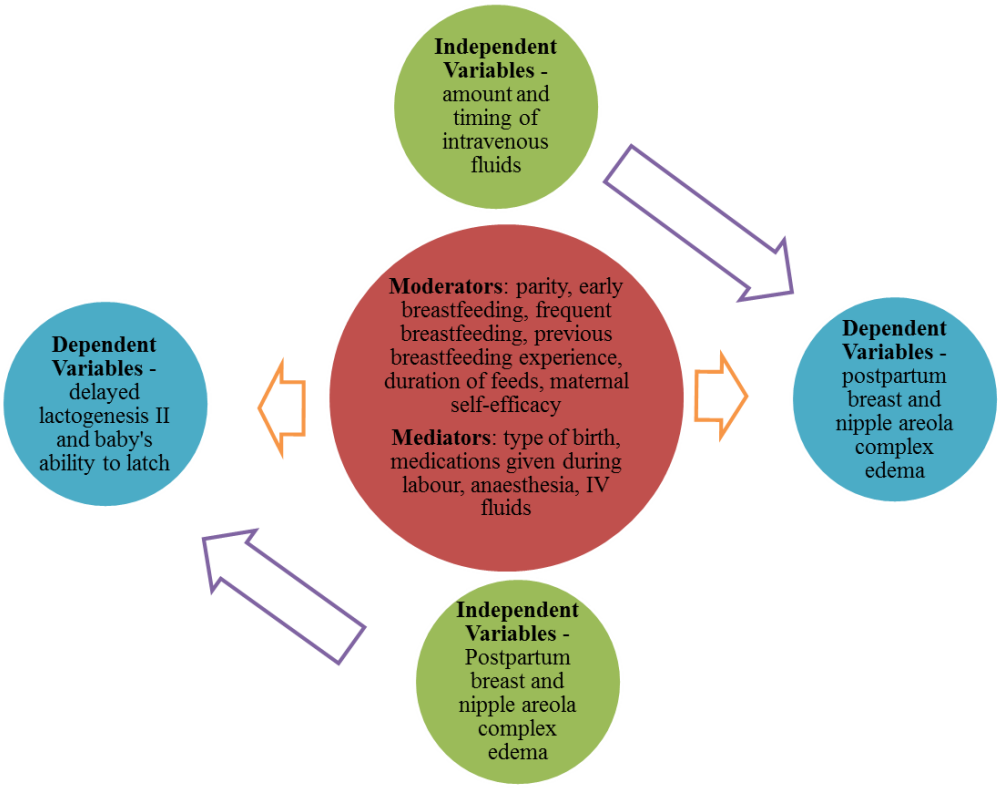

Figure 1: Conceptual Framework Illustrating Relationships Among Variables.

Research Question and Study Hypotheses

The research question cannot be conclusively answered with the pilot study. The pilot study was completed to determine if the research question would be feasible for a larger study and also to determine which variables should be measured when a larger study is conducted.

Research Question

What is the relationship between the amount of IV fluids given to labouring women and the edema of the breast and areola complex experienced by breastfeeding primiparous women in the first 10 days postpartum?

Study Hypotheses

1. There is a positive association between the amount and timing of IV fluid administered to mothers during intra and postpartum periods and the presence of postpartum breast, areola, and nipple swelling.
2. There is a positive association between the amount and timing of IV fluid administered to mothers during intra and postpartum periods and the onset of lactogenesis II.
3. There is a positive association between the presence of postpartum breast, areola, and nipple swelling and a delay in lactogenesis II.
4. There is a negative association between the presence of postpartum breast, areola, and nipple edema swelling and a baby's ability to latch.
5. Edema can occur independently of engorgement and has specific signs and symptoms that are not related to engorgement.

Chapter 2 - Review of the Literature

A narrative literature review (Grant & Booth, 2009) was completed to learn what is known about postpartum breast engorgement and edema and to determine how these phenomena are defined. It was done with a computerized literature search using the online databases of Medline (Ovid) via the University of Ottawa Health Sciences library proxy server. Articles that were not available were requested using interlibrary loan service. Several searches were conducted from January 2012 to March 2012 and were updated in September and October 2013. Search terms included edema, breast, engorgement, intravenous fluid, and swollen. Boolean operator AND was used to screen search terms. Searches were not limited on dates, but were limited on language; only those written in English were considered (see Table B1).

Further articles were obtained by following up on reference lists from articles found via the computerized literature search. The *Journal of Human Lactation* and the *Journal of Obstetric, Gynecologic, and Neonatal Nursing* were hand searched for relevant articles from 2007 to the present, and three relevant articles were obtained in this manner. An unpublished thesis from the University of Wyoming was found and retrieved.

Well established breastfeeding text books: *Breastfeeding: A Guide for the Medical Profession* (3rd ed.; Lawrence & Lawrence, 2011); *Breastfeeding and Human Lactation* (7th ed.; Riordan, 2005); *The Breastfeeding Atlas* (Wilson-Clay & Hoover, 2005); *Maternity and Women's Health Care* (9th ed., Lowdermilk & Perry, 2007), and *The Breastfeeding Answer Book* (Mohrbacher & Stock, 2003) were used to more fully understand the concepts discussed in this proposal. The Academy of Breastfeeding Medicine protocols were also referenced and The World Wide Web using Google search engine was used for information on basic concepts.

Inclusion criteria for studies included all studies relating to postpartum breast changes. Articles were excluded if breast changes occurred for reasons other than pregnancy and childbirth. Both primary and secondary studies were included in the literature review.

A total of 423 studies were found, 410 studies were excluded and 13 studies were included in this literature review (see Appendix B, Table B1). The main limitation to the studies was that they did not help determine the type of swelling. Studies about engorgement did not look at the effect of IV fluids on postpartum breast swelling and studies about the effects of IV fluids did not look at postpartum breast swelling.

Areas of knowledge included in this review are defining and differentiating between engorgement and edema; techniques to measure engorgement; when engorgement is likely to occur; factors that contribute to edema and engorgement; and which mothers are most at risk for engorgement and edema. In addition, literature that described the relationship between maternal IV fluids during labour and prior to birth was sought (see Appendix B for search strategies and Appendix C for a summary table of the literature).

Understanding Engorgement and Breast Edema

Engorgement versus Edema

Two related conditions that can cause difficulty in breastfeeding in the first few weeks postpartum are breast engorgement and breast edema. Both of these conditions cause swelling of breast tissue which may be painful and can interfere with breastfeeding (Mangesi & Dowswell, 2010).

Engorgement has been described as breasts that are so full of milk that they are overly firm, full, painful, and limit movement of milk, blood, and lymphatic fluid (Mangesi & Dowswell, 2010). There is an alternate definition that an increase in blood and lymph fluid in

the breast results in swelling of breast tissue with the same restrictions on milk, blood, and lymphatic fluid movement (Lowdermilk & Perry, 2007).

Treatment for engorgement is also somewhat contradictory and may depend on the underlying definition. If milk stasis is the cause then application of warm moist heat may help milk flow by possibly aiding the milk ejection reflex and relieve engorgement by making movement of milk possible (Lawrence & Lawrence, 2011), but if an increase of blood and interstitial fluid is the cause then using cold compresses may help reduce swelling by decreasing blood flow to breast tissue (L'Esperance, 1980).

Edema is defined as an increase of fluid in the interstitial space (Lewis at al., 2012) Treating edema with heat has the potential to increase swelling due to vasodilation, and this treatment may be counter-productive (Lawrence & Lawrence, 2011). Pumping milk is often used to relieve stasis and its accompanying pressure (i.e. engorgement; Academy of Breastfeeding Medicine, 2009). If breasts are edematous, then there is a risk of increasing the movement of more fluid into the nipple areola complex with pumping; thereby, making edema worse (Cotterman, 2004; Miller & Riordan, 2004).

Theories of Engorgement

In 1951, Newton and Newton suggested engorgement was caused by milk retention in the alveoli. The alveoli become distended and cause compression of the milk ducts which block milk flow as the baby nurses (Newton & Newton, 1951). If this cycle continues without any relief, vascular and lymph stasis will occur (Newton & Newton, 1951). Lawrence and Lawrence (2011) describe engorgement as involving three parts: increased vascularity in the breast, the onset of lactogenesis II (period of increased milk production), and edema as a result of decreased lymph drainage caused by the first two elements. These theories are somewhat confusing in that

they see the primary and secondary causes of engorgement as reversed, one states that an increase in milk is the primary cause, while the other states that it is increased vascularity in the breast that is the starting point.

In cases where engorgement becomes extreme, edema may be present (Lawrence & Lawrence, 2011; Newton & Newton, 1951), but edema may be present in the breast without signs and symptoms of engorgement (Cotterman, 2004). Both Lawrence and Lawrence (2011) and Wilson-Clay and Hoover (2005) identify areola and peripheral breast swelling as separate, though neither differentiate between engorgement or edema. Riordan (2005) states that excessive IV fluids given to mothers during labour can cause breast edema. Other than the Riordan (2005) text, the Riordan (2004) case study, and the Cotterman (2004) article, postpartum breast edema was not identified as a separate condition.

Mechanics of Edema

To understand edema, one needs to understand fluid movement between the intravascular and interstitial spaces. There are four forces at play (Cirolia, 1996; Witte & Witte, 1997) which are illustrated in Figure 2:

1. Blood (colloid) hydrostatic pressure which pushes against the internal capillary walls
2. Blood (colloid) osmotic pressure from within the capillaries which draws water into the capillaries
3. Interstitial fluid hydrostatic pressure pushes against the outside of capillaries, thus forcing fluid into the capillaries
4. Interstitial fluid osmotic pressure which pulls water into the interstitial space from the capillaries

Blood hydrostatic pressure (1) and interstitial fluid osmotic pressure (4) move fluid into the interstitial space while blood osmotic pressure (2) and interstitial fluid hydrostatic pressure (3) move fluid into the vascular system (Cirolia, 1996). An imbalance of these forces, with too much fluid being left in the interstitial space causes edema (Cirolia, 1996; Witte & Witte, 1997).

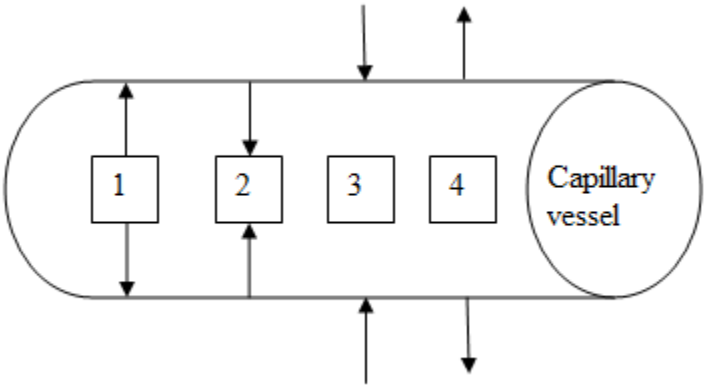

Figure 2: Mechanics of Edema

Timing of Engorgement

Of the studies reviewed, engorgement was not identified in the first 24 hours postpartum. By 48 hours postpartum 4.9% of mothers experienced engorgement and by 78 hours postpartum 65% of mothers had noticed breast changes (L'Esperance, 1980; Moon & Humenick, 1989; Newton & Newton, 1951). Overall, 95% of women experienced firm breasts with some tenderness, though only 47% of women experienced very firm, very tender breasts (Hill & Humenick, 1994). The length of engorgement for the majority of women ranged from 3 to 8 days postpartum, and the longest engorgement recorded was 14 days (Hill & Humenick, 1994). Mothers who gave birth by caesarean section (c-section) appear to experience engorgement 24 to 48 hours later than mothers who gave birth vaginally (Academy of Breastfeeding Medicine,

2009). Given these parameters, any swelling before 24 hours, and probably before 48 hours, postpartum would likely be edema as opposed to engorgement.

Mothers Who are Most at Risk for Engorgement and Edema

Factors associated with engorgement include: delayed initiation of breastfeeding, infrequent breastfeeding, limiting duration of breastfeeds, late maturation of milk, and supplementary feeds given to the baby (Moon & Humenick, 1989). Having a c-section appears to increase the risk for postpartum breast engorgement as well as extending the length of time mothers experienced this phenomenon (Hill & Humenick, 1994; Moon & Humenick, 1989). Hill and Humenick (1994) also found that mothers with previous breastfeeding experience experienced engorgement sooner, but it resolved more quickly than mothers with no previous experience regardless of parity.

Factors that contribute to edema seem to be different from but related to the factors that contribute to engorgement. Mothers who experience pregnancy induced hypertension, oxytocin-induced labours, and a large amount of IV fluid during labour are at increased risk for edema in the postpartum period (Cunningham et al., 2005). For women who have c-sections, increased IV fluids are common (Cyna, Andrew, Emmett, Middleton, & Simmons, 2006).

Intravenous Fluids During Labour

Intravenous fluids are commonly administered to mothers during labour to prevent hypotension (low blood pressure), a common side effect of spinal or epidural anaesthesia (Hofmeyr, Cyna, & Middleton, 2010). In Ontario, 63.1% of women receive regional analgesic (spinal or epidural analgesic) for pain relief during labour and vaginal birth (BORN Ontario, 2013). Mothers who receive IV fluids have been shown to have decreased blood osmotic pressure which has been shown to cause peripheral edema (Gonik, Cotton, Spillman, Abouleish,

& Zavisca, 1985; Lewis et al. 2012). These mothers may be at an increased risk for postpartum breast edema.

A study about infant weight loss found a significant positive correlation between total IV fluids given to a mother during labour and a delay in lactogenesis II (Noel-Weiss, Woodend, Peterson, Gibb, & Groll, 2011). Another study found that 13% to 18% of women who used formula did so because of difficulty in latching and concerns about low milk supply, they also reported a delay in lactogenesis II for 42% of mothers whose babies had excessive weight loss (Chantry, Nommsen-Rivers, Peerson, Cohen, & Dewey, 2011). Both Noel-Weiss et al. (2011) and Chantry et al. (2011) found a positive correlation between amount of IV fluids given to mothers during labour and excessive weight loss in babies. One of the reasons that there may be a delay in lactogenesis II and ongoing weight loss (after fluid balance in the newborn has been achieved) is increased postpartum engorgement and edema. The increased pressure in the breast may cause a decrease in milk removal, which will activate the feedback inhibitor of lactation (Lawrence & Lawrence, 2011). Wilson-Clay has noted in her clinical practice that when edema in the peripheries (ankles and feet) decreases, milk supply increases (Wilson-Clay & Hoover, 2005). The feedback inhibitor of lactation (FIL) is an autocrine feedback mechanism possibly triggered by a protein secreted in breast milk which decreases milk synthesis unless milk is effectively, frequently, and efficiently removed (Wilde, Prentice, & Peaker, 1995).

Knowledge Gap Relating to Engorgement and Edema

There is little distinction between postpartum breast engorgement and edema in the literature. While Lawrence and Lawrence (2011) state that edema may be a part of engorgement, the two conditions are not identified as being different in the literature, rather they are seen as two parts of the same phenomenon. The effects of IV fluids given to mothers during labour have

not been extensively studied, and there is little research on the effects of IV fluids on postpartum breast engorgement or edema.

The Academy of Breastfeeding Medicine (2009) state certain aspects of engorgement such as the influence of the type of labour, length of labour, anesthesia used, and premature birth have not been well studied. Given the blurring of understanding between breast engorgement and breast edema, more research is needed to understand these two conditions. Insight gained over years of research has broadened Newton and Newton's (1951) original definition of engorgement, but breast edema has not yet been researched as a separate condition. The effects of crystalloid IV fluids administered to a healthy population have been studied and have been shown to decrease pulmonary function and increase weight for 24 hours (Holte, Jensen, & Kehlet, 2003). One study (Gonik et al., 1985) looked at the effects of IV fluid on post-partum mothers. Administration of crystalloid IV therapy decreased colloid osmotic pressure in the postpartum period, and a decrease in colloid osmotic pressure results in increased edema (Gonik et al., 1985). No studies looked at the effects of IV fluid on postpartum breast swelling.

In my own clinical work as a registered nurse and lactation consultant I have observed that some women experience breast edema rather than engorgement as evidenced by pitting of breast areola tissue without evidence of the onset of lactogenesis II. One of my questions regarding the onset of lactogenesis II is whether the increase of pressure in the breast tissue leads to a lack of space for full onset of lactogenesis II to occur, so that mothers have what I call a "slow to increase" supply rather than a copious supply of milk. A slow to increase supply leads to increasing a mother's workload with the need to extract milk from her breasts with a pump or hand expression and supplementing the babies feeds until a full supply can be achieved.

Administrations of crystalloid IV fluids have been shown to contribute to a decrease in

colloid osmotic pressure, which can lead to an increase in edema. If risk of edema is increased in breast tissue, this swelling may interfere with normal physiological breast milk production and therefore breastfeeding. The purpose of this pilot study was to investigate whether IV fluids given to mothers during the peripartum period influence postpartum breast changes and to determine the feasibility of a larger study.

Chapter 3 - Methods

Research Design

The study design was a prospective, longitudinal, observational cohort pilot study with repeated measures and a within-subjects design. It was conducted at two sites, Oakville Trafalgar memorial Hospital and Milton District Hospital, both a part of Halton Healthcare Services. Participants were recruited in hospital while in labour. Data were collected daily from recruitment (to determine baseline measurements) until ten days postpartum. Ten days was chosen as the timeframe for this study as 90% of women will experience engorgement during this period (Hill & Humenick, 1994). The researcher documented breast and nipple changes that occur from when a mother was in labour until ten days postpartum, and the effects of those changes on breastfeeding. The research done by Noel-Weiss et al. (2011) and Chantry et al. (2011) indicated that IV fluids given to mothers may have an effect on lactogenesis II and breastfeeding. Due to the limited amount of information found during the literature review, a pilot study was conducted to explore this topic to determine if further research in this area is warranted, and which measures would be useful in measuring edema in a full study.

Setting

Recruitment occurred at Halton Healthcare Services (HHS) at the Oakville Trafalgar Memorial Hospital (OTMH) and Milton District Hospitals (MDH). Halton Healthcare Services is composed of three community hospitals in Oakville, Milton, and Georgetown. HHS's three hospitals are part of the Mississauga Halton LHIN (i.e., Local Health System Integration Network). Oakville Trafalgar Memorial Hospital has 2150 births per year, while Milton District Hospital has 986 births per year. After discharge, the data collection continued in participants'

homes. Participants lived in Burlington, Milton, Oakville, and Mississauga and were within a 30-minute drive of the hospital.

Participants

Inclusion Criteria

Eligible participants were primiparous women, who gave birth vaginally following spontaneous labour (induction of labour was an exclusion criteria while augmentation of labour was not), to a single, full term, healthy infant, and who planned to breastfeed without supplementation. Healthy was defined as mother and baby who were discharged home together. Participants had to be able to read, write, and speak English and had to live in the same geographical area as the researcher to allow for home visits by the researcher. Mothers and their babies were discharged with no contra-indications to exclusive, unrestricted breastfeeding.

Exclusion criteria were any factors that may have affected exclusive breastfeeding (e.g., mother baby separation or newborn facial anomalies, no breast growth during pregnancy, medically induced labour, or multiparity). The rationales were: although the relationship between breast growth during pregnancy and milk production remains unclear (Cox, Kent, Casey, Owens, & Hartmann, 1999), it is reasonable to assume that a lack of growth may be a sign of hypoplasia; planned medical induction of labour requires exogenous oxytocin which may depress a baby's primitive feeding reflexes (Olza Fernández et al., 2012); and multiparty was an exclusion factor since engorgement appears to resolve more quickly in mothers who have previously breastfed (Hill & Humenick, 1994).

Sample Size

For this pilot study, 25 women were recruited with a goal of 20 participants completing the ten day data collection. This number allowed for 20% attrition. When determining sample

size, other studies on engorgement were referred to. Most sample sizes were between 6 and 54, with 6 studies having 20 or less participants. It was deemed reasonable that a final sample size of 20 for this pilot study would be sufficient to achieve the goals of this pilot study, i.e. to determine if further research is warranted and to trial types of measurement and data collection protocol to determine feasibility for a larger study.

Recruitment

A convenience sample was obtained for this study. Recruitment occurred as eligible participants were admitted to the birthing suites at OTMH and MDH or assessed by the midwives as being in early labour. The potential participants were asked by their nurse or midwife if they were interested in being part of a breastfeeding study. If they agreed, the primary researcher was called in to the hospital to explain the study to the woman. If the potential participant agreed to participate, a signed informed consent was obtained and they were recruited into the study.

Protection of Human Rights

Ethical approval for this study and all amendments was granted by the University of Ottawa Research Ethics Board and from the Halton Healthcare Services Research Ethics Board (see Appendices D and E). Patient confidentiality and privacy was maintained by having nurses or midwives first approach clients to determine interest in participating in the study. The study was fully explained by the researcher to all mothers interested in participating and if they consented to be in the study, a signed consent form was obtained (see Appendices F and G). A separate consent was obtained regarding photography; so that participants could control their level of involvement regarding photographs (see Appendix H) and photographs would not be a deciding factor in participation. Photographs showed no identifiable characteristics.

All participants received a copy of the Patient Information Sheet and Consent (see Appendices F and G) and a list of available breastfeeding resources in the community (see Appendix I). If either mother or baby were in crisis, such as excessive baby weight loss without evidence of good breastfeeding or excessive postpartum bleeding, and were unable to contact available resources (e.g. healthcare providers such as lactation consultants, obstetricians, family doctors, midwives, and public health nurses), the primary researcher offered the minimum support needed until further help was found. Alphanumeric coding for patient identity was used to maintain participant confidentiality and the master copy was kept in a separate locked location from the consent forms and the data collection forms. All computerised data were encrypted and password protected, and only anonymous data were used for analysis and dissemination. Currently all consent and data collection forms are being kept in a locked location at the University of Ottawa.

All home visits were done at a mutually agreeable time and participants had the right to withdraw from the study at any point without penalty. Specific providers were contacted ahead of time to make them aware of the study and the possibility of referral. This study was compliant with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

Procedure

Baseline measurements were taken as soon as consent to participate in the study was obtained. Participants were also asked to fill out a prenatal information sheet (see Appendix J). Repeated measures started with measurements being taken within twelve hours after birth of the baby and then data collection continued on a daily basis for the following nine days. At the first postpartum data collection period, participants were asked to fill out a postpartum questionnaire

(e.g., type of birth, sex of baby, birth weight, any pre or post swelling; see Appendix K). The first postpartum visit was done within 12 hours of birth, with subsequent visits occurring either in the morning (if birth occurred between midnight and noon) or in the afternoon (if birth occurred between noon and midnight). If parents requested a different time, this was accommodated by the researcher. Data collection continued until postpartum Day 10.

For this study, data collected prior to birth is called prenatal data and Day 0 is defined as the day of birth. A suitable time to visit and collect data was arranged on a day to day basis with participants. To ensure consistency, all data collection was done by the principal researcher. Twelve variables were measured, and a total of 11 sets of measurements were recorded: baseline, day of birth, and then daily for nine days postpartum.

Measurement of Variables

Intravenous Fluids

In the intra-partum period, data were prospectively collected about timing, amount, and type of administered maternal IV fluids separately from routine hospital charting. Intravenous fluids were tracked by the nurses at shift change or more frequently as able. A brightly coloured separate form was provided for this purpose (see Appendix L). Nurses were also asked to keep all IV fluid bags, including those used to administer medication for the primary researcher to count and to compare with the IV tracking sheets. Reminder stickers and a container for the empty bags were provided for the used IV fluid bags. Intravenous fluid was tracked from commencement of IV therapy until IV therapy was discontinued. Intravenous fluid data were collected at the ratio level using millilitres.

Nipple and Areola Diameter, Height, and Shape

In the clinical setting changes in nipple shape and size in association with breast engorgement have been noted (Wilson-Clay & Hoover, 2005). Nipple diameter and areola diameter were measured using a Pickett circle template, a drafting tool designed to draw circles of a set diameter (as recommended by Wilson-Clay & Hoover, 2005). Each template has multiple circles of varying diameters measured in millimetres. Measurements were taken at the ratio level to determine changes during this study. Nipple height was measured using a metric ruler, measurements were at the ratio level and millimetres were used. The reason for measuring height is that it is hypothesized that the more swollen the breasts and areola, the flatter the nipple is pulled reducing the height of the nipple and making it harder for a baby to latch (Cotterman, 2004; Riordan, 2005; see Appendix M for the data collection sheet). Nipple and areola shape were captured by taking photographs and comparing the visual changes over the course of the study. Nipple shape was described using self description by mothers. These data were considered at the nominal level.

Milk Maturation Index of Colostrum and Milk

Milk maturation was measured according to the Maturation Index of Colostrum and Milk (MICAM) as developed by Humenick (1987; see Appendix N). This tool was found to be a reliable predictor of early milk maturation when compared to variables such as timing of initiation, frequency, and duration of breastfeeding (Humenick, 1987; Humenick, Mederios, Wreschner, Walton, & Hill, 1994).

Using MICAM helped determine the onset of lactogenesis II and should help distinguish the breast fullness associated with this process from pre-lactogenesis II edema. Earlier feedings ($p=0.05$), more frequent feedings ($p=0.005$) and increased total time at the breast ($p=0.02$) were

all associated with faster milk maturation (Humenick, Mederios et al., 1994). Moon and Humenick (1989) found that milk maturation at 24 hours was negatively associated with postpartum breast engorgement at 36 hours ($p=0.04$). This measure may be useful to distinguish the difference between postpartum breast engorgement and postpartum breast edema. Engorgement is typically associated with lactogenesis II, if there is breast swelling without milk maturation, it may indicate the presence of edema. (See Table 2 for MICAM patterns and Appendix O for details on the approved procedure.)

Table 2 - *MICAM Patterns* (Humenick, 1987)

Type of milk		Pattern
1.	Early colostrum	Dries hard and shiny Colour bright yellow to very pale Seen mainly in first 12 hours postpartum Occasionally up to 36 hours postpartum
2.	Late colostrum	Similar to early colostrum Distinguished by thin translucent outer ring Mainly seen in second 12 hours postpartum and is usually gone by 48 hours postpartum Rarely seen prior to 12 hours postpartum
3.	Early transitional milk	Dries with three easily seen rings Centre ring is a shade of yellow occupying 50% or more of the total area Middle ring is white Outer ring is translucent Typically seen between 36 and 48 hours postpartum Can be seen until 120 hours postpartum May be seen up to nine days postpartum
4.	Late transitional milk	Dries in a three ring pattern similar to early transitional milk Sizes of rings differ from early transitional milk (the centre ring is less than 50% of the total area) Most common pattern at day 5 postpartum May be present up to 28 days postpartum

(Table 2 continues)

(Table 2 continued)

Type of milk	Pattern
5. Mature milk	Has three rings Centre ring is hard to see because it is almost the same colour as the middle ring This pattern becomes the predominant pattern by day 14 postpartum It spreads and dries quickly

Breast and Areola Edema

Edema was measured by applying gentle pressure with an index finger pad on areola tissue just above the nipple and again about two inches above the nipple on a mother's breast for 5 seconds. Depth of impression and how long the impression took to rebound was noted, and then used to rate level of edema (see Appendix P). A classic edema rating scale measuring 1+ to 4+ (suggested in O'Sullivan and Schmitz, 2007) was used (see Table 3). This scale measurement tool has been found to have poor inter-rater reliability (Brodovicz et al., 2009), internal consistency was ensured by having the researcher do all data collection. These data were collected at the ordinal scale.

Table 3

Measuring Edema

Rating	Characteristics
1+	Barely detectable impression left when finger is pressed into the skin
2+	Slight indentation left when finger is pressed into the skin Takes 15 seconds to rebound
3+	Deeper indentation left when finger is pressed into the skin Takes 30 seconds to rebound
4+	Deep indentation left when finger is pressed into the skin Takes more than 30 seconds to rebound

Maternal Breast Self-assessment

Mothers were asked to rate the degree of breast firmness according to a 6-point scale (see Appendix Q). A 5-point subjective scale originally developed by Newton and Newton (1951) was adapted into a 4-point scale in 1989 by Moon and Humenick, and then adapted again into a 6-point scale by Hill and Humenick in 1994. The main reason for the re-adaptation to a 6-point scale was feedback from mothers who indicated that they would have preferred more options than the 4-point scale gave them (Riedel, 1994). This subjective scale has been found to correlate highly with breast surface tension measurements and is seen as being reliable ($r = 0.70$; (Riedel, 1994), although there is a report of it being subject to the placebo effect (Roberts, Reiter, & Schuster, 1998). The current 6-point scale asks mothers to describe changes in their breast as:

1. Soft, no change
2. Slight change
3. Firm, non-tender
4. Firm, beginning tenderness
5. Firm, tender
6. Very firm and very tender

Latching

Ability to latch was determined by asking the mothers if their babies were able to latch onto their breasts (see Appendix P). Latching was defined as the baby attaching to the nipple areola complex of the breast for breastfeeding (Lowdermilk & Perry, 2007), and needed to be accompanied by at least two minutes of active sucking (Humenick, Hill, & Anderson, 1994). Engorgement and edema have been seen to reduce a baby's ability to latch (Cotterman, 2004; Miller & Riordan, 2004).

Lactogenesis II

Onset of lactogenesis II was determined by asking mothers if their breasts felt fuller, heavier, were tender, and leaking milk (see Appendix Q; Lauwers & Swisher, 2005). A mother's perception of the onset of lactogenesis II has been found to be accurate (Chapman & Perez-Escamilla, 2000). The onset of lactogenesis II is often associated with engorgement, although edema may present in a similar manner. Milk maturation was also measured using MICAM patterns to help define onset of lactogenesis II.

Newborn Weight Measurement

An Ultrascale MBSC-55 Digital Scale was used to track baby weights. Daily baby weights, performed by mothers and supervised by the researcher were recorded when doing daily data collection, to help determine adequate breastfeeding (see Appendix S). Typically a baby will have reached maximum weight loss by 60 hours of age (Noel-Weiss et al., 2011) and onset of lactogenesis II postpartum is typically reported as occurring by 72 hours postpartum (Lawrence & Lawrence, 2011), indicating that weight stabilization and gain should be present by 96 hours (Day 4) postpartum.

Pumping and Supplementation

Mothers were asked about any pumping and supplementation that occurred, as these may have had an effect on the dependent variables measured (see Appendix T). If a baby cannot latch and mother is pumping, she may aggravate areola edema. Frequent effective breastfeeding reduces engorgement (Lawrence & Lawrence, 2011; Newton & Newton, 1951; Wilson-Clay & Hoover, 2005). A baby who is being supplemented may be less likely to nurse efficiently and engorgement may be slower to resolve. A baby who is unable to latch and therefore needs

supplementation may also indicate a degree of breast swelling that is interfering with establishing breastfeeding (Lawrence & Lawrence, 2011).

Data Collection

Developing Data Collection Sheets

Data collection sheets were developed for the selected variables. These sheets were primarily used by the researcher, except for the IV fluid tracking sheet. All data collection sheets were colour coded to make collection and data entry easier. All data collection sheets were approved by the thesis committee and the ethics review boards at the University of Ottawa and at Halton Healthcare Services.

Data Collection

Data collection took approximately 15 to 20 minutes. All data collection was done by the researcher except for baby weights, which the researcher supervised. All tools used for data collection were wiped down with Clorox antibacterial wipes after each use. Data collection packets were kept by the researcher in a secure place. Data collection packets included (a) patient information and consent forms, (b) consent for photography forms, (c) community breastfeeding resource sheet (copies of these three forms were left with each participant once signed consent had been obtained), (d) prenatal questionnaire, (e) postpartum questionnaire, (f) IV fluid sheet (placed in the patient's chart while IV fluid was being administered), (g) breast and areola measurement sheet, (h) baby weight sheet, (i) maternal breast self-assessment sheet, (j) latching sheet, (j) edema rating sheet, (k) milk and colostrum maturation index sheet, and (l) pumping and supplementing log.

Managing the Data

Once a participant was recruited, the alphanumeric coding used to identify that participant was written on all data collection sheets. Data were collected at 11 time points for each participant during the study: prior to birthing, within 12 hours of birthing, and daily for an additional 9 days. IV fluid tracking sheets were added to the participants chart and a client sticker was attached to the sheet to ensure that the form stayed with the correct chart. This form was then collected after IV therapy had been discontinued in the postpartum unit and the patient sticker removed and shredded. Triangulation of data (i.e., measuring the same variable in more than one way to ensure as accurate a result as possible) regarding IV fluid was done at this time to ensure as accurate an account as possible. The researcher kept all data collection forms in an envelope with the participants' alphanumeric coding on the front, and entered data on these sheets at each data collection time point. Once data collection was complete, forms were locked in a secure cabinet in the researchers' home office until they could safely be transferred to the University of Ottawa.

Rigour

Controlling for Bias

Subject bias includes selection bias which indicates the sample might not represent the population and be generalizable (Norman & Streiner, 1998). For this pilot, subject bias could not be avoided, because the planned sample was small and self-selected.

Bias is a variation in the value of a variable due to factors inherent in the research (Norman & Streiner, 1998), such as maternal fatigue over time or increased nipple pain due to damage could produce biased results. Bias might have occurred due to extreme fatigue of post-partum mothers affecting recall. By having mothers document events as they occurred, it was

reasoned this potential bias could be reduced. The principal researcher also did the majority of data gathering to prevent mothers from being overwhelmed by the study. Another strategy to avoid this bias was to have the primary researcher clarify information with participants and their partners as needed.

Measurement bias was avoided by having the same researcher perform all measurements using clinically approved tools. Mothers were asked to self rate their breasts to determine degree of change; this within subject design also helps reduce bias. The baby scale was checked by using a standardized weight prior to every weight done to ensure reliability. This standardized weight was kept in a plastic bag to limit the effect of moisture and had been previously weighed at the post office to establish its weight. Triangulation of data collection for IV fluids was done by comparing used IV fluid bags (or nurses' testimony) to the data collection sheet to help reduce measurement bias.

Social desirability bias is the risk of participants answering research questions according to what they believe the researcher wants to hear (Norman & Streiner, 1998). There was a risk of social desirability bias in this research as new mothers seem to want to do everything "right" and to show they are good parents. Due to the nature of repeated data collection, participants were given the opportunity to get to know the researcher, allowing them to gain a level of comfort with the researcher, which would help minimize the risk of social desirability. The researcher also planned to remain non-judgmental and open to responses given by participants, in the hopes that participants would feel free to give true responses to questions asked.

Potential researcher bias, specifically, influencing breastfeeding outcomes due to the researcher being an International Board Certified Lactation Consultant, was limited by making a list of available breastfeeding resources (see Appendix I) in the community available to all

participants. Potential researcher bias was also limited by using multiple data sources and previously established data collection tools to increase the validity of the findings. When mothers and babies were deemed to require further assistance, they were encouraged to contact the appropriate community resources, considered to be standard care, thus limiting involvement from the researcher.

In-services for Nurses and Midwives

To establish consistency with the protocol, nurses and midwives were informed of the study prior to recruitment commencing. The research question and hypothesis were reviewed and study protocol was discussed. Nurses were made aware of their level of participation and had free access to the researcher with any questions or concerns. A copy of the research proposal was available at each unit.

Data Analysis

SPSS 21 statistical software was used for descriptive statistics and tests of significance. Participants were described according to demographic data and descriptive statistics were used to describe findings. Plans for dissemination include publishing in professional journals, conferences, nursing in-services as well as to women outside of the health services field via open access journals.

This pilot observational cohort study intended to look at:

1. The association between the amount and timing of IV fluids given during labour and any postpartum breast, areola, and nipple changes in the first 10 days postpartum.
2. The association between the amount and timing of IV fluids given during labour and the timing of lactogenesis II and the baby's ability to latch.

3. The association between postpartum breast, areola, and nipple swelling and onset of lactogenesis II.
4. The association between postpartum breast, areola and nipple swelling and a baby's ability to latch.
5. Signs and symptoms specific to postpartum breast edema.
6. Whether further research is warranted and the feasibility of a larger study with respect to types of measurement, recruitment and data collection protocols

Chapter 4 – Findings

The aim of this pilot study was to determine if a larger study about the relationships between maternal perinatal IV fluids and breast or nipple changes would be warranted. In addition to gauging if a larger study would be worthwhile, the pilot trialled several different measurements; a recruitment method; and a data collection protocol. Data collection was complex with 12 variables measured at 11 time points: baseline (in labour), day of birth (Day 0), and then daily for nine days postpartum. Recruitment procedures and the data collection protocol proved to be challenging and labour intensive. This chapter presents the results of data collection, the determinations regarding utility of measurements, and the feasibility of recruitment and data collection protocols.

Characteristics of the Participants

Twenty-five nulliparous women were recruited into this pilot study between November 2012 and November 2013. Of the 25 participants recruited during labour, either in hospital or at home (i.e., in the case of home births), 8 participants who met the criteria in labour did not continue to meet the inclusion criteria post birth. These participants had caesarean births (n=3) or experienced prolonged mother-baby separation due to concerns for infant health (n=5). The inclusion criteria stipulated vaginal births and unrestricted breastfeeding.

Daily visits in the hospital and at home following discharge for data collection was carried out with the remaining 17 participants. The majority of women (12; 71%) had an epidural and oxytocin and 13 of the 17 (76%) participants had IV fluids in labour and post birth. Table 4 shows the characteristics of participating mothers and newborns.

No participants withdrew from the study, although one mother was lost to follow up. All participants who completed the study voiced their appreciation for the daily visits that continued

to Day 9, and they made comments about being reassured due to the visit and to their babies being weighed daily.

Table 4

Characteristics of Participating Mothers and Newborns (n = 17)

Characteristics	Mean [+/- SD(range)]	Frequency (%)
Maternal age (years)	30.1+/-4.0 (20-37)	
In committed relationship		16 (94)
Completed post-secondary education		15 (88)
Family income >78K (CAN)		11 (65)
First spoken language		
English		14 (82)
French		0 (0)
Other		3 (18)
Noted prenatal breast growth - Yes		14 (82)
Previous breast surgery – No		14 (82)
Gestation (weeks)	40.1 (39-41)	
Type of birth – Vaginal		14 (82)
Vacuum		3 (18)
Vaginal with epidural and oxytocin - Yes		12 (71)
Reported edema		
Prenatal - Yes		12 (71)
Postpartum – Yes		12 (71)
Newborn sex - Female / Male		11 (65) / 6 (35)
Newborn birth weight (grams)	3442 +/-241.8 (2950-3940)	
Timing of first feed - In first hour		16 (94)

Variables

Intravenous Fluids

IV fluids administered to mothers were tracked by nurses during and after labour, separately from usual charting, on a form provided by the researcher. Total IV fluids were tracked and pre birth as well as post birth amounts were calculated based on rate of infusion. Nurses would keep the empty IV fluid bags as a means to confirm IV fluids administered to the mother or would verbally confirm IV fluid administration with the researcher. At one hospital (n = 11), IV fluids were run through pumps at a set rate and thus mothers seemed to receive IV fluids according to an established standard of care. At the second hospital (n = 2), pumps were not used and there may have been a Hawthorne effect with nurses possibly slowing down IV rates due to the study. Of the final sample, 13 mothers had IV fluids and 4 mothers did not (see Table 5 for amounts of fluids administered).

Table 5

Maternal IV Fluids Administered

Particulars	Mean	+/-SD(range)	n*
Total IV fluids received (mls)	2787	+/-1044 (1050-4400)	13
Prenatal amount (mls)	1883	+/-872(550-3300)	13
Postpartum amount (mls)	904	+/-523 (250-2150)	13

* Participants with no IV fluids = 4

Breast and Areola Edema

Breast and areola edema were assessed on a daily basis from recruitment until postpartum Day 9. Initially edema was assessed by sight and not confirmed by touch. For the first four participants, the researcher measured edema by observing for rebound of skin tissue. However, participants had excellent skin turgor and visible skin would rebound faster than the underlying

tissue. To identify edema, the skin on a women's breast or areola needed to be palpated to determine if the underlying tissue had rebounded. Beginning with Participant 5, the researcher gently pressed for 5 seconds, and then she ran her finger over the site to determine if an indent remained below the visible skin. After the initial press and release, she checked every 5 seconds to see if area of indentation underneath had rebounded. Palpation, rather than visualization, provided a better assessment of edema by determining what was happening with the underlying tissue. As a result, the edema ratings with the first four participants were lower than they might have been with palpation. Very deep edema did not generally occur prior to Day 3 postpartum, but some participants did experience moderate edema on Day 0 (day of birth). Participants who did not have IV fluids typically only experienced mild to moderate edema by postpartum Day 3. This observation indicates edema related to IV fluids may begin sooner than lactogenesis II.

Breast edema was the most significant variable of the data collected. When no IV fluids had been given participants, their breasts felt noticeably different as compared to the breasts of participants who had IV fluids. Participants who had IV fluids had firmer breast tissue, as felt by the researcher, than participants who had no IV fluids. Participants who had no IV fluids had little to no edema, whereas participants with IV fluids would often have very deep pitting edema. Of note was how many participants with IV fluids had moderate to very deep edema as late as Day 8 and Day 9 postpartum (see Table 6 for results).

Peripheral Limb Edema

Peripheral limb edema was collected with the last 2 participants by asking whether women were able to wear their rings, indicating edema in hands; by measuring the participants' right ankle circumference; and measuring edema in the participants' right foot by palpation. This measurement was not originally in the study but the researcher believed that it would be useful to

understand the process of breast edema in relation to peripheral limb edema and to determine if both resolved within a similar timeframe. Due to the late inclusion of this variable data were only collected with the last 2 participants.

Table 6 *Breast Edema as Measured in Each Breast at 11 Time Points. (N = 17)*

		Frequencies (in number experienced)									
		No edema (0)		Slight edema (1+)		Moderate edema (2+)		Deep edema (3+)		Very deep edema (4+)	
Timing		Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
In labour	*IV*	7	7	6	6	-	-	-	-	-	-
	No IV	3	4	1	-	-	-	-	-	-	-
Day 0 (Birth)	*IV*	5	4	4	5	4	4		-	-	-
	No IV	3	3	1	1	-	-		-	-	-
Day 1	*IV*	7	5	2	6	4	1	-	1	-	-
	No IV	3	3	1	1	-	-	-	-	-	-
Day 2	*IV*	2	3	8	5	-	2	3	3	-	-
	No IV	3	1	1	3	-	-	-	-	-	-
*Day 3**	*IV*	2	2	3	3	4	4	-	1	3	2-
	No IV	2	1	1	3	1	-	-	-	-	-
*Day 4**	*IV*	0	0	4	4	3	2	-	1	5	5
	No IV	1	3	3	1	-	-	-	-	-	-
*Day 5**	*IV*	-	0	3	3	4	2	-	4	5	3
	No IV	2	3	2	1	-	-	-	-	-	-
*Day 6**	*IV*	2	1	2	1	2	4	1	2	5	4
	No IV	2	3	1	1	1	-	-	-	-	-
*Day 7**	*IV*	1	0	2	3	3	3	2	2	4	4
	No IV	2	2	2	2	-	-	-	-	-	-

(Table 6 continues)

(Table 6 continued)

		Frequencies (in number experienced)									
		No edema (0)		Slight edema (1+)		Moderate edema (2+)		Deep edema (3+)		Very deep edema (4+)	
Timing		Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
*Day 8***	*IV*	2	1	1	2	3	4	2	2	3	3
	No IV	2	3	2	1	-	-	-	-	-	-
*Day 9**	*IV*	2	1	2	2	4	2	2	5	2	2
	No IV	2	3	1	1	1	-	-	-	-	-

Note that participants could experience different levels of edema in their breasts on the same day
*n = 16 **n = 15 for right breast, n = 16 for left breast

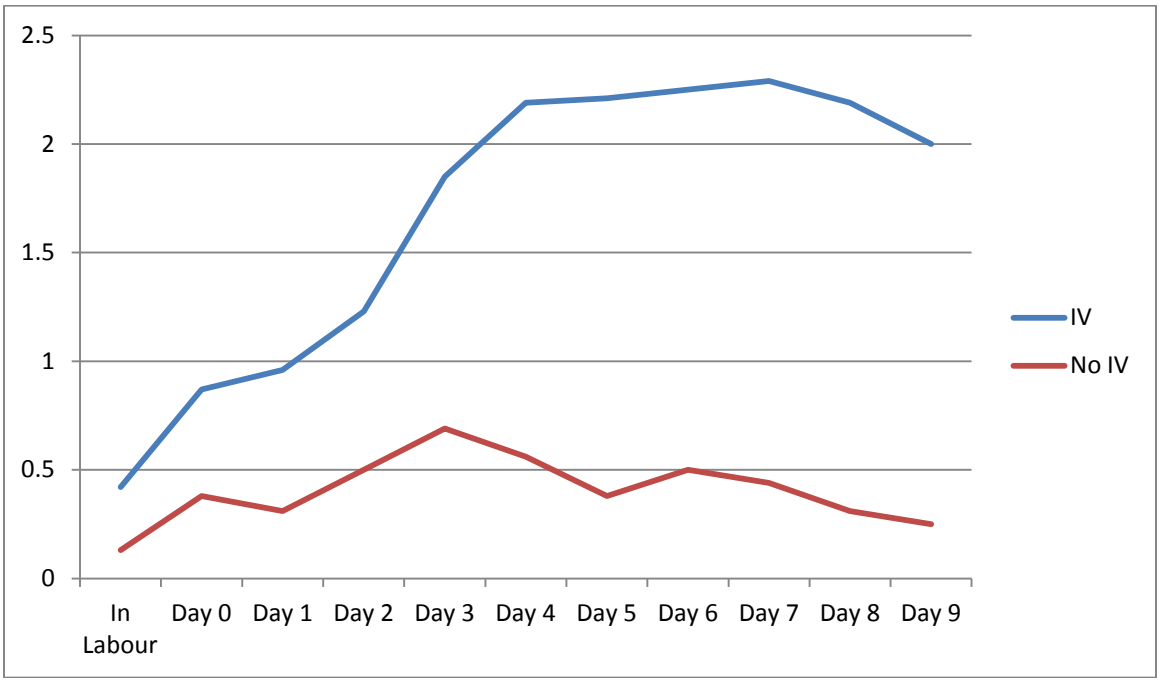

Figure 3. Line graph showing average level of edema in participants with IV fluids vs. participants without IV fluids

Maternal Breast Self Assessment

The variable deemed most at risk for social desirability bias was the maternal breast self assessment scale, but as changes were anticipated on a daily basis and the researcher always

responded positively to all responses by participants, it is assumed that the risk for this bias was minimized. Participants rated their breasts on a daily basis at the time of data collection. Ratings were based on a 6-point scale:

1	Soft, no change	4	Firm, beginning tenderness
2	Slight change	5	Firm, tender
3	Firm, non tender	6	Very firm and very tender

Participants would often rate their breasts as fuller than the researcher rated their breast edema level. This discrepancy appeared to occur most often in participants who did not receive IV fluids. Participants would rate their breasts as firm and tender or very firm and tender while the researcher's edema rating was 0 (no edema) or 1 (slight edema).

Participants who had no IV fluids had breasts that followed an expected pattern of fullness, peaking around postpartum Day 3 and 4 and then starting to subside indicating they were feeling and rating engorgement. Participants who had IV fluids had longer periods of extreme fullness, and generally rated their breasts as fuller than their non IV co-participants at each time point which suggests they were feeling and rating edema. It is important to note how many of the IV participants experienced firm and tender or very firm and very tender breasts on postpartum Days 7, 8 and 9 when, according to Hill & Humenick (1994) one would expect engorgement to be resolving.

Participants did not appear to like the term "slight change", instead they preferred "soft and tender" to describe what was happening. This variable provided insight as to how participants' breasts were changing postpartum, and allowed the researcher to understand when lactogenesis II was occurring. It would be important to track in a larger study as this pilot study demonstrated that there is a difference between IV participants and non IV participants in Maternal Breast Self Assessment Scores (see Table 7 for results).

Table 7

Maternal Breast Self Assessment as Reported in Each Breast by Participants. (N = 17)

		Frequencies (in number experienced)											
		Soft - no change		Slight change		Firm, non tender		Firm, beginning tenderness		Firm, tender		Very firm, very tender	
Timing		R	L	R	L	R	L	R	L	R	L	R	L
*In labour**	*IV*	4	4	4	4	5	5	-	-	-	-	-	-
	No IV	2	2	1	1	-	-	-	-	-	-	-	-
Day 0 (Birth)	*IV*	3	3	4	4	6	6	-	-	-	-	-	-
	No IV	4	4	-	-	-	-	-	-	-	-	-	-
Day 1	*IV*	1	1	6	6	5	5	1	1	-	-	-	-
	No IV	3	3	1	1	-	-	-	-	-	-	-	-
*Day 2**	*IV*	1	1	2	2	3	4	4	3	2	2	-	-
	No IV	1	1	-	-	-	1	3	2	-	-	-	-
*Day 3**	*IV*	-	-	-	-	1	1	5	5	6	6	-	-
	No IV	-	-	-	-	-	-	1	1	3	2	-	1
*Day 4**	*IV*	-	-	-	-	-	-	3	3	7	7	2	2
	No IV	1	-	-	1	-	-	-	-	1	1	2	2
*Day 5**	*IV*	-	-	1	1	-	-	2	2	6	6	3	3
	No IV	-	-	-	-	-	1	1	1	3	2	-	-
*Day 6**	*IV*	-	-	-	-	1	1	2	2	6	6	3	3
	No IV	-	-	2	2	1	1	-	1	1	-	-	-
*Day 7**	*IV*	-	-	-	-	1	1	2	2	6	6	3	3
	No IV	1	1	1	1	1	1	1	-	-	-	-	-
*Day 8**	*IV*	-	-	1	1	-	-	2	2	7	7	2	2
	No IV	1	1	1	1	2	2	-	-	-	-	-	-
*Day 9**	*IV*	1	-	1	1	1	1	1	2	4	6	4	2
	No IV	1	1	1	1	-	1	2	1	-	-	-	-

*Note participants could experience different levels of fullness in separate breasts * n = 16*

Lactogenesis II

This variable was assessed with self-reporting by participants who were advised that signs of lactogenesis II were fuller, heavier breasts, tender breasts, and breasts that may leak milk.

By Day 2, 53% of participants reported that lactogenesis II was starting. By Day 3, 65% of participants reported that lactogenesis II had occurred. By postpartum Day 6, all participants reported that lactogenesis II had occurred, however some of the participants found their milk supply was not adequate, and they needed to supplement their babies and enhance milk production with extra stimulation to their breasts (pumping). This measurement was valuable in understanding fullness as related to maternal breast self assessment and edema measurements, and it might be useful in helping understand the difference between edema and engorgement (i.e., onset of lactogenesis II; see Table 8).

Table 8 *Onset of Lactogenesis II*

	Onset of Lactogenesis II				*Onset of Lactogenesis II*		
	n = 17 (%)				*n* = 16 (%)		
Timing (Day)	*No*	*Starting*	*Yes*	*Timing* (Day)	*No*	*Starting*	*Yes*
Day 0 (Birth)	17 (100)	-	0	*Day 3*	2 (12)	3 (19)	11 (69)
Day 1	15 (88)	2 (12)	0	*Day 4*	1 (6)	1 (6)	14 (88)
Day 2	4 (24)	9 (53)	3 (18)	*Day 5*	-	1 (6)	15 (94)
				Day 6	-	-	16 (100)
				Day 7	-	-	16 (100)
				Day 8	-	-	16 (100)
				Day 9	-	-	16 (100)

Participants who had IV fluids appeared to be less aware of the fullness associated with lactogenesis II, even though they stated that their breasts were full and tender. The maternal

breast self assessment scores of participants with IV fluids paralleled their edema scores, while participants who did not have IV fluids had a spike in the maternal breast self assessment scores on day 3, which would coincide with the timing of lactogenesis II, and these scores did not follow the pattern set by their breast edema scores (see Figure 4).

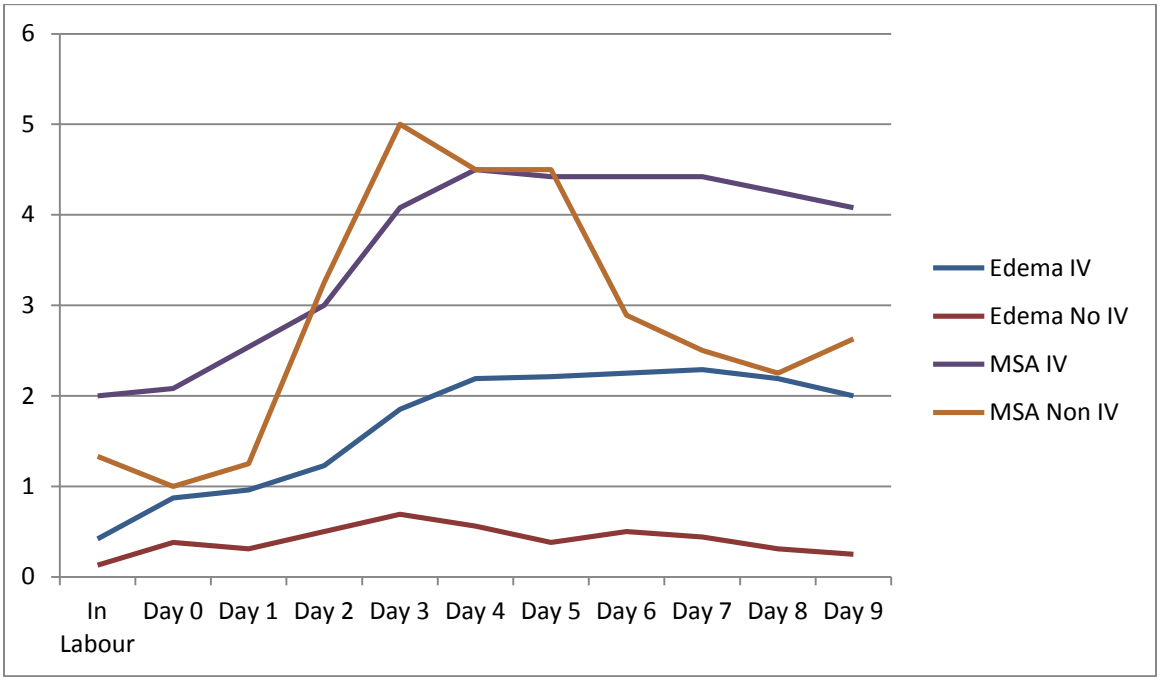

Figure 4: Line graph showing average maternal breast self assessment scores and average edema ratings.

Newborn Weight Measurement

Newborns were weighed on a daily basis on an Ultrascale MBSC-55 Digital Scale which was standardized prior to every weight done. This variable was included to help understand the possible cause of postpartum breast swelling. The rationale was if the newborn was not gaining weight then maternal breast swelling was more likely due to edema rather than engorgement. If the newborn was gaining weight, participants may be more likely to be experiencing lactogenesis II and engorgement. Because of inclusion criteria we were not expecting problems with weight gain. By Day 3 postpartum most newborns (n = 10) appeared to start gaining weight and by

postpartum Day 4 all newborns measured (2 = missing data) had either stabilized weight loss (n = 2) or started gaining weight (n = 13). Of note, most newborns did not gain weight in a linear fashion, but would gain and lose from one day to the next until an overall trend of gaining emerged. See Table 10 showing descriptive statistics of daily weight

Table 9

Descriptive Statistics of Daily Newborn Weight Measurements (N = 17)

Day	*n*	*Mean (g)*	*+/-SD (range)*
Day 0 (Birth)	17	3442	241.81 (2950 - 3940)
Day 1	17	3234.41	246.09 (2800 – 3760)
Day 2	15	3140	223.48 (2730-3640)
Day 3	15	3168	221.82 (2820 – 3690)
Day 4	15	3247.73	236.16 (2820 – 3820)
Day 5	14	3294.29	232.57 (2900 – 3860)
Day 6	15	3328.67	224.88 (2940 – 3840)
Day 7	16	3377.50	233.57 (2960 – 3860)
Day 8	15	3420.67	255.41 (2950 – 3890)
Day 9	15	3459.33	262.28 (3030 – 3950)

The lowest point for weight loss was seen on Day 2, with a mean of -290g and the lowest point of the range -475g. By Day 3 the overall trend was for infants to be gaining weight as can be seen by the mean increasing to -250g and the lowest point of the range at -415g. On average, the cohort sample of infants remained below birth weight until Day 8, and not all infants had regained birth weight by the conclusion of the study. See Table 11 for weight changes from birth.

Table 10

Average Weight Changes From Birth Weight N = 17

Day	*n*	*Mean (g)*	*+/-SD(range)*
Day 1	17	-208	+/- 42 (-285 to -150)
Day 2	15	-290	+/- 88 (-475 to -150)
Day 3	15	-250	+/- 118 (-415 to -130)
Day 4	15	-165	+/- 94 (-335 to 20)
Day 5	14	-126	+/- 101 (-275 to 100)
Day 6	15	-83	+/- 109 (-265 to 190)
Day 7	16	-62	+/- 113 (-245 to 170)
Day 8	15	-16	+/- 123 (-225 to 200)
Day 9	15	22	+/- 114 (-185 to 265)

Milk Maturation Index of Colostrum and Milk (MICAM)

The Milk Maturation Index of Colostrum and Milk is used to detect maturation of breast milk (Humenick, 1987). Breast milk usually transitions by 14 days postpartum and changes from early colostrum to transitional milk and finally to mature milk. To complete this test, colostrum or milk is dropped onto filter paper and, as the milk dries, a pattern is formed. This pattern changes as milk matures.

The original procedure, as designed by Dr Humenick (1987), asked mothers to supply a 1 ml sample of breast milk for testing. However, mothers in this pilot study did not provide the full sample at any time point. Hand expression was difficult prior to lactogenesis II and mothers were only able to provide a few drops of colostrum. Once lactogenesis II had occurred, mothers provided an average of 0.1 ml to 0.5 ml after lactogenesis II.

Testing was done on these samples, but results were difficult to read, and interpret as the three ring pattern was not always easy to identify. This may have been due to insufficient samples. Milk matured at different rates in each breast. The MICAM levels appeared to move back and forth, and colostrum did not appear to transition to mature milk in a linear fashion. Eventually, the milk transitioned over time, as expected. In some cases, even though milk was transitioning from early colostrum through to mature milk, the amount of milk available to the baby might not have been ideal.

The theory that MICAM would help identify edema versus engorgement by seeing milk transition more slowly if edema was present was not supported. Therefore, this test would not be recommended as part of the protocol for a larger study.

Table 11

Milk Maturation Levels

		Frequencies (in number experienced)									
		Early colostrum		Late colostrum		Early transitional milk		Late transitional milk		Mature milk	
Timing		Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
Day 0 (Birth) Missing 7	*IV*	4	4	3	2	-	1	-	-	-	-
	No IV	1	2	2	1	-	-	-	-	-	-
Day 1 Missing 2 rt, 3 lt	*IV*	5	3	4	5	2	2	-	-	-	-
	No IV	1	-	-	1	3	3	-	-	-	-
Day 2 Missing 0 rt, 1 lt	*IV*	2	-	4	5	6	6	-	-	1	1
	No IV	-	-	-	-	4	4	-	-	-	-
*Day 3** Missing 0 rt, 1 lt	*IV*	-	-	1	1	7	7	3	1	1	2
	No IV	-	-	-	-	1	1	3	1	-	2

(Table 11 continues)

(Table 11 continued)

		Frequencies (in number experienced)									
		Early colostrum		Late colostrum		Early transitional milk		Late transitional milk		Mature milk	
Timing		Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
*Day 4** Missing 1	*IV*	-	-	-	1	6	5	3	3		2
	No IV	-	-	-	-	3	2	1	1	2	1
*Day 5** Missing 0	*IV*	-	-	-	-	3	3	3	4	6	5
	No IV	-	-	-	-	1	2	2	1	1	1
*Day 6** Missing 0	*IV*	-	-	-	-	2	4	2	1	8	7
	No IV	-	-	-	-	1	1	2	2	1	1
*Day 7** Missing 0	*IV*	-	-	-	-	4	4	1	-	7	8
	No IV	-	-	-	-	2	1	-	-	2	3
*Day 8** Missing 2 rt, 3 lt	*IV*	-	-	-	-	5	5	2	2	3	3
	No IV	-	-	-	-	1	2	-	-	3	2
*Day 9** Missing 3 rt, 4 lt	*IV*	-	-	-	-	2	3	3	1	4	5
	No IV	-	-	-	-	1	1	1	1	1	1

** n = 16*

Diameter of Areola and Nipple and Height of Nipple

Participants' areola and nipple diameters and nipple height were measured on a daily basis, to determine if nipples decreased in height and areola increased in diameter as breasts became fuller. A Pickett circle template was used. Nipples and areola appeared to change in size dependent on timing of feeds. Nipple diameter changed in size anywhere from -3 to +8mm, though no pattern was identified as to why the changes in size occurred. Nipple height changes

ranged from -4 to +17, while areola diameter changes ranged from -25 to +20. Measurements varied across time but did not appear to change in a meaningful way.

Only one mother's nipples decreased in height after birthing, and she was the only mother who had pumped her breasts within 6 hours after birthing because the baby had been transferred to the special care unit. In the end, the mother was not eligible to remain in the study due to prolonged mother baby separation.

Latching and Nipple Shape on Delatching

Participants were asked if their newborn was latching and nursing for a minimum of 2 minutes at each feed. There were also asked to keep track of their nipple shape once their newborns had delatched at the end of breastfeeding. Newborns who are able to latch correctly on their mothers' breast will leave the nipple its normal shape though elongated, while newborns who are not able to latch deeply will leave the nipple misshapen (pinched or slanted). Overly swollen breast tissue can make it difficult for newborns to latch correctly.

Out of the 17 participants, two had newborns who did not latch on the Day 1. One of these infants was also unable to latch on Day 2. This participant started using a nipple shield on postpartum Day 2, and baby nursed with a nipple shield for the remainder of the study. For data collection purposes this baby was considered non-latching.

Another participant's newborn was latching for the first few days post birth but on postpartum Day 3 started refusing the mother's breast. This newborn had a 13% weight loss by postpartum Day 2, possibly indicating a lack of sufficient milk transfer to the newborn despite milk maturing as expected. This participant started supplementing with formula using a bottle.

One newborn struggled to latch on postpartum Day 3, refused to latch on Day 4 and 5 and then latched again for Days 6-8, refusing again on Day 9. This participant had a "slow to increase supply" and needed to use formula throughout the duration of this study.

Another participant had everted round nipples after feeding with no damage to nipple tissue until breast changes on Day 4 when visible damage was noted. At that time, the participant presented with extremely hard full breasts and reported difficulties in latching. Her edema rating had increased from an average of 0.5 to 1.25 (unfortunately this was one of the four participants whose edema was measured visibly rather than by palpation, and the researcher believes that edema ratings would have been higher if measured by palpation). This participant's newborn had difficulty latching on postpartum Days 4, 5 and 6.

Overall these measurements did not appear to be useful in understanding postpartum breast swelling as there were a variety of reasons for difficulty with latching, not all related to breast swelling. These measurements would be recommended for a study looking at the effects of breast swelling on nipple and breast pain. See Appendix U, Tables 8 and 9 for results.

Pumping and Supplementing

Participants were asked to keep track of how many times per day they extracted milk from their breasts (either by hand or with a breast pump). Participants were also asked how often and how much they supplemented their newborns with either breast milk or formula.

Three participants were pumping and supplementing on a regular basis by postpartum Day 2, then giving full replacement feeds by postpartum Day 3 (i.e., participants were either not feeding at breast or assumed no transfer of milk by baby while breastfeeding). One participant used hand expression from birth, started using a breast pump on postpartum Day 3, and only used expressed breast milk to supplement her newborn. The other two participants required

formula due to a "slow to increase" milk supply. This measurement did not appear to be useful in this study, due to the fact that changes in postpartum breast swelling did not appear to be affected by pumping and supplementing.

Research Questions and Data Analysis

1. **The association between the amount and timing of IV fluids given during labour and any postpartum breast, areola, and nipple changes in the first 10 days postpartum.**

Due to the small sample size in this pilot study, the researcher was unable to use inferential statistics to determine whether there is an association between the amount and timing of IV fluids given during labour and postpartum breast swelling. The researcher completed a linear regression model to determine if having IV fluid in labour had an influence on postpartum breast edema.

All 17 data sets were used for this analysis, even though 4 of the data sets may not have provided accurate readings, increasing the risk of a Type II error. Data was analysed using statistical software, SPSS v 21. The linear regression model showed a moderate effect of statistical significance between participants who received an IV (M = .75, SD = .43, n = 179) and average edema per day (M = 1.35, SD = 1.23, n = 179) with r = .437 and $p < .001$. *R squared* = .19, indicating that 19% of variance in edema can be accounted for by IV fluids.

In a larger study, the researcher would complete Pearson r or Spearman's rho to determine if there is a correlation between the amount and timing of IV fluids and breast swelling. Linear regression would be modelled to determine if amount or timing of maternal IV fluids were a predictor of breast swelling, and results could be presented in a scatter plot.

2. **The association between the amount and timing of IV fluids given during labour and the timing of lactogenesis II and the baby's ability to latch.**

Based on this pilot study, the researcher would not recommend pursuing data on a newborn`s ability to latch. There did not appear to be a dose effect of IV fluids on the timing of lactogenesis II, though this finding might be due to the small sample. For all participants who had IV fluids, there was marked breast edema in the postpartum period and some of those participants did have difficulties with breastfeeding. In a larger study, the researcher would track maternal IV fluids closely and the increased power would probably show a correlation between IV fluids and onset of lactogenesis II using Pearson r or Spearman's rho. A scatter plot would be useful to show associations. A logistic regression should determine whether the amount or timing of IV fluids given during labour are predictors of the timing of lactogenesis II.

3. **The association between postpartum breast, areola, and nipple swelling and onset of lactogenesis II**

Participants described feelings of fullness, firmness, and tenderness typically associated with lactogenesis II. This fullness appeared to be of internal nature as the researcher's edema ratings did not always coincide with a mother's perception of firm breast tissue. This difference of assessment was most noticeable in participants who did not have IV fluids.

In a larger study, the researcher would use multiple linear regression to determine whether postpartum breast swelling is a predictor of onset of lactogenesis II.

4. **The association between postpartum breast, areola, and nipple swelling and a baby's ability to latch**

One participant was able to directly relate swelling in her breast to the difficulty her newborn experienced in latching. For the other participants who had difficulty with

breastfeeding other factors seemed to be implicated. Although this pilot study indicates it is not worthwhile to pursue collecting data about latching in a larger study looking at maternal IV fluids and breast swelling, a separate study looking at factors interfering with a baby`s ability to latch would be recommended. Such a research study should take into account amount of IV fluids and look more fully look at the possible association between breast swelling and a baby's ability to latch.

5. **Signs and symptoms specific to postpartum breast edema.**

Breast edema appeared to present as more of an external fullness that could more easily felt by the researcher than fullness associated with lactogenesis II. Swelling from lactogenesis II appeared to be more an internal fullness mothers were able to feel. Tissue displacement associated with breast edema was easily palpated using routine procedure for assessing edema. Breast milk is produced deep in breast tissue, while interstitial fluid can be found in the tissues directly under the skin. This difference may be the way to help distinguish between edema and engorgement. If engorgement is described as being the fullness associated with lactogenesis II, then breast edema can be identified as a separate condition.

Chapter 5 - Discussion and Conclusions

This pilot study determined that a larger observational cohort study about the influence of IV fluids given in the perinatal period on postpartum breast swelling would be feasible and worthwhile. The preliminary results suggest maternal IV fluids increased postpartum breast swelling and the increased swelling produced breast and nipple pain. To support breastfeeding women this phenomenon needs to be studied.

Clinicians need evidence to understand this phenomenon and to develop strategies to help breastfeeding women. There is a risk that mothers may be experiencing edema but mistaking it for lactogenesis II, which might give them a false sense of security regarding milk production or transfer by their newborns. This pilot study identified variables that would be useful to collect, but it also demonstrated how labour intensive data collection proved to be.

Knowledge Gathered from the Pilot Study

Variables such as IV fluids (timing and amount), breast edema, peripheral limb edema, maternal breast self assessment, lactogenesis II, and daily newborn weights all proved to be useful in understanding the process of postpartum breast swelling. On the other hand, MICAM, nipple and areola diameter and height, latching, nipple shape on delatching, and pumping and supplementing did not appear to be useful. The results of this study could have benefitted from measuring peripheral limb edema to determine if peripheral limb edema and breast edema resolve simultaneously and to help us understand the development and resolution of edema more fully.

In order to get baseline data, women were recruited in labour and the researcher did not foresee how many participants would not meet the inclusion criteria following the birth. In

doing a larger study, it would be beneficial to anticipate an attrition rate of 30% to accommodate for exclusion factors such as cesarean section or illness in mother or newborn.

Challenges in Measuring Variables

Accurate tracking of IV fluids proved to be more challenging than expected and a larger study should look at ways this information can be captured. Understanding how health care providers view IV fluids may be useful in designing a tool for this purpose. If health care providers view IV fluid as medication, then charting may be able to be done on a medication tracking sheet, but if IV fluids are seen as benign and an expected part of care during labour, recording may prove to be more difficult.

While assessing nipple height for the purpose of understanding the role of IV fluids on postpartum breast swelling was not useful, a separate study looking at nipple height with regards to pumping may be of interest.

Regarding feasibility of data collection in a larger study, changes to the procedures used for the pilot would be recommended. The daily visit for data collection was onerous, and the same protocol would be expensive for a larger study. Data collection took 15 to 20 minutes per visit, and travel time was between 30 minutes and 60 minutes both directions. Travel costs were not calculated for this pilot study. Funding for a larger study should account for the research assistants' travel and visit time.

Based on this pilot study, the researcher would recommend that peripheral limb edema, maternal breast self assessment, and newborn weights should be recorded daily by the participants. Ideally, with appropriate funding, researcher-based data collection with home visits daily should be carried out, but it could continue at a reduced rate. The researcher recommends a minimum of the following time points: a) while in labour to determine baseline measurements;

b) Day 3 to coincide with the timing of lactogenesis II; c) Day 6 (the expected time frame for engorgement to be resolved); d) Day 9 which marked the end of this study and many mothers still had high levels of edema; and e) Day 12 to determine if edema has resolved by that time. Participant-collected data would be picked up at the final visit.

Participant Feedback

Participants commented on the wording of the 6 point maternal breast self assessment scale, stating that level 2 (slight change) did not adequately describe what they were experiencing. An addition of the terms "soft and tender" to 2 - "slight change" might be warranted based on these findings.

Participants also wanted the researcher to know how their nipples felt; they wanted to talk about their breastfeeding experiences if they were having difficulty. It might be useful if doing further research on breast changes to track nipple changes. Participants were appreciative of the daily access to the researcher, indicating a possible need for additional postpartum support structures to be put in place. Research is needed to identify if this additional support would be beneficial for mothers to better meet their breastfeeding goals.

Strengths of the Pilot Study

Strengths of this pilot study included: prospective data collection, a determination of variables worth measuring, insight gained by observations, and conclusively determining that a larger study is warranted.

Prospective data collection was completed for 10 days by the researcher ensuring internal validity. This intense data collection period helped the researcher understand the daily changes to breast tissue and how it influenced maternal comfort and breastfeeding. Prospective data collection is considered more rigourous than retrospective data collection (Nagurney, Brown,

Sane, Weiner, & Chang, 2005). For a larger study prospective data collection would be recommended even with normally charted variables such as IV fluids.

This pilot study provided the opportunity to test several measurements of variables to determine which of these are useful and which are unnecessary for the purposes of a larger study on the same topic. Some variables provided insight into the research question while others did not. Discovering which variables are worth measuring in a larger study is a significant contribution from this pilot study.

Another strength of this pilot study is that it provided the researcher with unexpected insight into the research question. Certain ideas regarding postpartum breast swelling were not supported, for example nipples being pulled flatter by swollen breasts was not evident. Also insight was gained about data collection regarding measuring edema by palpation.

This pilot study also determined conclusively that a larger study looking at the effects of IV fluids on postpartum breast swelling is warranted. Feasibility of data collection methods and protocols was established.

Limitations of the Pilot Study

Limitations of this pilot study included the homogeneity of the sample, a single data collector, and a change in how edema was measured during the study. For a larger study, these limitations should be taken into account.

One of the limitations of this pilot study was the homogeneity of the sample. For a larger study to have generalizability a more heterogeneous sample would be required. A larger study should include participants who are multiparous, have had c-sections, or have had an induced labour.

All data measurements were done by the same researcher, so no protocol was trialed with more than one person doing measurements. Consistency among multiple data collectors was not established.

Breast and areola edema were measured differently with the first 4 participants than with the remaining 13 possibly leading to measurement inaccuracies. For a larger study, edema should be measured using the palpation method for each participant.

Questions to Consider in a Larger Study

Participants noted an internal fullness associated with lactogenesis II that felt quite different from edema of breast tissue as palpated by the researcher. In a larger study, it may be worth exploring whether mothers can be taught to distinguish between this internal feeling of fullness and an external feeling of fullness. In short, is it possible to teach mothers to measure edema in breast tissue accurately and consistently?

Another area worth studying is whether maternal age or parity affects how IV fluids influence breast swelling. Are younger mothers better able to cope with IV fluids administered during labour? Do multiparous women overcome the negative effects of breast edema (i.e., delayed lactogenesis II)?

Peripheral limb edema should also be measured to determine if breast edema resolves within the same timeframe as peripheral limb edema and to help researchers understand edema in the postpartum period more fully.

Other variables to consider measuring in a larger study would be jaundice levels and breastfeeding rates to determine if IV fluids are related to jaundice levels and breastfeeding outcomes (i.e., duration and exclusivity). Inclusion of multiparous participants and participants

who have had a c-section would also be useful in more fully understanding the effects of IV fluids on postpartum breast edema.

Implications

Implications for Nursing Practice

Given the potential detrimental effects of breast swelling, birthing suite nurses working with women in labour should be aware of the detrimental effects of IV fluids. IV fluid administration should be closely monitored whether pumps are used or not. It is expected that a larger study would provide guidance for policy and procedures relating to the safe use of IV fluids.

Postpartum nurses should be aware that IV fluids given to women during labour may have an influence on breast swelling in the first few weeks postpartum. Anticipatory guidance should be given to women prior to discharge from hospital, as the timing of breast swelling suggests that it would occur after discharge from hospital.

A general statement regarding engorgement is provided in the "Breastfeeding Matters" (2011) booklet which is given to women in Ontario after giving birth. This advice appears to be simplistic, and women may require more detailed information to adequately deal with postpartum breast swelling in the postpartum period.

For example, Breastfeeding Matters states that swelling (engorgement) lasting for 24 to 48 hours is normal, and it suggests that prevention of engorgement by breastfeeding at least 8 times per day feeding at both breasts with each feeding and breast massage is the best approach (Best Start, 2011). For treatment of engorgement the recommendation is to feed frequently, to use ice or cold compresses between feeds, to express milk until breasts are soft, and to get help if baby is unable to latch (Best Start, 2011). No mention of use of heat is made, although this is a

recommendation made in various breastfeeding textbooks (Lawrence &Lawrence, 2011 and Riordan, 2005), and no mention of reverse pressure softening or areola compression is made, again a recommendation for overly swollen breasts (Cotterman, 2004; Miller & Riordan, 2004).

Women also need to be made aware that not all postpartum breast swelling is associated with breast milk production, Lawrence & Lawrence (2011) state that engorgement is caused by increased vascularity, increased milk production, and edema. Ensuring women know where to receive breastfeeding help in the postpartum period is essential.

Implications for Nursing Research

This pilot study indicates the need for further research about the influence or effect of IV fluids given to women during labour and birthing, as well as the feasibility of such a larger study. This pilot study found clear differences in firmness of breast tissue, in the postpartum period, between participants who had IV fluids and those who did not. A larger study should take into account the variables that proved to be useful (i.e., IV fluids, breast and areola edema, peripheral limb edema, maternal breast self assessment, lactogenesis II, and newborn weight measurement), and how those measurements should be taken (e.g., palpation for edema measurement).

Clinical practice has changed rapidly over the years, however, research evidence is not available to support change in some areas and ensure that negative outcomes from newer practices are minimized. Given the increased use of epidurals and IV fluids, further research is needed to increase understanding about how maternal IV fluid administration can influence breast swelling. Recent studies have highlighted some negative outcomes mothers and babies experience in the early postpartum period due to IV fluids (Noel-Weiss, et al., 2011; Chantry et al. 2011). If the results from these studies and this pilot study can be reproduced and validated in larger studies, it would provide strong evidence to guide clinical practice and increase healthcare

providers' knowledge about IV fluids. While the administration of IV fluids may be necessary (Hofmeyr et al., 2010, Cyna et al. 2006), nursing care should include instruction on what mothers can do to minimize the postpartum sequelae of IV fluids. Further research is required to determine which interventions (e.g. cold packs, cabbage leaf applications, heat, massage, and reverse pressure softening) would be most useful.

Implications for Nursing Policy

There are many ways for nurses to become involved in policy development. Gebbie, Wakefield, and Kerfoot (2000) suggest working on three levels: individual activity, organizational activity, and educational activity. One suggestion they make at the individual level is to link research to politics and policy (Gebbie et al., 2000). The idea for this study originated from working with women in the postpartum period and having questions about their experiences. Clinical practice led to this research which, in turn, could lead to further research and potentially to policy changes. Policy changes regarding the administration of IV fluids would be a possible result of a larger study and such a policy change for women in labour may improve outcomes in the postpartum period. Once these findings have been validated by a larger study, nursing policy regarding the use and administration of IV fluids should be assessed. Obstetricians and pediatricians should be made aware of the negative outcomes associated with IV fluid administration and every effort should be made to reduce the use to that of only what is medically indicated. Policy changes that may result are that IV fluids should be run through pumps, should be monitored closely or a saline lock could be put in place rather than running fluids to keep the vein open. Policy regarding postpartum care may also change as more ways are discovered to help relieve postpartum breast edema and to provide the anticipatory guidance given to mothers.

Conclusions

Breastfeeding is physiologically normal behaviour for mammals, yet women encounter challenges associated with breastfeeding that may lead them to wean prematurely. One of the main reasons mothers give for weaning is breast and nipple pain associated with breastfeeding. Postpartum breast swelling can aggravate this pain. As maternity practices have changed, and women receive more IV fluids than ever before (Hofmeyr et al., 2010), research is lacking to support the use of IV fluids and to understand the potential side effects of IV fluid administration.

To support breastfeeding women, clinicians need evidence about the effects of maternal IV fluids in the postpartum period. This pilot study was completed to assess whether there might be a relationship between breast swelling and maternal IV fluids and to decide if the results indicate that further research is warranted. Seventeen participants were included in this study to assess postpartum breast swelling and its relationship to IV fluids given in and after labour and birthing. In the end, the findings demonstrated that mothers who received IV fluids in labour and postpartum had higher levels of breast edema. The results merit a larger research study.

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Appendix A
Thesis Proposal Approval

ÉCOLE DES SCIENCES INFIRMIÈRES
Programmes des études supérieures

uOttawa
Faculté des sciences de la santé
Faculty of Health Sciences

SCHOOL OF NURSING
Graduate Programs

Approbation du projet de thèse – Thesis Proposal Approval

Nom de l'étudiante* / Student Name	Programme / Program
SONYA MYLES	MSN

Directrice de thèse / Thesis Supervisor: JOY NOEL WEISS — Nom / Name

Co-directrice de thèse/ Thesis Co-supervisor/ (s'il y a lieu / if applicable): — Nom / Name

[redacted] — Signature

Autres membres du comité de direction de thèse / Other Thesis Committee Members

Nom / Name

KERMALINE JEAN COTTERMAN — Nom / Name

Wendy Peterson — Nom / Name

SANDRA DUNN — Nom / Name

[redacted]

Rapport d'évaluation / Evaluation Report

☒ La proposition est acceptée / Proposal accepted

☐ La proposition devra être soumise à nouveau aux membres du comité, avec révisions, avant d'obtenir l'approbation finale / Proposal must be resubmitted to Committee members, with revisions, to obtain final approval.

☐ La proposition est rejetée. L'étudiante doit refaire le processus d'approbation à nouveau. Proposal is rejected. The student must complete the thesis proposal approval process again.

Approuvé par /: Approved by [redacted] grams — Date: Jun 14/12

Date: 11/07/12

* le feminin englobe le masculin

09/11/2007

Appendix B

Table B1

Search Terms

Search terms	Number of studies found	Number of studies included	Number of studies excluded	Reasons for exclusion
(Intravenous fluids and effects of).m_titl.	16	1	15	Not relevant to area of interest
(Intravenous fluids and labor).m_titl	2	0	2	Not relevant to area of interest
(Intravenous fluids and labour).m_titl.	4	0	4	Not relevant to area of interest
(Intravenous fluid and lactogenesis).m_titl	0	0	0	
Lactogenesis II.m_titl.	11	0	11	Not relevant to area of interest
(Intravenous fluid and lactogenesis II).m_titl.	0	0	0	
(Involution and breast).m_titl.	30	0	30	Not relevant to area of interest
(Breast and edema).m_titl.	80	1	79	Not relevant to area of interest
Understanding edema.m_titl.	1	1	0	
Computerised breast measurements.m_titl.	2	0	2	Not relevant to area of interest
On the causation of edema.m_titl.	1	1	0	
Occurrence of breast engorgement.m_titl.	1	1	0	
Engorgement.m_titl.	230	6	224	Not relevant to area of interest
Breast growth.m_titl.	6	0	6	Not relevant to area of study
(Breast growth and pregnancy).m_titl.	1	1	0	
(Oxytocin and antidiuretic).m_titl.	38	1	37	Unable to access Not relevant to area of interest
Total	423	13	410	

Appendix C

Table C1: Literature Review Table

Table C1

Literature Review Table

Reference	Author's purpose	Method	Sample size	Strengths/Limitations	Results/conclusions
Chantry, C., Nommsen-Rivers, L., Peerson, J., Cohen, R., & Dewey, K. (2011). Excess weight loss in first-born breastfed newborns relates to maternal intrapartum fluid balance	To describe weight loss in predominately breastfed babies and to identify risk factors for excessive weight loss.	Prospective study Observational study Convenience sample Data collected prenatally, within 24 hours of birth, on days 3 and 7 postpartum	n = 448	S = Relatively large sample size Diverse population L = Intrapartum fluid status on 63.8% of study population Infant weights done on day 3 and 7 No basis for definition of excessive weight loss (>10% on day 3) Inadequate capturing of infant breastfeeding Only 9% of mothers had no analgesia during labour	Excessive weight loss associated with maternal intrapartum fluid balance (p=0.0042) Excessive weight loss associated with a delay in lactogenesis II (p=0.0002)
Chapman, D. J., & Perez-Escamilla, R. (2000). Maternal perception of the onset of lactation is a valid, public health indicator of lactogenesis stage II	To validate a mothers perception of lactogenesis II as being a marker for lactogenesis II	Data collected as part of an RCT on the effects of pumping on lactogenesis II	n = 60	S = data collection 3x/day until LII L = small sample size Main study was on pumping and its effect on LII in women having a c-section	Mothers are able to determine correctly a delay in onset of lactogenesis II

Cox, D., Kent, J. C., Casey, T., Owens, R. & Hartmann, P. (1999). Breast growth and the urinary excretion of lactose during human pregnancy and early lactation: Endocrine relationships.	To look at growth and functionality of the human breast during pregnancy, to relate these changes to endocrine status and to relate initial breast size and breast growth to milk production at 1 month postpartum	Convenience sample Observational study	n = 8	S = detailed longitudinal study lasting 1 month L = small sample size	Milk production at 1 month not related to breast growth Milk production positively related to breast storage capacity
Geissler, N. J. (1967). An instrument used to measure breast engorgement.	Study done to validate the use of the pressure gauge as a tool to measure breast engorgement.	Observational study Convenience sample Measurements taken within 24 hours postpartum (pp) and then again between 64 and 82 hrs pp	n = 10	S = detailed data collection L = small sample size Tests of statistical significance not done Mixed sample of multiparous, primiparous, preterm infants, term infants	Device difficult to use due to size and structure
Gonik, B., & Cotton, D. B. (1984). Peripartum colloid osmotic pressure changes: Influence of intravenous hydration.	To determine if there is a relationship between intravenous fluids administered during labour and colloid osmotic pressure	observational study convenience sample Blood samples collected on admission and again 8 to 24 hours post delivery	n = 28 16 in IV group 12 in birthing room group	S = detailed data collection Presence of a control group L = small sample size	Differences in colloid osmotic pressure between groups significant (no p value given) No degree of reduction in colloid osmotic pressure in birthing room group, 5/16 in IV group had decreased osmotic pressure below 15.6mmHg

Gonik, B., Cotton, D., Spillman, T., Abouleish, E., & Zavisca, F. (1985). Peripartum colloid osmotic pressure changes: Effects of controlled fluid management.	To determine the effects of intravenous fluids on colloid osmotic pressure in labouring women	Prospective fluid controlled study of serially measured colloid osmotic pressure changes in the peripartum period Convenience sample Pre-test, post-test design, measurements taken at pre treatment, 10 minutes post treatment, then 6 and 24 hour post c-section	n = 17 all c/s moms	S = detailed data collection L = small sample size	Colloid osmotic pressure dropped after pre-op bolus of intravenous fluids given $p<0.01$ Lowest colloid osmotic pressure at 6 hour postpartum significantly lower with $p<0.05$ At 24 hours slight upward trend in colloid osmotic pressure noted
Holte, K., Jensen, P., & Kehlet, H. (2003). Physiologic effects of intravenous fluid administration in healthy volunteers.	To investigate the physiological effects of intravenous fluid infusion in a healthy population	Crossover study Randomized design Double-blinded design 40ml/kg Ringers Lactate infused over 3 hours	n = 12	S = detailed data collection L = older study population than mothers in childbearing years Small sample size	Decreased pulmonary function lasting 8 hours post infusion A weight gain of .85kg persisted for over 24 hours post infusion
Humenick, S., Hill, P. D., & Anderson, M. A. (1994). Breast engorgement: Patterns and selected outcomes.	To explore women's experiences of engorgement and to look for correlation of pattern with breastfeeding outcomes	Longitudinal descriptive study Used a 6 point scale (adapted from 4 point scale used by Moon and Humenick) Mothers self rated breasts twice a day, in the morning and in the evening	n=114	S = detailed data collection lasting 14 days L = did not take IV fluids or breast edema into account	Engorgement is experienced differently among women 4 patterns were identified

Humenick, S. S., Mederios, D., Wreschner, T. B., Walton, M. B., & Hill, P. D. (1994). The maturation index of colostrum and milk (MICAM): A measurement of breast milk maturation.	To develop the maturation index of colostrums and milk (MICAM) 4 phase study	Convenient sample 4 phase study Phase 1: random assignment 3 breast milk samples given twice daily, am and pm for 2 weeks Phase 2: Teaching and post test measurements Phase 3: Daily samples of breast milk until type 5 appeared Phase 4: Random sample, part of a larger random sample Time and duration of breastfeeds tracked for 7 days, breast milk samples collected twice a day for 4 days postpartum, then once a day for days 5 to 10 postpartum	Phase 1 N = 19 Phase 2 N = 10 Phase 3 N = 35 Phase 4 N = 120	S = acknowledges that milk maturation is not a linear process when looking at individual women Detailed data collection L = large amount of missing data	Phase III: MICAM is a valid marker of milk maturation Phase IV: The sooner the feed after delivery the sooner the milk matured, significant on days 4,7,10 p = .05 to .021 n 80 to 89 Increased number of feeds appears correlated to quicker milk maturation, significant on days 3 to 6 p = .005 -.001, n=61 to 69 Total minutes at breast, more time at breast appeared correlated with quicker milk maturation on days 3 to 6, p=.02 to .03, n 18 to 21
L'Esperance, C. M. (1980). Pain or pleasure: The dilemma of early breastfeeding.	To understand causes and effects of nipple pain Interview in first 24 hours	Longitudinal descriptive study Studied over first 96 hours postpartum Convenience sample	n=112	S = detailed data collection L = did not look at effect of IV fluids Only followed mothers for 96 hours	Engorgement related to nipple pain at 48 hours p = .05and at 96 hours p=.01

Liggins, G. C. (1963). Antidiuretic effects of oxytocin, morphine and pethidine in pregnancy and labour.	To determine whether drugs commonly used during labour add to oliguria of labour	Convenience sample Within subjects design Diuresis achieved with a low rate continuous IV of 5% dextrose, after two hours intervention administered	Oxytocin n = 19 Pethidine n = 8 Morphine n = 7	S = detailed data collection L = small sample size	Oxytocin had an antidiuretic effect Sodium and potassium secretion fell while oxytocin was being administered Pethidine had an antidiuretic effect lasting about 2.5 hours Morphine had an antidiurtic effect lasting about 7 hours
Moon, J. L., & Humenick, S. S. (1989). Breast engorgement: Contributing variables and variables amenable to nursing intervention.	To investigate if breast engorgement is associated with a delay in initial breastfeeding, shorter duration of breastfeeding, infrequent breastfeeding, supplementation and slow milk maturation	Longitudinal descriptive study Convenience sample Mothers asked to self monitor breast changes q 6 hourly for 78 h	n = 54	S = triangulation of feeding data Concrete suggestions for further research L = only followed participants while in hospital Convenience sample Did not look at effect of IV fluids	Earlier feeds led to greater engorgement p =.009 at 48 hours Frequency of breastfeeds significantly correlated with engorgement at 54 hours for primiparous mothers p = .007 increased length of feeds, less engorgement p = .05 (primups) p = .02 (multips) p = .04 (vag births)
Newton, M., & Newton, N. R. (1951). Postpartum engorgement of the breast	To explore the concept of engorgement	Observational study Random sample of a larger convenience sample Breast engorgement and milk production measured once at an average of 67 hours postpartum	n = 47	S = Study done prior to routine use of IV fluids so may give a more accurate picture of true engorgement L = limited data collection	Concluded milk retention is primary cause of engorgement

Noel-Weiss, J., Woodend, A. K., Peterson, W. E., Gibb, W., & Groll, D. L. (2011). An observational study of associations among maternal fluids during parturition, neonatal output, and breastfed newborn weight loss.	To determine if there is a relationship between intravenous fluids administered during labour and newborn weight	Observational prospective cohort study Convenience sample IV fluids collected from admission to birth Baby weights twice daily 72 hours after birth, then daily until 14 days postpartum Infant output measured for 3 days	n = 109	S = prospective data collection Detailed data collection L = missing data in first few weeks Not all urine and stools captured by weight	Significant positive correlation between total intravenous fluids and delayed lactogenesis II
Olza Fernández, I., Marín Gabriel, M., Malalana Martínez, A., Fernández-Cañadas Morillo, A., López Sánchez, F., & Costarelli, V. (2012). Newborn feeding behaviour depressed by intrapartum oxytocin: A pilot study	To study the effect of oxytocin given during labour on primitive neonatal reflexes and on breastfeeding	Prospective Observational pilot study Convenience sample	n = 20	S = detailed data collection L = small sample size No control group All participants had epidural analgesia	Higher doses of oxytocin administered during labour appeared to decrease sucking (p=0.03) Mothers receiving lower doses of oxytocin administered during labour were more likely to be breastfeeding at 3 months (p=0.04)

Riedel, L. J. (1994). Unpublished thesis.	To validate the use of the breast engorgement monitor To determine if there are patterns to engorgement To determine correlation between various forms of measurements for engorgement	Longitudinal descriptive study Convenience sample Measuring breast engorgement for 10 days postpartum	n= 6	S = identified variables not worth measuring All mothers primiparous Data collection lasted 10 days L = small sample size One participants data excluded from analysis as lost to follow up on day 6/10	Subjective ratings correlated highest with breast tension measurements
Roberts, K. L., Reiter, M., & Schuster, D. (1998). Effects of cabbage leaf extract on breast engorgement.	To determine the effects of cabbage leaf extract on breast engorgement	Double blind experiment Pretest/post-test design Convenience sample Randomized group assignment Measurements taken 3 times, baseline and then 2 post test measurements Study done postpartum, but how many days postpartum is not mentioned	n = 39 (21 in experimental group and 18 in control group)	S = control group present L = small sample size	They found the Roberts durometer best instrument to measure engorgement Chest measurements not effective Subjective measurements susceptible to placebo effect Frequent breastfeeding found to be most effective

Appendix D

Research Ethics Board Approvals

File Number: H08-12-09 **Date (mm/dd/yyyy):** 11/14/2012

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

Ethics Approval Notice

Health Sciences and Science REB

Principal Investigator / Supervisor / Co-investigator(s) / Student(s)

First Name	Last Name	Affiliation	Role
Joy	Noel-Weiss	Health Sciences / Nursing	Supervisor
Sonya	[redacted]-Myles	Health Sciences / Nursing	Student Researcher

File Number: H08-12-09

Type of Project: Master's Thesis

Title: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
11/14/2012	11/13/2013	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:

Recruitment and data collection may begin within the Halton Healtcare Research Ethics Board (permission letter received on November 14, 2012).

550, rue Cumberland 550 Cumberland Street
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada
(613) 562-5387 • Téléc./Fax (613) 562-5338
http://www.research.uottawa.ca/ethics/index.html
http://www.recherche.uottawa.ca/deontologie/index.html

File Number: H08-12-09 **Date (mm/dd/yyyy):** 11/14/2012

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

This is to confirm that the University of Ottawa Research Ethics Board identified above, which operates in accordance with the Tri-Council Policy Statement and other applicable laws and regulations in Ontario, has examined and approved the application for ethical approval for the above named research project as of the Ethics Approval Date indicated for the period above and subject to the conditions listed the section above entitled "Special Conditions / Comments".

During the course of the study the protocol may not be modified without prior written approval from the REB except when necessary to remove subjects from immediate endangerment or when the modification(s) pertain to only administrative or logistical components of the study (e.g. change of telephone number). Investigators must also promptly alert the REB of any changes which increase the risk to participant(s), any changes which considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project and safety of the participant(s). Modifications to the project, information/consent documentation, and/or recruitment documentation, should be submitted to this office for approval using the "Modification to research project" form available at: http://www.research.uottawa.ca/ethics/forms.html

Please submit an annual status report to the Protocol Officer four weeks before the above-referenced expiry date to either close the file or request a renewal of ethics approval. This document can be found at: http://www.research.uottawa.ca/ethics/forms.html

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5387 or by e-mail at: ethics@uOttawa.ca.

Signature:

[redacted]

Riana Marcotte
Protocol Officer for Ethics in Research
For Daniel Lagarec, Chair of the Sciences and Health Sciences REB

550, rue Cumberland
Ottawa (Ontario) K1N 6N5 Canada
550 Cumberland Street
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http://www.research.uottawa.ca/ethics/index.html
http://www.recherche.uottawa.ca/deontologie/index.html

Halton Healthcare

November 9, 2012

Ms. Sonya [redacted]-Myles

[redacted]

Dear Ms. Myles

Re: Research Study: "The Relationship Between Intravenous Fluid and Breast Changes in the Post-Partum Period"

We are pleased to inform you that the Board of Directors, at its meeting of November 8, 2012 approved the research study: "The Relationship Between Intravenous Fluid and Breast Changes in the Post-Partum Period" at Halton Healthcare Services.

We wish you success in your research endeavours and look forward to continued follow-up regarding progress with this study.

[redacted]

Lorne Martin, MD CCFP (EM)
Chief of Staff
Halton Healthcare Services

Appendix E

Research Ethics Board Ammendments

From: Riana Marcotte [redacted]
Sent: March 22, 2013 5:28 PM
To: SONYA MYLES
Cc: Joy Noel-Weiss
Subject: Ethics file H08-12-09: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Dear Professor Noel-Weiss and Ms. [redacted]-Myles,

Thank you for submitting the permission letter from Halton Healthcare for your research project entitled "The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period" (File H08-12-09).

The REB has approved the following modifications:

Recruitment process: recruitment posters will now be displayed in obstetricians and midwives' offices to inform women about the study prior to their arrival at the hospital.

These changes are approved and are now covered under the ethics certificate valid until November 14, 2013.

If you have any questions or comments, please do not hesitate to contact me via email or at extension [redacted]

Best regards,

Riana

Riana Marcotte

Protocol Officer for Ethics in Research

Office of Research Ethics and Integrity

University of Ottawa

From: Riana Marcotte [redacted]
Sent: March 22, 2013 5:45 PM
To: SONYA MYLES
Subject: RE: Ethics file H08-12-09: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Hello Sonya,

Sorry about the oversight.

Yes, you may start your recruitment at the Oakville Trafalgar Memorial Hospital as it has been approved by the Halton Healthcare Services.

Best,
Riana

From: SONYA MYLES [redacted]
Sent: March 22, 2013 5:37 PM
To: Riana Marcotte
Subject: RE: Ethics file H08-12-09: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Hi Riana

I was wondering about recruitment at Oakville Trafalgar Memorial Hospital, which was part of my amendment application, am I approved to start recruitment at the additional site?

Halton Healthcare

March 15, 2013

Ms. Sonya [redacted]-Myles
[redacted]

Dear Ms. Myles

Re: Research Study: "The Relationship Between Intravenous Fluid and Breast Changes in the Post-Partum Period"

We are pleased to inform you that the Board of Directors, at its meeting of March 14, 2013 approved the amendment to your research study: "The Relationship Between Intravenous Fluid and Breast Changes in the Post-Partum Period" to include the Oakville site, Halton Healthcare Services.

We wish you success in your research endeavours and look forward to continued follow-up regarding progress with this study.

Sincerely,

[redacted]
Halton Healthcare Services

Georgetown Hospital • Milton District Hospital • Oakville-Trafalgar Memorial Hospital

uOttawa

[redacted]

Ethics file H08-12-09: The relationship between intravenous fluid and breast changes in the post-partum period

Riana Marcotte <[redacted] Mon, Sep 30, 2013 at 11:14 AM
To: Joy Noel-Weiss [redacted]

Dear Professor Noel-Weiss and Ms. [redacted]-Myles,

Thank you for submitting the approval letter from Halton Healthcare for your research project entitled **"The relationship between intravenous fluid and breast changes in the post-partum period" (File H08-12-09).**

The REB can now grant approval for the following modifications:

Research instruments: New measurements will now be included to measure edema in participants' hand and right ankle and foot. New data collection sheets have been submitted.

Consent forms/Information sheets: Consent and patient information forms have been revised to include the new measurements.

These modifications have been approved and are now covered under the **certificate valid until November 13, 2013.**

If you have any questions or comments, please do not hesitate to contact me via email or at extension [redacted]

Best regards,

Riana

Riana Marcotte

Protocol Officer for Ethics in Research

Office of Research Ethics and Integrity

University of Ottawa

[redacted]

[redacted]

Halton Healthcare

September 19, 2013

Ms. Sonya [redacted] Myles

[redacted]

Dear Ms. Myles

Re: Research Study: "The Relationship Between Intravenous Fluid and Breast Changes in the Post-Partum Period"

We are pleased to inform you that the Board of Directors, at its meeting of September 12, 2013 approved the amendment dated May 22, 2013 to the research study: "The Relationship Between Intravenous Fluid and Breast Changes in the Post-Partum Period" with Sonya Myles at Halton Healthcare Services, Milton and Oakville Sites.

We wish you success in your research endeavours and look forward to continued follow-up regarding progress with this study.

Sincerely,

[redacted]

Chief of Staff
Halton Healthcare Services

GEORGETOWN • MILTON • OAKVILLE **HOSPITALS**

Appendix F

Participant Information Sheet and Consent Form

uOttawa

Université d'Ottawa
Faculté des sciences de la santé
École des sciences infirmières
University of Ottawa
Faculty of Health Sciences
School of Nursing

Patient Information Sheet and Consent Form

Title of the Study: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Researcher: Sonya Myles - [redacted]

Thesis Supervisor: Professor Joy Noel-Weiss – [redacted]

Introduction

You are being asked to participate in a research study which will be conducted in English only. The study is part of Sonya Myles' Masters in Nursing thesis. The research study will aim to understand the relationship between intravenous fluids given during labour and postpartum breast changes and breastfeeding. Twenty five women will be recruited for this study. You may ask the researcher any questions you wish about any part of the study.

Background, Purpose, and Design of the Study

Postpartum breast engorgement and edema can cause nipple pain and damage which have been identified as reasons women stop breastfeeding. This study will try to understand the role of intravenous fluids on breast swelling following birth and how this swelling affects breastfeeding.

Study Procedures

- Sign an informed patient consent to participate in the study (you will keep a copy for your records).
- Complete short demographic sheet when you consent to be in the study (about 5 minutes).
- Baseline measurements of nipple diameter, areola diameter, nipple height, nipple and areola shape by photograph, edema rating, and maternal breast self assessment will be taken before your baby's birth, following the birth of your baby, and then daily for 9 days.
- As this study will last longer than your anticipated hospital stay, home visits will be required at a time that is convenient to your family. Visits are expected to take 15 to 30 minutes.

613 562-5473
613 562-5443
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Ottawa ON K1H 8M5 Canada
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- Feeding your baby should not be interrupted or held off to accommodate the research, the researcher will call you each morning to set up a time that is approximately 2 hours from the start of your baby's last feeding. If your baby is hungry in the time between the phone call and the visit, you should feed your baby.

Data collection

1. Your nurses will document how much intravenous fluid you receive during your stay in hospital.
2. The researcher will measure your nipple size and height, breast and areola edema, baby's weight, ask if your baby is latching, and take a photograph of your breasts showing only your nipple and areola (not your face).
3. You will also be asked to supply a milk sample each day and keep a log of any hand expression, pumping or supplementing you do. Milk samples will be dropped onto filter paper to dry. Once the pattern has been read, the filter paper will be discarded in your garbage.
4. You will be asked how firm and tender your breasts are and if you have experienced fullness (if your milk coming in).

Study Duration

Participation ends with the final visit on postpartum day 10 or if you have weaned before then.

Possible Risks

Answering questions and volunteering personal information may cause you to feel uncomfortable or inconvenienced. You are free to not answer any question and to request photographs not be taken. There may be a risk of physical discomfort as the researcher will be touching your breasts to take measurements. You may experience some discomfort when squeezing out a small milk sample from your breasts. If this occurs, I will advise you of how to care for your breasts and nipples accordingly. You are free to request that certain measurements are not taken. The researcher will ensure that the scale is placed on a stable surface in your home and will teach you to weigh your baby. The researcher will only hold your baby if you request. You may withdraw from this study at any point without any consequences.

Benefits of the Study

Your participation in this study may directly help researchers who are researching breastfeeding and may indirectly help mothers and their babies by helping nurses and doctors learn more about breast changes following birth.

Voluntary Participation and Withdrawal from the Study

Your participation in this study is voluntary. If you choose not to participate, your decision will not affect the care you receive at this Institution or with Public Health at this time or in the future. You will not have any penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time.

You may also choose to not answer any questions without consequence. If you have a caesarean birth, you will no longer be eligible to be in the study. If you choose to withdraw, the researcher will still use the data already collected from you unless you ask for it to be destroyed. No new information will be collected.

Study Costs

There is no cost to participating in the study. You will not be paid for your participation.

Confidentiality

All personal health information will be kept confidential, unless release is required by law. You will not be identifiable in any publications or presentations resulting from this study. A copy of your consent form will be kept in a locked secure area at the University of Ottawa. All study data leaving the hospital will be coded with an independent study number.

The link between your name and the independent study number will only be accessible by the researcher Sonya Myles and the thesis supervisor, Professor Joy Noel-Weiss. The link and study files will be stored separately and securely. Both files will be kept for a period of 10 years after the study has been completed. All paper records will be stored in a locked file, first in the researcher's home office and then in Professor Joy Noel-Weiss's office at the University of Ottawa as soon as data collection is complete. Electronic data (specifically, the anonymous data) will be stored on a USB with security encryption capabilities. Any mobile devices used (e.g., laptops, CDs and DVDs) including the USB will be password protected and only accessible by Sonya Myles, her thesis supervisor Professor Joy Noel-Weiss, and a statistician at the University of Ottawa. At the end of the retention period, all paper records and photographs will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Questions about the Study

If you have any questions about the study, you may contact:

Sonya Myles: [redacted]
Professor Joy Noel-Weiss: [redacted]

The Halton Healthcare Services Research Ethics Board (HHSREB) has reviewed this protocol. The HHSREB considers the ethical aspects of all research studies involving human participants at The Milton District Hospital.

If you have any questions about your rights as a research participant, you may contact the Chairperson of the Halton Healthcare Services Research Ethics Board at 905-845-2571, extension 6361.

The office of Research Ethics and Integrity at the University of Ottawa has also reviewed this protocol. If you have any questions or concerns regarding this study, you can contact them at phone number (613) 562-5387, fax number 613-562-5338, or email ethics@uottawa.ca

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University of Ottawa
Faculty of Health Sciences
School of Nursing

Consent Form
The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Consent to Participate in Research

I understand that I am being asked to participate in a research study to understand how intravenous fluids given to me during my labour may affect my breasts and breastfeeding after the birth of my baby. This study has been explained to me by _____.

I have read this 4 page Participant Information Sheet and Consent Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Information Sheet and/or Consent Form will be provided to me.

Signatures

_____
Participant's Name (Please Print)

_____ _____
Participant's Signature Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

_____
Name of Investigator/Delegate (Please Print)

_____
Signature of Investigator/Delegate

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Ottawa ON K1H 8M5 Canada
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Appendix G

Amended Participant Information Sheet and Consent Form

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Halton Healthcare

Patient Information Sheet and Consent Form

Title of the Study: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Researcher: Sonya Myles - [redacted]

Thesis Supervisor: Professor Joy Noel-Weiss - [redacted]

Introduction

You are being asked to participate in a research study which will be conducted in English only. The study is part of Sonya Myles' Masters in Nursing thesis. The research study will aim to understand the relationship between intravenous fluids given during labour and postpartum breast changes and breastfeeding. Twenty five women will be recruited for this study. You may ask the researcher any questions you wish about any part of the study.

Background, Purpose, and Design of the Study

Postpartum breast engorgement and edema can cause nipple pain and damage which have been identified as reasons women stop breastfeeding. This study will try to understand the role of intravenous fluids on breast swelling following birth and how this swelling affects breastfeeding.

Study Procedures

- Sign an informed patient consent to participate in the study (you will keep a copy for your records).
- Complete short demographic sheet when you consent to be in the study (about 5 minutes).
- Baseline measurements of nipple diameter, areola diameter, nipple height, nipple and areola shape by photograph, edema rating, and maternal breast self assessment will be taken before your baby's birth, following the birth of your baby, and then daily for 9 days.
- As this study will last longer than your anticipated hospital stay, home visits will be required at a time that is convenient to your family. Visits are expected to take 15 to 30 minutes.

- Feeding your baby should not be interrupted or held off to accommodate the research, the researcher will call you each morning to set up a time that is approximately 2 hours from the start of your baby's last feeding. If your baby is hungry in the time between the phone call and the visit, you should feed your baby.

Data collection

5. Your nurses will document how much intravenous fluid you receive during your stay in hospital.
6. The researcher will measure your nipple size and height, breast, areola, and peripheral (hands and feet) edema, baby's weight, ask if your baby is latching, and take a photograph of your breasts showing only your nipple and areola (not your face).
7. You will also be asked to supply a milk sample each day and keep a log of any hand expression, pumping or supplementing you do. Milk samples will be dropped onto filter paper to dry. Once the pattern has been read, the filter paper will be discarded in your garbage.
8. You will be asked how firm and tender your breasts are and if you have experienced fullness (if your milk coming in).

Study Duration

Participation ends with the final visit on postpartum day 10 or if you have weaned before then.

Possible Risks

Answering questions and volunteering personal information may cause you to feel uncomfortable or inconvenienced. You are free to not answer any question and to request photographs not be taken. There may be a risk of physical discomfort as the researcher will be touching your breasts to take measurements. You may experience some discomfort when squeezing out a small milk sample from your breasts. If this occurs, I will advise you of how to care for your breasts and nipples accordingly. You are free to request that certain measurements are not taken. The researcher will ensure that the scale is placed on a stable surface in your home and will teach you to weigh your baby. The researcher will only hold your baby if you request. You may withdraw from this study at any point without any consequences.

Benefits of the Study

Your participation in this study may directly help researchers who are researching breastfeeding and may indirectly help mothers and their babies by helping nurses and doctors learn more about breast changes following birth.

Voluntary Participation and Withdrawal from the Study

Your participation in this study is voluntary. If you choose not to participate, your decision will not affect the care you receive at this Institution or with Public Health at this time or in the future. You will not have any penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time.

You may also choose to not answer any questions without consequence. If you have a caesarean birth, you will no longer be eligible to be in the study. If you choose to withdraw, the researcher will still use the data already collected from you unless you ask for it to be destroyed. No new information will be collected.

Study Costs

There is no cost to participating in the study. You will not be paid for your participation.

Confidentiality

All personal health information will be kept confidential, unless release is required by law. You will not be identifiable in any publications or presentations resulting from this study. A copy of your consent form will be kept in a locked secure area at the University of Ottawa. All study data leaving the hospital will be coded with an independent study number.

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Questions about the Study

If you have any questions about the study, you may contact:

Sonya Myles: [redacted]
Professor Joy Noel-Weiss: [redacted]

The Halton Healthcare Services Research Ethics Board (HHSREB) has reviewed this protocol. The HHSREB considers the ethical aspects of all research studies involving human participants at The Milton District Hospital.

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Consent Form
The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Consent to Participate in Research

I understand that I am being asked to participate in a research study to understand how intravenous fluids given to me during my labour may affect my breasts and breastfeeding after the birth of my baby. This study has been explained to me by _____.

I have read this 4 page Participant Information Sheet and Consent Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Information Sheet and/or Consent Form will be provided to me.

Signatures

_____
Participant's Name (Please Print)

_____ _____
Participant's Signature Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

_____
Name of Investigator/Delegate (Please Print)

_____
Signature of Investigator/Delegate

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Appendix H

Consent Form for Photography

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Consent Form for Photography

Title of the Study: The Relationship Between Intravenous Fluid and Breast Changes in the Postpartum Period

Researcher: Sonya Myles - [redacted]
Thesis Supervisor: Professor Joy Noel-Weiss – [redacted]

Université d'Ottawa
Faculté des sciences de la santé
École des sciences infirmières

University of Ottawa
Faculty of Health Sciences
School of Nursing

Photography of Breasts, Areola, and Nipples

I understand that the researcher, Sonya Myles, would like to take photographs of my breasts, showing my nipple and areola to be able to track changes in the first 10 days after my baby is born. My face or other recognizable features will not be included in the photographs.

These photos will be used for analysis and may be used in presentations or journal articles. I understand that I may withdraw my consent at any time and request the photos to be destroyed.

I hereby consent only to the taking and use of photographs for data collection purposes. (please initial) _____

I hereby consent to the use of photographs in presentations and journal articles (please initial) _____

A copy of the signed Consent Form for Photography will be provided to me.

Signatures

_____
Participant's Name (Please Print)

_____ _____
Participant's Signature Date

_____
Name of Investigator/Delegate (Please Print)

_____
Signature of Investigator/Delegate

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Appendix I

Breastfeeding Community Resources

Milton District Hospital Breastfeeding Clinic

Phone number: 905-878-2383 ext. 7610

Hours of operation:

Mondays: 12:0 p.m. - 4:00 p.m.

Tuesdays: 9:30 a.m. - 2:00 p.m.

Wednesdays: 12:00 p.m. - 4:00 p.m.

Thursdays: 6:00 p.m. - 9:00 p.m.

Fridays: *by appointment only.*

The drop-in session (for women and babies only) is held on Fridays from 10:00 a.m. - 11:30 a.m., no appointment is necessary. The session is now held at Our Kids Milton Hub (540 Commercial Street, Milton at the corner of Commercial and Derry Road) attached to Our Lady of Victory School. *Follow the colourful footprints to the door.*

Public Health: Healthy Babies Healthy Children

Phone number: 905-825-6000

Service is available Monday - Friday 8:30 a.m.- 4:30 p.m.

Telehealth Ontario

Telehealth Ontario is a free, confidential telephone service you can call to get health advice or general health information from a Registered Nurse. Available 24 hours a day, 7 days a week.

Phone number: 1-866-797-0000

Oakville Trafalgar Memorial Hospital Breastfeeding Clinic

Phone number: 905-338-4131

Hours of operation:

Monday to Friday 09:00 to 15:00

Saturday and Sunday: 09:00 to 13:00

Appointments required

Halton Breastfeeding Connection

A mother to mother telephone support service for breastfeeding mothers

Phone number: 905-825-6000

La Leche League

Breastfeeding support provided via a telephone warm line and monthly meetings

Phone number: 1-800-665-4324

Mother Risk Warm Line

The Toronto Hospital for Sick Children provides evidence-based information about the safety or risk of drugs, chemicals and disease during pregnancy and breastfeeding.

Phone number: 416-813-6780

Private Lactation Consultants

Private lactation consultants provide in-home help with breastfeeding, please note that private lactation consultants charge a fee.

http://www.ilca.org/i4a/pages/index.cfm?pageid=3432

Appendix J

Prenatal Questionnaire

Participant ID#_____

1. What will your age be when your baby is born? _____
2. What is your marital status?

   ___Married or common law

   ___Single or never married

   ___Separated or divorced
3. What is the highest level of education have you completed?

   _____
4. What is your average family income before taxes?

   ___less than $39,000

   ___$39,000 - $78,000

   ___over $78,000
5. What is your first spoken language?

   _____
6. Did your breasts get bigger during your pregnancy ___ yes ___ no ___ I don't know
7. Have you had any breast surgery? Yes No

If yes, what type of surgery? _____

Appendix K

Postpartum Questionnaire

Participant ID#_____

1. How far along was your pregnancy when your baby was born?

_____(number of weeks/months)

2. What is your baby's sex? Female_____ Male_____

3. What was your baby's weight at birth?

_____(grams or lbs.)

4. What was the type of birth?

___Vaginal ___Vacuum extraction ___Forceps extraction

5. Did you have:

___epidural ___pitocin/oxytocin ___antibiotics

6. When did you breastfeed your baby for the first time?

_____(number of hours after birth)

7. Did you have an opportunity to spent time skin to skin with your baby in the first two hours after birth?

___yes ___no If yes, did baby breastfeed in this time ___yes ___no

8. At any point during your labour or your baby's birth did your nurse give you extra intravenous fluid (e.g. baby was in distress, your blood pressure dropped a bit)

___Yes ___No ___I don't know

9. Did you have swelling (edema) in your hands or feet **before** or **after** your baby's birth (e.g. your rings would not fit, your ankles were puffy)

Before: ___yes ___no ___I don't know

After: ___yes ___no ___I don't know

Appendix L

Intravenous Fluid Sheet

Participant ID#_____

Please include all medication given intravenously, as well as the solution it is given in Please keep all empty bags of IV fluid in the bin lined with a plastic bag provided

Intravenous therapy started at ____h____ on ___/___/201___

Time of baby's birth: ____:____

Date and time	Amount infused	Type of solution	Medication

Intravenous therapy discontinued at ___h___ on ___/___/201___

Appendix M

Breast and Areola Measurement Sheet

Participant ID#_____

Day and time	Right Nipple height	Right Nipple diameter	Right Areola diameter	Left Nipple height	Left Nipple diameter	Left Areola diameter
Prenatal Time:						
Day 0 (0-24) Time:						
Day 1 (25-48) Time:						
Day 2 (49-72) Time:						
Day 3 (73-96) Time:						
Day 4 (97-120) Time:						
Day 5 (121-144) Time:						
Day 6 (145-168) Time:						
Day 7 (169-192) Time:						
Day 8 (193-216) Time:						
Day 9 (217-240) Time:						

Appendix N

Milk and Colostrum Maturation Index Sheet

Participant ID#_____

Day and time of sample	Right breast	Left breast	Day and time of MICAM test	MICAM level	
				Right breast	Left breast
Day 0 (0-24) Time:			Day Time:		
Day 1 (25-48) Time:			Day Time:		
Day 2 (49-72) Time:			Day Time:		
Day 3 (73-96) Time:			Day Time:		
Day 4 (97-120) Time:			Day Time:		
Day 5 (121-144) Time:			Day Time:		
Day 6 (145-168) Time:			Day Time:		
Day 7 (169-192) Time:			Day Time:		
Day 8 (193-216) Time:			Day Time:		
Day 9 (217-240) Time:			Day Time:		

Appendix O

Procedure for Using the Maturation Index of Colostrum and Milk (MICAM)

One millimetre of breast milk is collected from the second breast immediately prior to nursing the baby on that side. Samples must be tested within 48 hours, and may be refrigerated in that time period. Two to three drops of milk are dropped onto a piece of Whatman filter paper #1. Samples take about half an hour to dry and must be read within 24 hours. The height the milk is dropped from and the amount of milk are not critical to MICAM patterns (Humenick, 1987).

Appendix P

Edema Rating Sheet

Participant ID#_____

Rating	Characteristics
1+	Barely detectable impression left when finger is pressed into the skin
2+	Slight indentation left when finger is pressed into the skin Takes 15 seconds to rebound
3+	Deeper indentation left when finger is pressed into the skin Takes 30 seconds to rebound
4+	Deep indentation left when finger is pressed into the skin, Takes more than 30 seconds to rebound

Day and time	Left breast	Left areola	Right breast	Right areola
Prenatal Time:				
Day 0 (0 - 24) Time:				
Day 1 (25 - 48) Time:				
Day 2 (49 - 72) Time:				
Day 3 (73 - 96) Time:				
Day 4 (97 - 120) Time:				
Day 5 (121 - 144) Time:				
Day 6 (145 - 168) Time:				
Day 7 (169 - 192) Time:				
Day 8 (193 - 216) Time:				
Day 9 (217 - 240) Time:				

Appendix Q

Maternal Breast Self-Assessment Sheet

Participant ID#_____

1. Soft, no change
2. Slight change
3. Firm, non-tender
4. Firm, beginning tenderness
5. Firm, tender
6. Very firm and very tender

Day and time	Left breast	Right breast	Has "your milk come in"?
Prenatal Time:			
Day 0 (0-24) Time:			
Day 1 (25-48) Time:			
Day 2 (49-72) Time:			
Day 3 (73-96) Time:			
Day 4 (97-120) Time:			
Day 5 (121-144) Time:			
Day 6 (145-168) Time:			
Day 7 (169-192) Time:			
Day 8 (193-216) Time:			
Day 9 (217-240) Time:			

Signs of Lactogenesis II (also known as "milk coming in" are fuller, heavier breasts, tender breasts, and breasts that may leak milk.

Appendix R

Latching Sheet

Participant ID#_____

Day and time	Is baby latching with strong sucking for at least 2 minutes	What is the shape of your nipple after your baby delatches
Day 0 (0-24) Time:		
Day 1 (25-48) Time:		
Day 2 (49-72) Time:		
Day 3 (73-96) Time:		
Day 4 (97-120) Time:		
Day 5 (121-144) Time:		
Day 6 (145-168) Time:		
Day 7 (169-192) Time:		
Day 8 (193-216) Time:		
Day 9 (217-240) Time:		

Appendix S

Baby Weight Sheet

Participant ID#_____

Day 0 (0 - 24 hours) Time of birth:	Weight at birth
Day 1 (25 - 48 hours) Time of measurement:	Weight:
Day 2 (49 - 72 hours) Time of measurement:	Weight:
Day 3 (73 - 96 hours) Time of measurement:	Weight:
Day 4 (97 - 120 hours) Time of measurement:	Weight:
Day 5 (121 - 144 hours) Time of measurement:	Weight:
Day 6 (145 - 168 hours) Time of measurement:	Weight:
Day 7 (169 - 192 hours) Time of measurement:	Weight:
Day 8 (193 - 216 hours) Time of measurement:	Weight:
Day 9 (217 - 240 hours) Time of measurement:	Weight:

Appendix T

Pumping and Supplementing Log

Participant ID#_____

Day and time	Pumping	Supplementing
Day 0 (0 to 24 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 1 (25 to 48 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 2 (49 to 72 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 3 (73 to 96 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 4 (97 to 120 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 5 (121 to 144 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula

Day and time	Pumping	Supplementing
Day 6 (145 to 168 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 7 (169 to 192 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 8 (193 to 216 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula
Day 9 (217 to 240 hours)	Pumped _____ times today Hand expressed ____ times today	Supplemented _____ times today Average supplement _____ml or _____oz Breast milk Formula

Appendix U
Latching and Nipple Shape on Delatching Results

Table U1

Newborns who were able to Latch and Breastfeed for Longer than 2 Minutes

	Latching			
	n = 17*			
Timing (Day)	*Yes*	*No*	*Difficult*	*With nipple shield*
Day 0 (Birth)	15 (88)	2 (12)	0	0
Day 1	16 (94)	1 (6)	0	0
Day 2	16 (94)	0	0	1 (6)
Day 3	13 (77)	1 (6)	1 (6)	1 (6)
Day 4	11 (65)	2 (12)	2 (12)	1 (6)
Day 5	12 (71)	2 (12)	1 (6)	1 (6)
Day 6	13 (77)	1 (6)	1 (6)	1 (6)
Day 7	14 (82)	1 (6)	0	1 (6)
Day 8	14 (82)	1 (6)	0	1 (6)
Day 9	13 (77)	2 (12)	0	1 (6)

*****One participant lost to follow up from day 3 onwards

Table U2

Nipple Shape After Breastfeeding

		Frequencies (in number experienced)				
Timing	*n*	Unsure	Elongated	Pinched	Slanted	Not applicable
Day 0 (Birth)	17	5	8	2	2	0
Day 1	17	1	10	3	2	1
Day 2	17	0	10	6	1	0
Day 3	16*	0	8	6	1	1
Day 4	16*	0	9	3	2	2
Day 5	16*	0	11	3	1	1
Day 6	16*	0	10	3	2	1
Day 7	16*	0	12	1	2	1
Day 8	16*	0	12	2	1	1
Day 9	16*	0	14	0	0	2

***** one participant lost to follow up from day 3 onwards