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MATERNAL HYDRATION AND INFANT WEIGHT:

A CASE-CONTROL STUDY IN BREASTFEEDING INFANTS

DELIVERED BY CESAREAN SECTION

BY

DIANE J. THULIER

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY

IN

NURSING

UNIVERSITY OF RHODE ISLAND

DOCTOR OF PHILOSOPHY DISSERTATION

OF

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Abstract

Growing evidence suggests that infants may experience increased weight loss due to maternal medical interventions during labor such as intravenous fluid hydration. When breast fed infants lose $\geq 7\%$ of their birth weight, formula supplementation is often initiated. Formula supplementation is a variable unequivocally associated with shorter breastfeeding duration. Supplementation should not be initiated if the cause of infant weight loss is unrelated to breastfeeding adequacy. The purpose of this study is to examine the impact of intrapartum maternal hydration and regional anesthesia on infant weight.

A retrospective, case-control research study was designed. Data was collected from maternal and infant hospital records. A sample of 272 women and their full-term breastfeeding infants delivered by cesarean section were assigned to either a case ($\geq 8\%$ loss) or control (< 8% loss) group depending on the infant's weight on day three of life. Exclusion criteria included significant maternal or infant illness. Analysis revealed that the mean weight loss for all infants was 7.34% and that 54% of the infants lost $\geq 8\%$. Maternal demographic variables were similar between groups. More mothers in the case group had private insurance (p = .03) and less mothers underwent induction of labor (p = .01). Infants in the case group had heavier birth weights (p = .001). On day four, the exclusive breastfeeding rate had dropped to 53% in the case group compared to 80% in the control group. In the case group infant stools were significantly lower on days two to four and there was a trend toward more voids on day one (p = .09). Maternal IV fluid volume and type of anesthesia were not significantly different between groups. Only 69 (25%) of the women received ≥ 3000 ml of IV fluid. An exploratory analysis of 20

infants whose mothers received \geq 4000 ml showed that 14 (70%) did experience weight loss \geq 8%.

Epidural anesthesia does not appear to impact infant weight compared to spinal anesthesia. The effects of IV fluid on infant weight remain undetermined. Studies need to examine the impact of maternal IV fluid \geq 3000 ml on infant weight.

Acknowledgments

To Dr. Debra Erickson-Owens, words cannot express my gratitude. You were my major professor and became my greatest role model and mentor. You had more confidence in me than I had in myself and always knew when to gently push in the right direction. A kinder, smarter, more patient woman and teacher I have never known.

To Dr. Patricia Burbank, you inspired me ... and you understood. Thank you.

For my committee members, Dr. Andrea Rusnock, Dr. Mary Sullivan, and Dr. Patricia Morokoff, I thank you all. I could not have surrounded myself with a more supportive team.

To Bridget Fitzgibbons, my partner in data collection. We shared many hours, gallons of coffee and laughs. I will always be grateful for your help and look forward to working with you again someday.

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Chapter I

Introduction

Breastfeeding initiation rates in America are currently at 75%, higher than they have been since the mid-20th century. Yet, the 2013 Center for Disease Control (CDC) Breastfeeding Report Card has indicated that at six months of age only 49% of United States (US) infants are still doing some breastfeeding. This falls far short of the 2020 Healthy People objective of a national 60% breastfeeding rate at six months (US Department of Health and Human Services). The data is even more concerning in regards to the three- and six-month exclusive breastfeeding rates. The Healthy People 2020 goals are for 46% exclusive breastfeeding at three months and 25% at six months exclusive breastfeeding rates. Yet, the 2013 CDC national outcomes indicate that at three and six months, exclusive breastfeeding rates in this country are only 38% and 16% respectively. Clearly, the majority of US women initiate, but do not continue to exclusively breastfeed their infants.

In their discussion of these outcomes, the CDC noted that fewer than 5% of US infants are born in Baby-Friendly Hospitals (CDC Breastfeeding Report Card, 2013). The Baby-Friendly Hospital Initiative is a global program supported by the World Health Organization (WHO) and the United Nations Children's Fund that recognizes hospitals and birth centers that give optimal breastfeeding support. The program is based on the premise that birth facilities significantly influence whether a woman chooses to breastfeed and how long she continues to breastfeed. Many of the Baby-Friendly policies and practices impact the likelihood that a breastfeed infant will not receive formula in the first two days of life. In a review of the variables that impact breastfeeding duration,

Thulier and Mercer (2009) concluded that human lactation is a complex phenomenon influenced by many demographic, physical, social, and psychological variables. They found, however, that formula supplementation is a variable that is unequivocally associated with shorter breastfeeding duration.

One of the most frequently used measures to assess breastfeeding adequacy in the early days of life is the percentage of lost birth weight. It is important to note that studies show that infant feeding outcomes are unrelated to methods of delivery. Breastfeeding success in the early weeks of life is no better or worse for infants born by cesarean section (CS) compared to infants delivered vaginally (Watt et al., 2012). Expected physiological weight loss in the first week of life for breastfed infants is 5% to 7% (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2003; Hintz et al., 2001; MacDonald, Ross, Grant, & Young, 2003). Weight loss in excess of 7% may indicate hypernatremic dehydration and hyperbilirubinemia (Livingston, Willis, Abdel-Wareth, Thiessen, & Lockitch, 2000). In the Clinical Guidelines for the Establishment of Exclusive Breastfeeding, published by the International Lactation Consultant Association (2005), healthy full term breastfeeding infants are expected to lose no more than 7% of their birth weight in the first week of life. Experts from the Academy of Breastfeeding Medicine (2009) reported that most infants who remain with their mothers and breastfeed adequately lose less than 7% of their birth weight. They suggested that loss in excess of 7% may be an indication of inadequate milk transfer or low milk production. Finally, according to the American Academy of Pediatrics (AAP) (2012), exclusively breastfed infants who exceed 7% weight loss, especially those that lose up to 10% or more of their birth weight, should be evaluated for poor breastfeeding management. Indeed, when

weight loss is greater than 7%, ineffective breastfeeding is often the presumed cause (Yaseen, Salem, & Darwich, 2004; Yildizdas et al., 2005) and formula is frequently offered (Gagnon, Leduc, Waghormn, Yang, & Platt, 2005).

While some infants may lose excessive weight due to ineffective breastfeeding, other infants may experience weight loss due to medical interventions they are exposed to during labor. One medical intervention that may impact infant birth weight is the administration of large amounts of intravenous (IV) fluid given to mothers during labor. Intravenous fluid may transfer in utero to neonates and result in inflated infant weights at birth, with subsequent diuresis, diagnosis, and treatment of infant weight loss (Lamp & Macke, 2010; Mulder, Johnson, & Baker, 2010). Evidence does suggest that as birth interventions increase, the amount of IV fluid women receive in labor also increases. Lamp and Macke showed that women who had a vaginal delivery without epidural anesthesia received an average of 2, 522 milliliters (mls) of fluid prior to birth. Women with vaginal delivery and epidural received an average of 3,121mls. When labors were augmented with oxytocin, women received 3,683 mls. Finally, when women were delivered by unplanned CS after labor, this figure rose to a staggering 5,014 mls (over a gallon) of IV fluid. Approximately four million infants are born in the US annually and 32% of these infants are delivered by CS (Hamilton, Martin, & Ventura, 2011). Thus, the effects of the medical interventions previously described may impact widespread numbers of women and infants throughout the US.

Over the last several decades, epidural anesthesia has become the most common type of pain relief provided to women in labor (Bucklin, Hawkins, Anderson, & Ullrich, 2005). Epidural anesthesia involves the insertion of a small flexible catheter into the

space between the spinal column and outer membrane of the spinal cord (epidural space). This area is then numbed with local anesthetic which is often administered via a continuous pump, allowing pain relief to last for many hours (Ricci, 2013). Epidural rates across the US have risen to nearly 80% (Glance et al., 2007). Indeed, many women, health care providers, and laypersons have come to view labor with epidural anesthesia as the new normal (Kennedy, 2010).

Spinal anesthesia is administered in a fashion similar to the epidural. The local anesthetic administered, however, is injected directly into the cerebrospinal fluid that surrounds the spinal cord. Spinal anesthetic is faster and shorter acting; it is most often administered via one injection. This is the drug of choice for planned CS (Ricci, 2013).

The use of epidural and spinal anesthesia is not without potential risks. Women who have epidural anesthesia are more likely to experience episodes of fetal distress, longer duration of second-stage of labor, increased rate of instrument-assisted vaginal deliveries, and increased oxytocin administration (Gilbert, 2011; Hawkins, 2010). The most common side effect of epidural and spinal anesthesia is hypotension. Augmentation of the central blood volume with IV volume expanders has been shown to prevent or control these hypotensive episodes (Morgan, Halpern, & Tarshis, 2001). Therefore, IV fluid boluses of at least 500 mls are routinely administered to women receiving epidural or spinal anesthesia (Anim-Somuah, Smyth, & Howell, 2005). Spinal anesthesia is usually in place for approximately 15 – 20 minutes before the infant is born. Epidural anesthesia, in contrast, may be in place for many hours prior to delivery. Infants are therefore exposed to epidural anesthesia and its associated side effects for longer than they are exposed to spinal anesthesia.

To date, there are no published protocols or guidelines that address fluid management for labor patients or the impact that maternal fluid administration and epidural anesthesia may have on infant weight (Watson, Hodnett, Armson, Davies, & Watt-Watson, 2012). Recent studies on the topic have revealed contradictory results. Lamp and Macke (2010) found that neonatal weight loss during the first two days of life was not significantly related to intrapartum maternal fluid intake. Yet they did find that neonates who were born by vaginal birth accompanied by an epidural lost about one and ³/₄ more percentage points of their birth weight than those who were born by vaginal birth without epidural. In 2011, Chantry, Nommsen-Rivers, Peerson, Cohen, and Dewey found that the two variables that most predicted excessive weight loss during the first seven days of life were maternal intrapartum IV fluid > 100 mls/hour and delayed lactogenesis. In contrast, Watson, Hodnett, Armson, Davies, and Watt-Watson found no significant differences in infant outcomes on days two to four that were related to maternal IV intake. The proposed study will contribute to the available literature by exploring if intrapartum medical interventions (i.e. maternal intrapartum fluid intake) impact infant weight and may provide evidence based information to help guide practice.

Theoretical Framework

Much of the existing literature on breastfeeding research is atheoretical. This is not altogether surprising. In many nursing studies, the theoretical framework for research is not explicit and the underlying rationale is often not explained (Polit & Beck, 2008). Yet, research is strengthened by the use of theory. According to Kerlinger and Lee (2000), the basic aim of science is understanding theory and the most usable and satisfying relations are those that are tied theoretically to others. Two different theoretical

approaches have been selected for this proposed study. The first is Post Modern Feminist theory (PFT). PFT is used to question established assumptions related to infant weight and supports an exploration of whose knowledge has been valued when deciding what was "best" for laboring women and newborn nutrition. The second is a physiological approach to newborn weight loss. Related physiological principles will be presented that support a theory of maternal over-hydration and infant weight loss.

Postmodern feminist theory. Feminist and Critical Theory share several similar beliefs. Both explore oppression through understanding of common meanings. Both theories agree that the individual is led to believe that self-perception is a function of the self's own true condition rather than a condition imposed by social codes of behavior (Kim & Holter, 2001). The two theories believe in countering oppression and seek the redistribution of power and resources to those who are oppressed (Aranda, 2006; Weaver & Olson, 2006). A major assumption of feminist theory is that knowledge produced by science cannot escape the fact that it is part of the social and political traditions, structures and constraints within which it is produced (Ginzberg, 1995).

PFT, a distinctly feminist theory, will be used as a framework for this study. PFT calls for an examination of power relations. This examination is useful to determine whose knowledge dominates and whose knowledge is suppressed (Weedon, 1987). History reveals how pediatricians used artificial feeding and obstetricians used anesthesia to gain power and control. In addition, history shows how women's decisions regarding medical care for themselves and their children have been influenced not only by science and politics but also by the culture of their times. All of these influences shape not only

the past but continue to impact how modern day pediatric and obstetrical care is provided.

A major assumption of PFT is to critique the key enlightenment assumptions of reason, truth, and progress. PFT call for an active critique of how knowledge is founded. In studying infant weight, defining the expected weight loss patterns of infants is vitally important. It is well accepted in clinical practice that breastfed infants are expected to lose 5-7% of their birth weight (American Academy of Pediatrics, 2012). Recent studies, however, suggest that formula fed infants typically lose much less, only 1 - 4% of their birth weight (Grossman, Chaudhuri, Feldman-Winter, & Merewood, 2012; Regnault et al., 2011). Established knowledge about normal and expected weight loss patterns for breastfeeding infants that was generated from studies of formula fed infants, must therefore be questioned.

Physiologic theory. A specific physiologic theory that explains the relationship between maternal hydration and infant weight does not exist. A review of several physiological principles will demonstrate support for a physiologic basis for this relationship. The changes that occur in women's bodies during pregnancy and birth put them at increased risk for acute hydration. During pregnancy there is expanded body water and plasma volume. There is increased secretion of antidiuretic hormone and a resetting of osmotic thresholds for thirst and vasopressin secretion, as well as slower excretion of excess body fluid (Lindheimer, Barron, Durr, & Davison,1987). The secretion of the hormone oxytocin by laboring women also increases the risk of fluid overload and water intoxication. Due to these changes, IV solutions can cause fluid and/or solute overload resulting in over-hydration, dilution of serum electrolytes, and

edema (Lactated Ringers Official FDA, 2009). Changes in maternal osmolarity can lead to the transfer of water to the fetal compartment to achieve homeostasis. The placenta is a low resistance circuit in the fetal circulatory system (Blackburn, 2003). The IV solution, Lactated Ringers (LR) solution transfers easily across the placenta by passive diffusion, facilitated diffusion, and active transport. When fluid overload occurs in pregnant women, parallel changes may be experienced by the neonate. In the first few days after birth, the glomerular filtration rate of the newborn remains low (Bell & Oh, 1999). Although the newborn is able to regulate sodium and water balance, it does so within a much narrower range than that of the older child or adult. Several days may be required before excess fluid can be eliminated from the neonate's system. These basic physiological principles, taken as a whole, support a theory that maternal over-hydration may impact infant weight.

Purpose of the Research

The purpose of this study is to examine the impact of maternal hydration and anesthesia during labor and birth on neonatal weight loss. Specifically, it explores the effects on the weight of the breastfed infant on day three of life.

Hypothesis 1. Term breastfed infants born to mothers who receive large amounts of IV fluids (\geq 3000 mls) during labor and birth will have a higher occurrence of excessive weight loss (EWL) compared to term infants born to mothers who receive less IV fluids (< 3000 mls) during labor and birth.

Hypothesis 2. Term breastfed infants born to mothers who receive epidural anesthesia will have a higher occurrence of EWL compared to term infants born to mothers who receive spinal anesthesia.

Significance of this Study for the Discipline of Nursing

The study of medical interventions and the potential impact on neonatal weight and breastfeeding are significant to nursing practice. The benefits of breastfeeding are no longer debated among health care providers. Immediate breastfeeding benefits include a passive immunity transferred from mother to child, and less stomach upset, diarrhea, and colic in the infant. Breastfeeding protects against food allergies, and reduces overfeeding and the occurrence of Sudden Infant Death Syndrome (Duijts, Jaddoe, Hofman, & Moll, 2010; Roth, Cauleld, Ezzati, & Black, 2008). Long term benefits of breastfeeding for infants include stronger immune systems with fewer respiratory, gastrointestinal, and ear infections along with better jaw and teeth development (Duijts et al.; Roth et al.). Recent studies have also found that breastfed infants have less Type I and II diabetes, heart disease and obesity later in life (Feig, Lipscombe, Tomlinson, & Blumer, 2011, Rosenbauer, Herzig, & Giani, 2008). Women who breastfeed have less postpartum uterine bleeding and increased postpartum weight loss. In the long term, women who have breastfed their children have less breast cancer and osteoporosis (Blincoe, 2005).

In a review of the variables that impact breastfeeding duration, Thulier and Mercer (2009) found that breastfeeding duration is negatively impacted by an insufficient milk supply. In fact, insufficient supply is reported as the most common reason for weaning. Whether real or perceived, insufficient supply is described as a mother feeling that her milk supply is inadequate to either satisfy her infant's hunger or support adequate weight gain (Hill & Humenick, 1989). Health problems in the infant have also been found to impact breastfeeding duration (Thulier & Mercer). Excessive newborn weight loss can be viewed by both health care providers and parents as a significant health problem. Supplementation with infant formula is the most common intervention. Yet, formula supplementation has unequivocally been associated with shorter breastfeeding duration (Thulier & Mercer).

In consideration of these variables, if the cause of infant weight loss is excessive IV hydration and not ineffective breastfeeding, formula supplementation is not warranted. Infants should not be subject to unnecessary formula supplementation and mothers should not be made to feel that their milk supply is inadequate if the cause of the weight loss is not related to infant feeding. The role of the nurse is to advocate for the health of mothers and infants, to promote, protect and support breastfeeding. Studies are needed to determine if infant weight loss is indeed related to various medical procedures which women are subject to during the intrapartum period.

Summary

It is vital to determine if EWL in the infant is related to intrapartum medical interventions. The diagnosis of EWL often leads to the introduction of formula supplementation, a variable that is known to negatively influence breastfeeding duration. Weight loss in excess of 7% may be routine for infants of mothers who experience labor, epidural and/or an unplanned CS. Some studies have indicated that increased intrapartum fluid administration is associated with infant weight loss but the evidence to date is contradictory. In addition, no studies have explored the relationship between epidural anesthesia and infant weight.

Chapter II

Theory

In research, the purpose of theory is to describe, explain, predict and control phenomena. Theories may be abstract or concrete; they may be arrived at either inductively or deductively. Theories may function at a grand, middle or micro level. They are chosen, analyzed, utilized and often critiqued by nursing researchers. Two theories have been chosen for use in this study. The first is feminist theory, specifically PFT. An overview of feminism and Critical Theory will be presented. PFT will then be described and its scope, logic, preciseness, testability, and use will be critiqued. The second theory used in this work is physiology theory. Currently a physiologic principle that explains the potential relationship between maternal hydration and infant weight does not exist. Several related physiological principles or mechanisms will therefore be examined. These principles include IV fluids, fluid compartments, maternal physiology, over-hydration, placental function and fluid transfer, fetal fluid balance, and neonatal physiology.

Feminism and Critical Theory

Critical Theory originated in Germany during the 1930s and is a reappraisal of Marxist Theory led by Max Horkheimer (Kim & Holter, 2001). A major belief of Critical Theory is that ideas are shaped by social, political, cultural, gender, and economic factors over time (Weaver & Olson, 2006). Marxist Theory purports that people are fundamentally social creatures, shaped by material and social circumstances. Under capitalism, the ruling class controls the development and circulation of knowledge. Capitalism generates perceptions of human nature and social reality which are distorted in order to appear natural. According to Marxist views, women are oppressed under capitalism because of the sexual division of labor that serves the interests of men, the dominant sex, directly, and serves the interests of capitalism indirectly (Code, 2000). Critical Theory challenges positivism and the objectification of knowledge.

Feminism has its roots in Critical Theory. Critical Theory and feminism share several similar beliefs. Both explore oppression through understanding of common meanings. Both philosophies agree that the individual is led to believe that selfperception is a function of the self's own true condition rather than a condition imposed by social codes of behavior (Kim & Holter, 2001). Finally, both philosophies believe in countering oppression and seek the redistribution of power and resources (Aranda, 2006; Weaver & Olson, 2006).

An assumption of feminism is that knowledge produced by the practice of science cannot escape the fact that it was part of the social and political traditions, structures and constraints within which it was produced (Ginzberg, 1995). Feminism's major contribution to research has been to recognize and make known the political, historical, and gendered processes embedded in all knowledge production. Feminists have revealed how frequently research has been centered on men, often men of a particular social or cultural group (Harding, 1993; Hooks, 1989). To the feminist, theory is provisional, representing a perspective that needs to be exposed and construction understood (Aranda, 2006).

Feminism and Postmodern Feminist Theory

PFT is a feminist approach well suited to support research of maternal overhydration. To use PFT researchers must first critique the key enlightenment assumptions

of reason, truth, and progress that are embedded in nursing research practices. This active critique of constructions of knowledge and power relations will reveal whose knowledge dominates and whose knowledge is suppressed (Weedon, 1987). PFT scholars refuse to accept or privilege any theory, or truth about research without close examination of the evidence upon which is was established.

In research on infant weight loss, defining the concept of weight loss is vitally important. Breastfed newborns may lose up to 10% of their birth weight in the first week of life (Kliegman, Behrman, Jenson, & Stanton, 2007). However, according to the International Lactation Consultant Association (2005), the Academy of Breastfeeding Medicine (2009) and the AAP (2012), healthy term breastfeeding infants should not loose > 7%. This is despite the fact that researchers show that breastfed infants frequently loose more than 7% of their birthweight (Chantry, Nommsen-Rivers, Peerson, Cohen, & Dewey, 2011; Lamp & Macke, 2010; Mulder et al., 2010). Studies are also demonstrating that formula fed infants usually lose less than 5% of their birthweight. In a large study of over 2000 infants, Regnault et al. (2011) found that the average weight loss for formula fed infants on day three of life was 2.5-4%. In another study of 121 infants, Grossman, Chaudhuri, Feldman-Winter, and Merewood (2012) reported that the maximum weight loss for formula fed infants in the first week of life was 1-3% (2012). These differences in weight are likely due to the different feeding patterns of breast and formula fed infants in the first few days of life. Formula fed infants routinely consume one to two ounces of milk every three to four hours, starting on the first day of life. Breastfed infants consume only tiny amounts of colostrum every two to three hours until their mother's milk "comes in", usually on the third day of life (Ricci, 2013).

The different growth trajectories of breast versus formula fed infants are being recognized. The 2012 AAP policy statement titled 'Breastfeeding and the Use of Human Milk' noted that "the growth patterns of healthy term breastfed infants differ from the existing CDC "reference" growth curves, which are primarily based on data from few breastfeeding infants" (2012, p. e835). Indeed, close examination of both past and present breastfeeding research reveals that it has been plagued with lack of distinctions among types of feeding groups. In many feeding studies, infants are categorized as breastfeeding (Thulier, 2010). Since 2010, the AAP has recommended the use of the WHO growth curves for all children less than 24 months of age, a more reliable tool, and discouraged the use of the CDC growth curves.

Despite the fact that different growth trajectories for breast versus formula fed infants is being recognized, no published studies have questioned the accuracy of the expected 5-7% weight loss at birth. In this study, the use of PFT therefore provides a strategy to question and reexamine the basic variables in research on infant weight loss and breastfeeding.

The use of PFT also calls for an active critique of constructions of knowledge and power relations. In order to critique the current status of infant feeding and obstetrical care in the US, it is necessary to understand the history of how each has developed. This provides increased understanding of our infant feeding practices and the routine use of obstetrical interventions such as IV fluid and epidural anesthesia. In *Breastfeeding in America: A History of Influencing Factors*, Thulier (2009) discussed how medicine, science and industry have affected women's choices about childbirth and infant feeding.

She also noted, however, that cultural practices, feminism, politics, and religion have also played important roles in shaping women's choices about childbirth and how to feed infants.

Issues of vocabulary must also be explored when using PFT. For researchers using this theory, the use of language constitutes rather than reflects reality. It is believed that dominant meanings come to define and construct the actual and possible forms of social organizations (Weedon, 1987). Language has the capacity to shape knowledge in contrast to the notion that language is merely reflective of pre-existing entities (Weedon).

In contemporary obstetrical practice language is used in powerful ways. Common language related to the phenomenon of over-hydration and infant weight loss include, 'fetal distress', 'failure to progress', 'failure to thrive', 'inadequate weight gain', and 'inadequate milk supply; and 'low milk supply'. A known variable that impacts the duration of breastfeeding for women is confidence (Thulier, 2010). The use of this kind of negative language by health care providers when speaking with women is likely to undermine their confidence. Indeed a recent analysis of popular childbirth education books by Kennedy, Nardini, McLeod-Waldo, and Ennis (2009) demonstrated that for women the "language about labor, birth, and cesarean sections is frightening and abdicates decisions to medicine and institutions" (p. 199).

Theory Analysis

According to Kim (1989), essential elements of theory analysis involve examination of a theory in respect to its scope, form, testability and use. Scope of a theory refers to the degree to which a given theory provides explanations for various subject matters (Stevens, 1984). When discussing scope, Peterson and Bredow (2004)

asked how wide or narrow is the range of phenomena that a theory covers. PFT is applicable to a wide range of phenomena associated with women. Its scope can entail all of the phenomena associated with feminism. These phenomena range from issues related to the client including the body and self to issues related to practice such as oppression, domination, and sexism. This scope of practice could also apply to phenomena in the environment; for example, feminist theory could be utilized with studies related to family, class, race, justice, equity, power, and politics.

Questions regarding form and testability refer to the internal structure of a theory (Kim, 1989). Form addresses the clarity and consistency with which key concepts in a theory are specified. According to Peterson and Bredow (2004), there is clarity if the main components are well outlined and the theory is easily understood by the reader. A review of PFT reveals two main concepts which are clear. First, there is a strong commitment to critiquing modern truth and reason and to deconstructing their assumptions. Second, there is a distinct focus on multi vocabulary. Consistency determines if the theory maintains the definition of the key concepts throughout the explanation of the theory. It also determines if it has congruent use of the terms, interpretations, principles, and methods (Peterson & Bredow). Review of PFT reveals that there is consistency in this regard.

Testability deals with the degree to which a theory can be translated for empirical testing (Kim, 1989). In order to be testable, concepts need to be measurable and operational. Given the nature of PFT, its research cannot be easily tested. Most studies conducted that use PFT are broad and abstract in nature, and difficult to reproduce. Aranda (2006) noted that in order to utilize PFT, a reassessment of the epistemological

and ontological assumptions embedded throughout feminist qualitative research must be pursued. Postmodern feminist methodologies demand that feminist politics and practices are studied while attending to differences and diversity. Re-interrogation of key values and ideals is required, such as equality and justice in health-care (Aranda, 2006). This type of research is distinguishable by the type of questions asked, the location of the researcher within the process, their location within theorizing, and the intended purposes of the work (Letherby, 2003).

A theory's use refers to the degree with which a theory contributes to the development of science (Kim, 1989). There are many ways in which PFT contributes to nursing science. PFT utilizes insights from postmodern thought to build upon feminist theorizing and research. It also encourages researchers to think differently and imaginatively about key feminist concepts such as gender, sexuality, power, and politics (Weedon, 1987).

Unfortunately, despite its innovative approach, PFT has not been frequently utilized by many feminist theories. Likely this is related to the many assumptions it makes regarding social structures, women, science, truth, and knowledge (Aranda, 2006). Although it has demonstrated usefulness, it has not led to further theory development. It should be remembered however that PFT remains relatively new, having only been introduced in the early 1990s.

Physiological Principles

In order to begin to describe, explain or even predict the occurrence of neonatal weight loss as it relates to maternal hydration, some associated concepts must be examined. These principles are physiologic in nature and include IV fluids, fluid

compartments, maternal physiology, over-hydration, placental function, fluid transport, fetal fluid balance, and neonatal physiology.

Intravenous fluid. Administering IV fluids to increase vascular volume is one of the most frequently implemented interventions in medicine. Volume expanders are available in two types: crystalloid and colloid solutions. The most commonly used crystalloid solutions in the US are normal saline and LR (Martin, 2005). Crystalloids are made up of a solution of sterile water with water soluble molecules that approximate the mineral content of human plasma. Crystalloids are prepared in a variety of formulations, including those that are hypotonic, isotonic or hypertonic. Hypotonic solutions have a salt content that is lower than the human body and blood. Isotonic solutions have salt content that is equal; and hypertonic solutions have salt content that is greater than the body and blood. When a cell's cytoplasm is bathed in a hypertonic solution the water will be drawn into the solution and out of the cell by osmosis (Martin). In obstetrics, a number of problems have been associated with the use of hypertonic glucose solutions. These problems include rises in maternal blood glucose, fetal hyperglycemia and hyperinsulinemia, and neonatal hypoglycemia. For this reason, the use of LR, an isotonic solution, has become routine in obstetrical care (Martin). Colloid solutions, the second type of volume expander, contain water and electrolytes but they also contain much larger substances that do not freely diffuse across a semipermeable membrane. Starch, gelatin, albumin and blood products are all examples of colloid solutions (Martin). These solutions are infrequently used in obstetrical care.

IV fluid therapy is not benign. Well documented complications of IV fluid therapy include infection, phlebitis, fluid overload, and hyponatremia (Newton et al.,

1988). Despite these concerns, in most obstetrical settings routine orders specify that patients have an IV infusion of LR, administered at a rate of 125 mls/hour. IV access allows for the administration of fluids, medicine, and or blood products. When epidural anesthesia is used during labor, IV fluid boluses of at least 500 mls are administered to prevent or control hypotensive episodes, the most common side effect of epidural anesthesia (Anim-Somuah et al., 2005). Augmentation of the central blood volume with IV volume expanders has been shown to prevent or control these episodes (Morgan et al., 2001). Additional fluid boluses may also be given to treat maternal fever and to help resolve episodes of fetal distress. The most commonly used IV crystalloid solutions in the US are normal saline and LR (Martin, 2005).

Crystalloid solutions rapidly redistribute to the extracellular fluid compartment (Martin & Lewis, 2004). They predictably reduce serum protein concentrations and packed red cell volume. These changes may alter tissue perfusion and increase the risk of tissue edema (Martin, 2005). LR is an isotonic solution, its salt content is equal to that of the body and blood, and is therefore considered the fluid of choice for IV hydration in most laboring women.

Fluid compartments. There are two fluid compartments in the human body, each with several subdivisions. The first is the intracellular fluid compartment which makes up approximately 60-65% of total body water (Patlak, 1999). Intracellular fluid is found inside the plasma membrane and is the substance in which cellular organelles are suspended and chemical reactions take place (Blackburn, 2003). The intracellular compartment contains approximately 28 liters of fluid and usually remains in osmotic equilibrium with the extracellular fluid (ECF) (Patlak, 1999).

The ECF compartment makes up the other 35-40% of body water. Within the ECF are three compartments: the interstitial, intravascular, and third space (Patlak, 1999). The interstitial compartment is the space that surrounds the cells of any given tissue (Fleischhauer, Lehmann, & Kléber, 1995). This space allows for the movement of ions, proteins and nutrients across the cell barrier. When excessive fluid accumulates in the interstitial space, edema develops (Wiese, 2005). The intravascular fluid compartment contains blood; total blood volume is a combination of plasma and red blood cells (Blackburn, 2003). The third space is between the skin and the fascia; fluid does not normally perfuse this area (Redden & Wotton, 2002). Fluid in the third space is physiologically nonfunctional, as it is not readily available for the body to use (Drain, 2003.

Maternal physiology. Due to the normal physiologic changes that occur with pregnancy and birth, laboring women are at increased risk for acute hydration. During pregnancy there is expanded body water and plasma volume. Due to a resetting of osmotic thresholds for thirst and vasopressin secretion, there is also slower excretion of excess body fluid. (Lindheimer et al., 1987). During labor, multiple stimuli such as pain, emotional stress, and nausea, can all increase the secretion of antidiuretic hormone. Antidiuretic hormone increases the permeability of the collecting ducts of the kidney, so that water enters the hypertonic interstitium of the renal pyramids. Water can then be retained in excess of solute, thus reducing plasma osmolality, and predisposing women to water intoxication if fluid intake is too high (Paech, 1998). The secretion of oxytocin by laboring women also increases the risk of fluid overload and water intoxication. Oxytocin is a hormone naturally produced by the hypothalamus that causes uterine

contractions. Oxytocin can also be synthetically manufactured and is used to induce or augment labor and to manage postpartum hemorrhage (Thornton, Davison, and Baylis, 1988). It also has an antidiuretic effect, further increasing the risk of water intoxication among obstetrical patients (Wasserstrum, 1992).

Over-hydration. It seems that even the most common IV solutions carry a certain amount of risk for an individual patient (Martin, 2005). IV solutions can cause fluid and/or solute overload resulting in over-hydration, dilution of serum electrolytes concentrations, as well as peripheral and pulmonary edema (Lactated Ringers, 2009). Martin and Lewis (2004) noted that crystalloid solutions rapidly redistribute to the extracellular fluid compartment. These solutions predictably reduce serum protein concentrations and packed red cell volume. These changes may alter tissue perfusion and increase the risk of tissue edema (Martin, 2005). Peripheral edema is the accumulation of fluid that leads to the swelling of body tissues. It is commonly found in the lower extremities but can also occur throughout the body. Nommsen-Rivers, Chantry, Peerson, Cohen, and Dewey (2010) found that the delayed onset of lactation was associated with the presence of edema in the first 48 hours postpartum. While edema is concerning, a more significant effect of fluid excess is water intoxication. Water intoxication causes a decreased plasma osmolarity and a rapid fall in extracellular sodium concentration (Paech, 1998). Osmolarity is defined as the measure of solute concentration, or the number of osmoles of solute per liter. A fall in extracellular sodium concentration results in intracellular hypernatremia with subsequent influx of water (Paech, 1998). Clinical findings of water intoxication are non-specific and often mimic other conditions such as dehydration and pre-eclampsia (Fraser & Arieff, 1997).

Placental function. When assessing the effects of large amounts of maternal IV fluid and the impact this may have on neonatal weight, it is important to consider the role of the placenta. The human placenta is essential for transfer of nutrients and gases from the mother to the fetus and for removal of waste products from the fetus (Blackburn, 2003). The placenta consists of the outer epithelial layer and an inner vascular and connective tissue network (Blackburn).

The fetal portion of the placenta is divided into 50-60 lobes, each arising from a primary stem villus. Stem villi arise from the chorionic plate and attach to the maternal decidual basalis. These stem villi consist of initial embryonic and fetal blood vessels, which include arteries, veins, arterioles, and venules. They are supplied by primary branches of the umbilical vessels (Wigglesworth, 1984) and make up about one-third of the villi in the mature placenta (Kaufmann & Scheffen, 1998). Mature intermediate villi grow from the side of stem villi and project into the intravillous space in the placental tissue. They contain fetal capillaries, arterioles and venules and are the major area of exchange between the maternal and fetal circulation (Fox, 1997). The intermediate villi, constitute approximately 25% of the villi in the mature placenta. Finally, the terminal villi are formed after fetal viability. They contain multiple dilated capillaries and account for 30% to 40% of the mature villus tree (Kaufmann & Scheffen, 1998).

The maternal side of the placenta is divided into an average of 15-20 lobes, each containing two or more main stem villi and their branches (Arck, Dietl, & Clark, 1999; Cunningham & Whitridge, 1997). The mature placenta is established approximately 40 to 50 days after ovulation. Due to the proliferation of terminal villi however, the surface

area for placental exchange continues to increase until late in gestation (Blackburn, 2003).

Changes in the placental structure, increased fetal and maternal blood flow, and greater fetal demands result in increased transport of nutrients, gases, and wastes throughout the pregnancy (Blackburn, 2003). According to Blackburn the placenta is considered a low resistance circuit in the fetal circulatory system. The low resistance of the uteroplacental circulation allows it to receive a large proportion of maternal cardiac output (Carlson, 1999).

Placental transfer is influenced by the area of the placenta, physiochemical characteristics of the diffusion substance, concentration gradients, electrical potential differences, diffusing distance, degree of binding of a substance to hemoglobin or other blood proteins, permeability of the placental barrier, and the rates of maternal and fetal blood flow through the intervillous space and villi (Blackburn, 2003, p. 115).

At term gestation, the placenta occupies up to one-third of the inner uterine surface (Blackburn). It weighs approximately 480 grams (\pm 135) and has a diameter of 18 to 22 centimeters (cm) and thickness of 2 to 2.5 cm (Schuler-Maloney, 2000). A bidirectional movement of gases, nutrients, waste materials, drugs, and other substances crosses the placenta from maternal-to-fetal circulation and from fetal-to-maternal circulation (Blackburn). Blood flows through the placenta at an astounding rate of about 500mls/minute (Fox, 1997). This blood flow through the placenta is regulated by fetal heart activity, blood pressure, fetal right to left shunts, and systemic and pulmonary vascular resistance (Ahmed and Klopper, 1985; Faber & Thornberg, 1983). For adequate

exchange of nutrients, gases and waste products, there must be adequate blood flow to and through the placenta from both fetal and maternal circulations (Blackburn, 2003).

Fluid transport. Substances transfer across the placenta by several mechanisms that include passive diffusion, facilitated diffusion, active transport, pinocytosis, endocytosis, bulk flow, solvent drag, accidental capillary breaks, and independent movement (Blackburn, 2003). As noted, LR is an isotonic solution, considered the fluid of choice for IV hydration in most laboring women. For this reason, the contents of LR as well as the transport mechanism for the components of LR will be discussed. According to the Food and Drug Administration (Lactated Ringers, 2012), one liter of LR solution contains:

- Water quantity sufficient
- 130 mEq of sodium
- 110 mEq of chloride
- 28 mEq of lactate
- 4 mEq of potassium ions
- 3 mEq of calcium ions

Passive diffusion is movement of a substance from a higher to a lower concentration (Blackburn, 2003). Diffusion is the major mechanism of placental transfer and is generally limited to smaller molecules than can pass through pores in the cell wall (Bourget, Roulot, & Fernandez, 1995; Cunningham & Whitridge, 1997; Reynolds & Knott, 1989). Water soluble substances cross easily if less than 100 molecular weight (MW). Free water crosses the placenta at a rate of 180mls/second, faster than any other known substance (Faber & Thornburg, 1983). The MW of sodium in LR solution is 58.44 and the MW of chloride in LR is 74.55 (Lactated Ringers, 2009) therefore they are transferred to the fetus via passive diffusion. In facilitated diffusion, protein carriers and other transporters move substances across the placental membrane, from higher to lower concentrations (Redline, 1997). Lactate is transported by way of facilitated diffusion (Reynolds & Knott, 1989). In active transport, energy-dependent carrier systems and other transporters move substances such as amino acids, potassium, water-soluble vitamins, calcium, phosphate iron, and iodine across the placental barrier. Calcium in LR moves across the placenta via active transport. Active transport systems may become saturated at higher concentrations, when similar molecules compete, thus reducing their movement across the placenta (Blackburn, 2003). Of interest, Longo (1981) examined the transfer of nutrients across the placenta. Sodium and chloride were found to be higher in the fetus than in the mother.

Fetal fluid balance. Maternal fluid and electrolyte balance during labor directly affects the infant (Theunissen & Parer, 1994). "Water is continuously exchanged between mother and fetus, with a net flux in favor of the fetus, placenta, and amniotic fluid" (Blackburn, 2003, p. 384). Serum osmolarity is also similar in the fetus and the mother. As a result, changes in maternal or fetal osmolarity will lead to transfer of water from the opposite compartment to achieve homeostasis. Indeed, acute changes in maternal plasma osmolarity induce parallel changes in the fetus (Brace, 1986). Fetal fluid and electrolyte balance is dependent on maternal homeostasis and placental function. While in utero, significant blood flow to the kidneys is not required; the fetus depends

upon the placenta to serve as the major organ of excretion. During this time, there is increased renal vascular resistance (RVR) with only a small percentage of fetal cardiac output flowing to the kidneys (Blackburn, 2003).

Neonatal physiology. After birth, the renal system must rapidly assume control of fluid and electrolyte balance and excretion of metabolic waste (Blackburn, 2003). RVR falls as the blood flow and glomerular filtration rate (GFR) increase (Guron and Friberg, 2000). Glomerular filtration occurs when plasma is filtered from blood that moves through the glomerulus and into the Bowman's capsule. The glomerulus is permeable to water and small molecules and impermeable to colloids and larger molecules. Filtration is influenced by hydrostasis and colloid osmotic pressure (Vander, Sherman, & Luciano, 2000). This increase in the GFR after birth is due to redistribution of placental blood flow, decreased RVR, and increased systemic blood pressure, increasing glomerular surface area, and increased permeability of the glomerular membrane (Al-Dahhan, Haycock, Chantler, & Stimmler, 1983; Stewart & Jose, 1985).

During the first 12 hours after birth, 4-6% of the cardiac output perfuses the kidneys. Over the next several days, this increases to 8-10%. Despite this increase, the GFR of the newborn remains significantly lower than the adult, in which 25% of the cardiac output perfuses the renal system (Bell & Oh, 1999). Initial voiding usually occurs within 24 hours of life (Blackburn, 2003). Thereafter, urine output for the neonate varies with fluid and solute intake, renal concentrating ability, gestational age, and perinatal events (Blackburn). The newborn is able to regulate sodium and water balance but does so within a much narrower range than that of the older child or adult. The newborn is therefore much more likely to develop fluid and electrolyte imbalances within a shorter

period of time (Leung et al., 1980). Indeed, neonatal kidneys have a limited ability to excrete both concentrated and dilute urine (Blackburn, 2003). As a result, expected infant outputs during the first few days of life are minimal. One or two wet diapers a day are expected for the exclusively breastfed infant during the first two days after birth. By the third and fourth day of life, after lactogenesis has occurred, voiding is expected at least six to eight times daily (Mohrbacher, & Stock, 2002).

In summary, available evidence as outlined above supports a physiological transfer of IV fluid from mother to fetus during labor and birth. Physiologic changes of the maternal body during pregnancy and the ability of IV fluid to flow freely through the placenta may contribute to this fluid transfer. This extra fluid may result in an inflated infant weight at birth. Due to immature neonatal physiology, it will take one to two days for the infant to complete diuresis of this fluid. This diuresis may result in excessive infant weight loss and subsequent treatment for this weight loss. (Chantry et al., 2011; Mulder et al., 2010).

Chapter III

Review of the Literature

A review of the literature yields four studies which have explored the issue of intrapartum fluid administration and infant weight loss. Two of the studies found that increased intrapartum IV fluids impacted neonatal weight loss in the first few day of life (Chantry et al., 2011; Mulder et al., 2010) (Table 1). The other two studies concluded that the amount of intrapartum IV fluid mothers received did not impact infant weight loss (Lamp & Macke, 2010; Watson et al., 2012) (Table 1). These contradictory findings as well as study strengths and weaknesses will be discussed. In addition a historical review will examine the link between pediatric care and infant feeding as well as obstetrical care and maternal anesthesia. The impact of culture on women in regards to childbearing and feeding practices will be explored.

This literature review was conducted by searching the health science reference database of CINAHL (EBSCO host), MEDLINE, and PubMed. Keywords used in this search included *breastfeeding, weight, weight loss, intravenous fluids* and *epidurals*. Several texts were also obtained from the library collection and interlibrary loan services at the University of Rhode Island. No date ranges were used, all available literature was reviewed. English only publications were utilized.

In 2010, Mulder, Johnson, and Baker completed a study which examined breastfeeding frequency, voiding, and stooling in two groups of infants; those who had lost more or less than 7% of their birth weight. Data collection was completed in 2005 at a Midwestern community hospital. It was a secondary analysis of data acquired to investigate the reliability of the Mother Infant Breastfeeding Progress Tool. Postpartum

women were recruited during their in-hospital postpartum stay. The sample included mothers (n = 53) who were breastfeeding. The eligibility criteria included healthy, postpartum women, > 18 years old, in stable medical condition and English speaking. Eligible infants were between 35 and 42 weeks gestation, clinically stable, and did not receive supplemental oxygen or IV fluids. Mothers were interviewed and observed while breastfeeding. Maternal and infant data were collected via chart review. The data collected during the chart review were used for this study of excessive infant weight loss.

The infants were divided into two groups: those with weight loss < 7% and those with weight loss \geq 7% at two days of age. Variables included breastfeeding frequency, voiding, and stooling; data was collected by counting the number of breastfeeding sessions, voids, and stools on the day of birth and on day one of life. Maternal IV fluid volume was not measured. The authors found that 21% of breastfed infants experienced \geq 7% loss of birth weight by the second day of life. These infants had significantly more voids and higher breastfeeding frequency on the day of birth than infants with a weight loss < 7%. Due to the increased number of voids, the authors suggested that infants with a large weight loss during the first two days of life might be experiencing a large diuresis as opposed to inadequate breast milk intake. Based on these findings, Mulder et al. (2010) concluded that breastfeeding infants who lose \geq 7% of their birth weight during the first two days of life may experience a physiologic diuresis shortly after birth.

In 2010, Lamp and Macke completed a study focusing on the relationships among intrapartum maternal fluid intake, type of delivery, neonatal urine output, and neonatal weight loss during the first 48 hours after birth. The researchers used a prospective, descriptive design and a convenience sample of 200 mothers and their infants. The study

took place in a Midwest, regional acute care hospital with 6,700 births annually. Women who were healthy, 18-40 years of age, with healthy, term, singleton or twin infants met the study's inclusion criteria. Data collection began on the labor and delivery unit and concluded at mother/infant discharge from the hospital.

Lamp and Macke (2010) were able to show that women with epidurals received more IV fluid than women who did not receive epidural anesthesia, no matter the type of delivery. They found that women who had vaginal deliveries without epidurals were given an average of 2522 mls of IV fluid prior to delivery. Similarly, women who had a planned cesarean section were given an average of 2759 mls of fluid. In contrast, women with vaginal deliveries with epidurals received a mean of 3121mls of IV fluid. Women who had vaginal deliveries with induction and epidurals received an average of 3638 mls. Women who experienced labor and unplanned, cesarean section totaled an average of 5,014 mls of IV fluid. These amounts of IV fluids were higher than reported in past studies.

Despite recording these large amounts of IV fluid, the researchers concluded that neonatal weight loss was not significantly related to intrapartum maternal fluid intake (Lamp & Macke, 2010). Using logistic regression analysis, they found that strong predictors of neonatal weight loss within the first 48 hours were related to the type of feeding (p = 0.000) and average number of wet diapers (p = 0.003). In infants with excess weight loss, the numbers of stools decreased in infants from day one into day two but the number of wet diapers increased (p = 0.003). Infants born vaginally with an epidural lost about 1¾ % more of their birth weight than those born vaginally without epidural. Researchers also found that infant urinary outputs exceeded previously

published reports. Kenner and Lott (2007) reported that, in the first few days of life, the neonate produced at least 1ml/kilogram/hour. Lamp (2010) found that the overall mean urine output, within the first 24 hours, was 1.35 mls/kilogram/hour and during the second 24 hours it was 1.42mls/kilogram/hour (Lamp & Macke, 2010).

In 2011, Chantry et al. examined excess weight loss in first-born breastfed newborns and explained how this was related to maternal intrapartum fluid balance. The authors focused on infant weight loss and attempted to identify potentially modifiable risk factors for EWL. They recruited 458 pregnant women from the University of California-Davis Medical Center between December 2006 and January, 2007. Eligibility criteria included healthy primigravida women between 32 - 40 weeks gestation, and English or Spanish speaking. Exclusion criteria included any high-risk obstetrical or medical conditions, contraindications to breastfeeding and maternal age < 19 years. Participants were interviewed prenatally, and were visited at three time frames: within 24 hours of birth, day three and day seven.

Based on their feeding behavior, the infants were divided into three groups; exclusively breastfed (n=134), formula supplementation ≤ 60 mls (n= 95), and formula supplementation > 60 mls (n=87). Variables included breastfeeding intention, labor and delivery interventions, breastfeeding behaviors, formula and pacifier use, the onset of lactogenesis, maternal nipple type, and nipple pain. The results indicated that the prevalence of EWL was "alarmingly high". A total of 18% of this sample of breastfeeding infants who received ≤ 60 mls of formula lost greater than 10% of their birth weight by day three of life. Chantry et al. (2011) found that the prevalence of EWL was significantly related to maternal intrapartum fluid balance and this finding was

independent of delayed lactogenesis. In addition, it was suggested that the prevalence of EWL was likely underestimated as the infants' weights were not measured again until the 7th day of life (Chantry et al., 2011).

Most recently, Watson et al. (2012) conducted a randomized controlled trial to determine the effect of conservative versus usual maternal IV fluid hydration on weight loss in breastfed newborns. The study included 200 healthy, singleton, term infants. Inclusion criteria for enrollment required well hydrated mothers (no vomiting or diarrhea in the previous 24 hours) anticipating a vaginal delivery with adequate fetal growth, epidural use, and an intent to breastfeed. Women were categorized into one of two groups: usual care and conservative care. In the conservative care group, IV LR was infused at a rate of 75 - 100 mls/hour and women received a mean of 1430 mls of fluid prior to delivery. In the usual care group, IV LR was infused at a rate of >125 mls/hour and women received a mean of 2477mls of fluid. The primary outcome measure was infant weight loss > 7% prior to hospital discharge (at two-four days of age). Forty three women were delivered by cesarean section. It is therefore presumed that, while the majority of infants were discharged on day two, these 43 infants may have remained in the hospital until day four of life as is normal practice after CS.

Watson et al. (2012) found no significant differences in infant outcomes related to maternal IV intake. They concluded that an IV intake volume of < 2500 mls was unlikely to have a clinically meaningful effect on weight loss in breastfed infants. In their exploratory analysis of data, however, they did find that that 25% of the infants (n = 51) whose mothers received > 2500 mls of fluid lost significantly more weight during the first 48 hours of life (p = 0.03). The mean weight loss for all infants was 6.85%. Almost

half of the infants (46%) lost > 7% of their birth weight prior to hospital discharge. The researchers also found that 8% of the infants lost >10% of their birth weight and these mothers had a mean IV intake of 2434 mls. The authors suggested that the infusion of larger amounts of IV fluid may make a difference in infant weight loss.

Table 1

Author (year)	Design	Primary Outcome Variables	Sample	Results	Limitations	Definition of Weight Loss
Chantry, Nommsen-Rivers, Peerson, Cohen, & Dewey (2011)	Prospective, convenience	Infant WL IV amount BF behaviors Formula amount Onset of lactogenesis	229 singleton, firstborn infants, WG 32-40, mothers without high- risk conditions; Davis, California.	EWL = 18% of infants EWL SRT intra partum fluid balance and delayed lactogenesis	No DC on days 3-7 Included formula fed infants (≤ 60ml).	EWL ≥ 10%
Mulder, Johnson, & Baker (2010)	Secondary data analysis, convenience	Infant WL BF amount Infant output	53 clinical stable BF dyads, WG 35-42; mid- western community hospital.	EWL = 21% of infants EWL SRT more total voids and higher BF frequency on day1	DC for 2 days only Included preterm infants No IV amounts Included formula fed infants	EWL ≥ 7%
Lamp & Macke (2010)	Prospective, convenience	Infant WL IV amount BF amount Infant output	200 healthy, term mother/infant dyads; mid-west, regional acute care facility.	EWL not SRT IV EWL SRT type of infant feeding and number of voids Epidural group had greatest wt. loss	DC for 2 days only No BF assessment Included formula fed infants	EWL ≥ 10%
Watson, Hodnett, Armson, Davies, & Watt-Watson (2012)	RCT	Infant WL Exclusive BF BF referrals Delayed discharge	200 healthy, term mother/infant dyads; tertiary, perinatal care center.	EWL not SRT IV volume < 2500mls IV volume > 2500mls may contribute to EWL	DC for 2 days only Included formula fed infants Total IV amount ≤ 2500 mls	EWL ≥ 7%

Evidence: Studies of Maternal IV Fluid and Infant Weight

 \overline{BF} = breastfeeding; EWL = excessive weight loss; RCT = randomized controlled trial; SRT = significantly related to; WG = weeks gestation; WL = weight loss

Limitations of Studies

The work by Lamp and Macke (2010) and Watson et al. (2012) concluded that the volume of IV fluid women received in labor was not related to infant weight loss. Close examination of these studies will reveal several important limitations in their research. The sample size for Lamp and Macke's work was small, only 53 mother/infant dyads were studied. In the work done by Lamp and Macke as well as Watson et al., the researchers only evaluated infant weights on day one and two of life. Presumably this was done because infants born vaginally are typically discharged within 48 hours postpartum. Yet, it is well documented that peak infant weight loss occurs on day of life two to three (Noel-Weiss, Curant, & Woodend, 2008). It is reasonable to consider that many of these infants had not reached their maximum peak weight loss before they were discharged and the researchers were no longer collecting weight loss data.

More importantly, it should be noted that in both of these studies, it was not made clear exactly how infants were fed. Lamp and Macke (2010) reported that their sample included infants whose diets were formula, infants with a "mixed" diet (breast milk and formula), and breastfed infants. In the study done by Watson et al. (2012), inclusion criteria required that mothers had a positive intent to breastfeed. The researchers did not indicate how long mothers intended to breastfeed and they did not report if breastfeeding actually occurred. It is reasonable to conclude that some of the infants in their sample received formula and some may not have breastfed at all. In studies that explore the impact of variables on infant weight, it is not prudent to group breastfed infants together with formula fed infants. Patterns of infant weight loss are distinctly different in breast versus formula fed infants, who lose much less weight in the early days of life (Regnault

et al., 2011). Variables that may significantly impact the weight of breastfed infants may have much less of an impact on infants that are formula fed.

Lamp and Macke (2010) found that feeding type (breast milk or formula) was a strong predictor of significant weight loss. They also found that the number of wet diapers was a strong predictor of weight loss. Once again, the potential impact of diuresis on weight in the formula fed infant is minimal compared to the impact of diuresis on the exclusively breastfed infant. Excessive infant weight loss is a problem primarily among breastfed, not formula fed infants (Grossman et al., 2012). To determine the impact of maternal overhydration on breastfed infants' physiology and weight loss patterns, the sample groups must accurately reflect what the infant is consuming.

The study done by Watson et al. (2012) concluded that when maternal IV fluid volume is < 2500 mls there is little effect on infant weight loss. The researchers came to this conclusion by comparing weight loss in two groups of women; the 'conservative care' group who received 75 – 100 mls/hour of fluid (x =1430 mls) and a 'usual care' group who received > 125 mls/hour of fluid (x = 2477 mls). One could argue that both of these groups received 'conservative care'. Watson et al. referenced the work done by Lamp and Macke (2010) whose study showed that women who receive epidural and then unplanned cesarean section may receive 5000 mls or more of IV fluid prior to birth. Given the current documented practices, it would have been helpful for Watson and colleagues to include in their study a sample of women and infants who received \geq 3000 mls of fluid.

The study done by Chantry et al. (2011) was the most comprehensive work reviewed. The researchers collected infant weights on day of life one, two, three, and again on day of life seven.

Researchers accounted for many more potentially confounding factors, including labor and delivery interventions, breastfeeding behaviors, pacifier use, nipple type, and pain. Although the use of formula was a limitation, the researchers measured how much formula was consumed. They categorized the infants into three groups, exclusively breastfed, breastfed with < 60 mls of formula in the first three days of life, and breastfed with > 60 mls of formula in the first three days of life. They found that the amount of maternal IV infusion did impact the weight loss of exclusively breastfed infants and breastfed infants who consumed < 60 mls of formula supplementation.

Pediatrics and Infant Feeding

Over the past 150 years, the use of formula has not only greatly impacted the health of women and infants, but has had powerful social, political, and financial implications for the nation (Thulier, 2009). Until the mid-1800s, physicians uniformly supported infant feeding of mother's milk. This was based primarily on the observations that infants not fed human milk, especially their own mother's milk, has much less probability of surviving (Cone, 1976). When mothers were not able to feed their infants, wet-nursing was the best alternative. If a wet nurse was not available, infants were fed milk from goats, mules, or cows (Hymanson, 1934). Feeding infants these foods often led to high infant mortality rates. The primary reason for the development of infant formula was the management of infants in orphanages (Wolfe, 2001).

In 1856 formula became commercially available to the public. The next 40 years brought limited use of these artificial milks as they were associated with increased infant morbidity and mortality (Thulier, 2009). It was not until the late 1890s when the process of pasteurization made it possible to safely feed infants artificial milk. By the early 1900s the field of pediatrics emerged as a medical specialty based on the need for expertise in infant feeding (Brosco, 1999). When a woman made the decision to feed her infant with artificial milk, she was obliged to make continued pediatric visits to obtain updated "formulas" or directions to prepare the artificial milk. This formula would frequently change according to the infant's weight, age, and health status.

By the 1930s, it is estimated that 25% of pediatric visits were for routine infant feeding care (Apple, 1987). Formula feeding had gained significant economic importance to physicians. Apple (1987) described how physicians often viewed pediatric care as an issue of control. Educated women were aware of the important advances in science and medicine and were receptive to their physician's directions. Physicians wanted mothers to visit doctors and to follow their instructions but not to possess so much information that they could ignore or interfere with their physician's advice (Apple, 1987). When prescribing formulas, many physicians may have been acting on their convictions that they truly thought they knew what was best for infants. It is likely, however, that some pediatricians had an economic motivation (Thulier, 2009).

Ironically, the women's movement in the early part of the 20th century negatively impacted breastfeeding rates in the US (Carter, 1995). The emancipation of women that began in the1920s was symbolized by formula feeding (Rhodes, 1982). By the 1930s and 1940s, most women viewed breastfeeding as old-fashioned and viewed it as an

unnecessary chore forcing them to be tied to their infants. During this same time period, the breast began to be seen as a sex symbol as opposed to a source of nutrition for infants (Bean, 1990). World War II also had a dramatic and long lasting effect on the role of women as workers and mothers. Women shifted from their roles as homemakers to workers outside the home. As a result, the widespread use of formula became much more socially acceptable and widespread (Apple, 1987).

A truly modernized household in the 1950s included a formula-fed infant (Parfitt, 1994). By this time, most pediatricians had come to believe that formula feeding was better than breastfeeding. When educating new mothers, emphasis was placed on the health benefits and ease of medically directed bottle-feeding (Apple, 1987). By 1979, breastfeeding initiation rates in the US hit a record low of 28% (Hirschman, 1979).

Research on the benefits and limitations of human milk did not begin in earnest until the 1970s. Early studies demonstrated health benefits for breastfed infants (Atkinson, Bryan, & Anderson, 1978; Gross, Geller, & Tomarelli, 1981). Yet by the 1980s, manufacturers of infant formula had gained tremendous power and influence in US society. In 1981, the International Code of Marketing of Breast Milk Substitutes was introduced by the WHO. This document addressed the concerns of marketing practices by the companies that produced infant formula. Implementation of the code was overwhelmingly supported by the World Health Assembly and passed by a vote of 118 to 1. Sadly, the US, concerned with the negative effects of this code on the financial impact on business, cast the lone dissenting vote (World Health Organization, 2008). It was not until the 1990s when the US government took a stand against formula companies and began to initiate programs to support breastfeeding. In 1990, the US government co-

sponsored the landmark Innocenti Declaration on the Protection, Promotion, and Support of Breastfeeding (UNICEF, 2005). Other initiatives included the US Department of Health and Human Services Blueprint for Action on Breastfeeding, the National Breastfeeding Awareness Campaign, and the Baby-Friendly Hospital Initiative (Thulier, 2009). Despite these positive initiatives to support breastfeeding nationally, the power and influence of the formula companies have waivered little in the past 20 years.

The Medical Model

A historical review of obstetrical care helps to demonstrate how the medical model of care came to be established in the US. In particular, a review of obstetrical anesthesia and its development is especially revealing in terms of understanding the present widespread use of epidural anesthesia. This review outlines power relations between men and women during the 19th and 20th centuries and demonstrates whose knowledge dominated and whose knowledge was suppressed.

During the late 1800s through the early twentieth century, medicine, practiced mainly by men, gained nearly full control of childbirth in the US. In turn, the art of midwifery, practiced usually by women, came to be almost nonexistent (Simonds, Rothman & Norman, 2007). While some physicians viewed birth as a normal physiological experience, the dominant view held by physicians was that childbirth was a pathological event. This belief led to the development of the "medical model" of care which came to dominate childbirth practices in the US. The primary characteristic of the medical model is that it is based on the ideology of technology. Efficiency and rationality, practical organization, systematization, and control are all highly valued. This model fostered the development of the body-as-machine attitude among medical

practitioners (Simonds et al., 2007). The second major ideological basis of the medical model stems from a patriarchal history. In this model, men are seen as the comparative norm. According to this viewpoint, reproductive processes are physiological stresses on the body, and therefore disease-like in nature (Simonds et al.).

Childbirth Practices – A Historical Perspective

For most of the 19th century, virtually all women gave birth in their own homes, and were attended by a midwife for delivery. The vast majority of women had no access to anesthesia and therefore relied on the midwife and other women in the community for comfort and support during their labor and births (Leavitt, 1986). Birth was a social event in which female relatives and neighbors played an important role. Women often looked forward to the opportunity to assist each other safely and comfortably through labor. Childbirth was considered part of the social fabric of the time, an important event for women only (Leavitt, 1986).

Over the course of the 19th century, in an effort to build their medical practices, physicians began to replace midwives as birth attendants. This occurred, despite the fact that most physicians had little or no training in obstetrical care. Indeed, many physicians felt that obstetrics was unworthy of their professional training (Wolf, 2007). Medical schools received no pressure to offer adequate training in childbirth to their students. In fact, as late as 1904, many physicians received degrees verifying their competence to attend births without ever having witnessed a single birth (Williams, 1911). Clinical experience in obstetrics did not become a requirement of medical schools' curriculums until the 1920s (Wolf, 2007).

This shift from midwife to physician attended births had important and long lasting impact on the way obstetrical care would be delivered in the US. One of the most significant developments was a growing and pervasive sense of fear among women in regards to childbirth. This is thought to be the result of several factors. A physician's company at birth was very different compared to the camaraderie offered by other women. With the physician present, women attended each other's birth less and less frequently (Theriot, 1996). During the mid to late 1800s there was also a growing unwillingness on the part of women to discuss any aspect of reproduction with their daughters. Mothers hoped that by keeping information about reproduction from their daughters, it would protect them from sexual dangers. This did little, of course, to prevent unwanted pregnancy and as a result pregnancy and birth became shrouded in mystery. Attendance by a male physician, lack of female support, and increasing ignorance in regards to normal reproductive processes likely caused childbirth to be viewed in a much more formal, anxiety ridden, and fearful manner (Jacobs & Brumberg, 1997; Theriot, 1996).

In addition, society's collective views of women would come to have a significant impact on the delivery of obstetrical care. During the late 19th century, society idealized the weak, unhealthy, and physically fragile woman. Women were not viewed as strong enough to cope with the demands of labor and birth without anesthesia (Wood, 1973). It was during this period when the use of anesthetic agents first became widespread. In 1846, ether, a mixture of sulfuric acid and alcohol was introduced as an inhalation anesthetic. A year later, chloroform, a combination of whiskey and chlorinated lime also became available as an inhalant anesthetic. Many physicians originally rejected

the use of these anesthetic agents, considering them unnecessary and dangerous (Wolf, 2007). Other physicians, however, quickly recognized that the offer of ether or chloroform attracted patients and was an effective tool in building new medical practices (Leavitt, 1986). By the end of the 19th century, virtually all practicing physicians administered inhalation agents to women in childbirth.

The desire for obstetric anesthesia by women allowed physicians to exert more control over birth practices. Physicians dictated when the anesthesia would be administered during labor (Leavitt, 1986). Curiously, in homes and hospitals alike, the vast majority of women were rendered unconscious or semiconscious only at the moment of birth. It is thought that the normal sights and sounds of second stage labor were likely unsettling to the physicians and likely why they administered the anesthetics at this time. This practice of providing anesthetic just moments before birth continued well into the 1960s (Wolf, 2002). Ironically, most women welcomed the ether or chloroform even though this treatment saved them little if any discomfort. Having not participated in social birth, most women did not know any better. Women came to rely on their physicians to tell them what they needed

Problems with the use of inhalation agents developed soon after their introduction. Chloroform and ether were associated with postpartum hemorrhage, damage to maternal vital organs, and in some cases, sudden maternal death (Wolf, 2002). Women reported a malodorous smell, a suffocating feeling of the mask, and disquieting recollections of helpless semi-stupors. There were no professional standards related to administration of anesthetic agents. Individual physician protocol depended on their view of labor pain. Physicians found that talking to patients under chloroform could cause

agitation. As a result, they began to refrain from conversing with laboring women (Wolf, 2007). Sadly, this isolation from emotional support reinforced the need for increased anesthesia among women.

Throughout the 20th century the search for therapies that would provide relief of labor pain continued. In 1902, Dämmerschlaf, an injectable combination of scopolamine and morphine that acted as an amnesiac during labor and delivery, was introduced in Europe. An investigation by US physicians found the drug to be unsafe for both women and neonates. Ten years later however, American women began requesting this drug be available during labor and birth. Known as "twilight sleep" the drug was presented in popular magazines as a totally new discovery from Europe. The author of these magazine articles criticized physicians for withholding this pain relief from American women (Tracy & Leupp, 1915).

During the early part of the 20th century, an entirely new and different cultural view of the ideal woman predominated in the US. The Gibson girl, an image of a sturdy bicycle-riding, confident woman was in vogue. Popular magazines suggested that the use of twilight sleep would help women to achieve a strong, healthy Gibson girl image (Wolf, 2007). Authors claimed that the use of twilight sleep could help women recover more quickly from birth. Many even suggested that twilight sleep could help produce stronger, healthier babies (Meckel, 1990). Public reaction to the news of this drug was unprecedented. Women wanted and even demanded this anesthetic for childbirth. A consumer driven movement was underfoot.

This call to action reflected the powerful influence of women's activism during the Progressive Era (1890 - 1920). Physicians who ignored these demands from women

put their medical practice at financial risk (Wolf, 2007). The medical community ultimately complied and American women were granted access to twilight sleep. Yet in order to follow the required protocol for administration, women needed to be closely monitored by trained personnel. For the first time in history, women of all social classes would move from the home to the hospital for their childbirth experience (Leavitt, 1986).

By 1914, it was clear that the wide scale administration of twilight sleep had overwhelmingly negative outcomes. In *The Evolution of Obstetric Analgesia*, Claye (1939) described how babies born to mothers who received twilight sleep were often born asphyxiated, their respiratory depression caused by the morphine. The morphine often slowed or stopped uterine contractions. Many women experienced unquenchable thirst and intense headaches for several days after delivery. Uncontrolled delirium was so common that women needed to be routinely restrained; some hospitals used strait jackets to protect women from injury. Other hospital protocols required that women be blindfolded to decrease stimulation (Wolf, 2007). Two short years after the public demand for twilight sleep, the movement for this drug vanished from the public scene. Despite these negative outcomes, scopolamine, one of the drugs in twilight sleep, continued to be used well into the 1960s for women during childbirth (Rosenfeld, Lapan, Kurzner, and Morton, 1954).

Not by coincidence, between 1900 and 1920, the maternal mortality rate rose a staggering 27%. In the hospital, many women died of postpartum infections caused by staphylococcus and streptococcus bacteria. This high death rate remained until the 1940s when antibiotics and blood transfusion became available (Loudon, 2000). Another leading cause of increased morbidity and mortality was the use of anesthesia (Preston &

Haines, 1991). Women under anesthesia had no urge or ability to push when the time arrived to deliver their infants (Kane & Roth, 1935). The use of forceps became routine. This occurred despite the fact that the misuse of forceps could result in trauma and even death for mothers and babies (Leavitt, 1986). Episiotomies also became routine when anesthesia was used. An episiotomy allowed for easier application of forceps. Episiotomies also hastened delivery, arguably in order to spare the infant's head from undue pressure. Physicians argued that episiotomies were done to protect against ragged tears of the perineum and pelvic floor damage. In addition, DeLee (1920) claimed that "virginal conditions" could be restored with episiotomy repair. Overwhelming evidence would later demonstrate that episiotomies led to increased perineal damage and pain for women (Thacker & Banta, 1983). Anesthetics also led to relaxation of the smooth muscles and increased rates of postpartum hemorrhage.

By the 1940s and 1950s, 95% of all births in the US occurred in hospital. Hospital personnel struggled to cope with the increased numbers of patients and found that the routine use of the above mentioned obstetrical interventions (i.e. forceps, episiotomy) aided in making birth more predictable and routine (Wolf, 2007). Women who were anesthetized were quiet, cooperative, and less demanding (Garcia, Waltman, & Lubin, 1953). Interestingly, this method of birth was acceptable to most women as it fit the growing cultural imperative for convenience. Ultimately, labor induction, heavy use of analgesics during the first-stage, general or regional anesthesia during the secondstage, episiotomy, and forceps delivery became completely routine, the new normal (Leavitt, 1986). Ironically, during most of the 20th century, women often experienced more pain in the hospital than they would have if they had given birth at home. In hospitals women were isolated from social support and they were left alone with their pain. Hospitalized women were confined to bed during labor. Not only did this horizontal position increase women's pain but it slowed the progress of labor (Simons, Rothman, & Norman, 2007). Physical contact, comfort, and reassurance were simple, effective, low cost interventions that were not implemented in a hospital birth. Instead, techniques used to reduce pain in labor were strictly pharmacological.

During the 1940s, 1950s and 1960s obstetricians often demanded that women receive anesthesia, despite their request to avoid it. Beginning in the 1950s, mothers began writing to women's magazines charging that poor treatment by nurses and doctors in maternity wards worsened their childbirth experiences (Shultz, 1958). Reports from women who received these unwanted treatments were growing (Haggerty, 1973). By the late 1960s, women charged that their treatment during birth bordered on the inhumane. By the early 1970s, organized groups of women were rebelling against obstetrical procedures that they described as impersonal, unnecessary, and potentially dangerous. The image of women strapped to delivery room tables, unconscious or drugged from unnecessary and unwanted drugs, became abhorrent (Wolf, 2007). Activists encouraged women to shun anesthesia and demand control over their own bodies and their medical treatment. The natural childbirth movement had begun and would go on to ignite a sweeping consumer movement of birth reform in the US.

The 1970s was a time when women became increasingly involved in American economic and political life. During this decade, the image of strong, fearless women

giving birth without anesthesia became very appealing (Tong, 1998). The Lamaze method of breathing and relaxation became a popular childbirth method that helped many women gain some control over their body's responses to pain. Unfortunately, despite the natural childbirth movement, little would change in terms of women's control over their birth experience. The Lamaze method challenged the use of anesthesia, but challenged no other aspect of the American way of birth. In the end, the nationwide interest in natural birth did not last long. Many women were not able to endure the discomfort of labor without requesting pain medication. Women's magazines soon ran stories of women describing their frustrations over these "failed" natural births. By the 1990s the same magazines that had supported natural childbirth were now calling it unreasonably demanding and dangerous. By the early 21st century, the use of regional anesthesia for control of labor pain had increased to 60% (Osterman & Martin, 2011).

Over the past 20 years, American women have grown up with the expectation of full time work outside the home in addition to raising a family. The use of epidural anesthesia has assured busy, working women that childbirth can not only be pain-free but stress free (Simpkin, 1999). In the 1970s, natural childbirth supported control by allowing women to take charge of their labors and births. Since the 1990s, epidural anesthesia allowed laboring women the ability to maintain their composure and to socialize normally during labor. These different views of control reflect two very different generations of American women (Simpkin).

This review of the history of pediatrics and formula feeding in the US has provided insight about current infant feeding practices. In the US, physician-directed use of formula has dominated infant feeding since the 1940s. To this day, formula, produced

by pharmaceutical companies, is the primary source of nutrition for infants in the US (Thulier, 2009). The review of the medical model of care and childbirth practices provides increased understanding of how and why the use of obstetrical interventions such as IV therapy and epidural anesthesia are so widespread. This history has revealed the immense power of the medical model and how women's knowledge of childbirth and childrearing and has been suppressed over time. In addition, this history demonstrates the influence not only of science and politics, but also of culture on childbirth and childrearing practices. Ever changing cultural views of women influence how women are viewed, by society, by men, by other women, and by themselves. Society's collective views of women also influence how they are treated and how they think they should to be treated. A vast majority of women are significantly influenced by the culture they live in.

Chapter IV

Methodology

Purpose

When infants have a significant weight loss in the first few days of life, the cause is often thought to be ineffective breastfeeding (Gagnon et al., 2005; Yaseen et al., 2004; Yildizdas et al., 2005). Formula supplementation is frequently given to treat this weight loss despite the fact that formula is associated with shorter breastfeeding duration (Thulier & Mercer, 2009). The cause of EWL, however, may be related to medical interventions that occur during childbirth (intrapartum) such as IV hydration and epidural administration. The purpose of this study was to determine if infant exposure to excess maternal IV hydration and epidural anesthesia during labor and birth are associated with an increased occurrence of infant EWL on the third day of life.

Research Hypothesis

Hypothesis 1: Term breastfed infants born to mothers who receive large amounts of IV fluids (\geq 3000 mls) during labor and birth will have a higher occurrence of EWL compared to term breastfed infants born to mothers who receive less IV fluids (< 3000 mls) during labor and birth.

Hypothesis 2: Term breastfed infants born to mothers who receive epidural anesthesia will have a higher occurrence of EWL compared to term infants born to mothers who receive spinal anesthesia.

Research Design

A case-control research design was used to examine the relationship between maternal IV fluid intake and EWL in the newborn on day three of life. Infants born to mothers with CS were chosen as these mothers and infants remained hospitalized for three to four days after birth and access to reliable data on infant weight during that period was available. According to the 2011 Annual Report, in the hospital where data was collected, the CS rate was 32%, which matched the nationwide CS rate (Hamilton et al., 2011). Two groups of mothers and their infants (dyads) were identified. The 'controls' were dyads in which the infant had weight loss < 8% on the 3rd day. The 'cases' were dyads in which the infant had weight loss \geq 8% on the 3rd day of life.

In the literature, there are inconsistencies among professional organizations in regards to the 7% threshold of weight loss. Some studies suggest that a 10% loss of birth weight in the first few days of life may be expected for breastfeeding infants (Kliegman et al., 2007). No national agency, however, supports this amount of weight loss. The International Lactation Consultant Association (2005) stated that infants should lose no more than 7% of their birth weight. The AAP (2012) also warned that exclusively breastfed infants who exceed 7% weight loss need breastfeeding evaluation and follow up. Yet, experts from the Academy of Breastfeeding Medicine (2009) noted that infant weight loss should be less than 7%. These subtle differences in recommendations may result in confusion among medical professionals regarding whether or not 7% weight loss is considered "normal" weight loss. Eight percent weight loss was therefore chosen as the threshold between the case and control groups in this study as this is clearly outside the normal weight loss parameters of 5-7%.

Intrapartum, postpartum, and neonatal data was collected by retrospective chart review. The dependent variable was the percentage of lost birth weight on the 3rd day of life. The primary medical interventions that were examined included: 1) the amount of

IV fluid administered during labor, and 2) the type of anesthesia (epidural, spinal, epidural/spinal combination). Other antenatal data that were assessed included the type of CS (planned or unplanned), the number of hours of maternal IV therapy, the total hours of labor, the medical indication for CS, the presence and number of maternal episodes of hypotension during labor, the use of the drug oxytocin, and the documentation of maternal fever and subsequent treatment. Data that were collected from infant chart reviews included birth weight, gestational age, Apgar scores, LATCH score on day three, daily weights, percentage of daily weight gain or loss, number of voids and stools per day, number of feedings, the type of infant feedings, and gestational size. Gestational size can be one of three categories: Large for gestational age infants (LGA) are those with a birth weight > 4000 grams , small for gestational age, newborns with a birth weight between 2500 and 4000 grams (Ricci, 2013).

Setting. A level III maternity hospital in the Northeast region of the US was selected for this study. This facility is considered one of the nation's leading specialty hospitals for women and newborns. It is the eighth largest stand-alone obstetrical hospital in the country with 8,400 deliveries per year. In Rhode Island, 72% of all infants are delivered at this facility annually.

The March of Dimes PeriStats (2011) Rhode Island data reports the 2008 birth and maternal racial and ethnic characteristics as follows: White (49.8%), Black or African American (8.4%), American Indian and Alaska Native (0.9%), Asian (4.3%), Hispanic (21.6%) and others-not reported (15%). Ethnicity was expected to reflect the race and ethnic origin demographics within the state of Rhode Island.

Sample. A convenience sample of 272 mothers and their infants who were born between July 1 – Dec. 31, 2010 were included in this study. Approximately 200 women per month are delivered by CS at this hospital. Seventy-four percent of those women, or approximately 148 mothers per month were expected to breastfeed their infants (Lactation Consultant, personnel communication, August 14, 2012). Approximately 20% of these mother/infant dyads were not expected to meet the eligibility requirements for this study. Of the remaining 118 infants, research suggested that 12 % – 18% would experience EWL (Chantry et al., 2011; Dewey et al., 2003). It was therefore estimated that 14 - 21 infants would meet the criteria for the case group every month. Access to 18 months of patient medical records, from July 2010 to December 2011, ensured that there would be adequate infants in both the case and control groups.

Eligibility criteria included women \geq 18 years of age who were 38 to 41 6/7 weeks gestation with a healthy, singleton infant delivered by CS. Only dyads in which the infant was exclusively or predominately fed breast milk for the first 72 hours of life were included (Appendix A). Infants born prior to 38 weeks gestational age were excluded as increasing evidence suggests that earlier gestational age may negatively impact feeding behavior (Zanardo, 2013). Maternal exclusion criteria included significant medical or obstetrical illness, gestational diabetes, gestational hypertension, or postpartum hemorrhage. Exclusion criteria for infants included a diagnosis of intrauterine growth restriction, serious congenital anomalies, or NICU admission. It was determined by power analysis that a total sample of 272 dyads would be sufficient to test the primary hypothesis that infants born to mothers receiving large amounts of IV fluids during labor

and birth will have a higher occurrence of EWL compared to infants born to mothers receiving less IV fluids during labor and birth.

Sample size. The power analysis was based on the study by Chantry et al. (2011). The mean maternal intrapartum fluid total for the infants of mothers who received < 100mls/hour was 2442 mls (+ 1368) and the mean maternal intrapartum fluid total for the infants of mothers who received > 200 mls/hour was 2964 mls (+ 1681). The difference between these means (2964 – 2442 = 522) was divided by the standard deviation (1681 + 1368 = 3049 / 2 = 1524) resulting in an effect size of .34. Using Cohen's d Table for determination of appropriate sample size, with an alpha of .05 (for two-tailed tests), an effect size of .34, and a power equal to .80, the estimated sample size (n) is 272 mother/baby dyads (136 in each group) (Polit & Beck, 2008).

Protection of human subjects. Approval to conduct this study was obtained from the hospital and the University of Rhode Island Institutional Review Boards (Appendix B). Patient confidentiality and protection of personal health information were maintained throughout the duration of the study. Patient names were not recorded. The link between the patient's medical record number and clinical findings was known only by the student investigator. The two excel spreadsheets containing clinical data were stored on a hospital issued encrypted laptop. An additional password and encryption program were utilized for the excel spreadsheets.

Procedure

Data collection was conducted from Dec. 1, 2012 to May 31, 2013. A research assistant aided the student investigator in data collection. Six months of data were examined, all entries noted in the hospital birth log from July 2010 to December 2010

were reviewed. Birth log entries were screened for eligibility requirements: maternal age, route of delivery, singleton or twin delivery, and gestational age of the infant. A total of 1019 subjects in the birth log met these initial eligibility requirements. Individual infant electronic medical records were then reviewed; if further infant eligibility requirements were met, the mother's medical record was screened. For a variety of reasons, 551 infants and 196 women were excluded (See Appendix C).

The 272 mother/infant dyads who met enrollment criteria were assigned to either the case (day three weight loss \geq 8%) or control (day three weight loss < 8%) group. Data from both the maternal and infant electronic medical records were recorded on excel spread sheets.

All infants were weighed daily between 0000 and 0200 hours by the nursery staff, despite the time of birth. This resulted in some variation of infants' ages when daily weights were compared. For example, some infants were close to 24 hours of age for their first weight check, while other were only a few hours of age. The number of feedings and voids were recorded based on time of birth and therefore reflected a true 24 hours' worth of data. For example, if an infant was born at 1400 hours, all feeding and outputs were counted from that point until 1400 hours the following day.

Measurement Tools

Two tools were utilized in the collection of data for this study. These included the LATCH scoring system and infant feeding categories. The LATCH scoring system is an assessment tool used by health care workers to determine effective breastfeeding (Appendix D).

A numerical score of 0, 1, or 2 is assigned to all components for a maximum score of 10 points (Schlomer, Kemmerer, & Twiss, 1999). Researchers have found that the LATCH score is positively correlated with duration of breastfeeding (r = .26, P = 0.003) and that this tool is useful for identifying mothers at risk for breastfeeding problems (Riordan, Bibb, Miller and Rawlins, 2001).

The feeding categories that were used for this research study were exclusive breast milk and predominant breast milk (Thulier, 2010) (Appendix A). The proposed categories allow researchers to classify infants into appropriate feeding groups that may ultimately lead to greater reliability and validity in research on infant feeding (Thulier, 2010). These categories have been successfully tested in a small unpublished study (Erickson-Owens, personal communication, Sept. 1, 2011).

Definition of Terms

Term Cesarean Section: Delivery of the fetus (\geq 38 weeks gestation) through an incision in the abdomen and uterus; may be planned or unplanned. Thirty-two percent of US births occur by this delivery method. Spinal, epidural, combination epidural/spinal or general anesthesia is used with cesarean section.

Planned Cesarean Section: A CS that is scheduled (or planned) in advance of labor, at a predetermined time and date. The mother may or may not be in active labor prior to the surgery.

Unplanned Cesarean Section: A CS that is unexpected and not scheduled in advance of the date and time in which it occurs. The mother may or may not be in active labor prior to the surgery.

Intrapartum IV Fluid: The net total of IV fluids, measured in mls from the time of IV catheter insertion until the birth of the infant. Mother/infant dyads were assigned to one of five groups: < 2,000 mls, 2,000 - 2,999 mls; 3,000 - 3,999 mls; 4,000 - 4,999 mls; and $\ge 5,000$ mls.

Routine Weight Loss (RWL): Weight loss < 8% of the birth weight in the first week of life; considered a physiological response to extra uterine life. Infants are expected to regain birth weight by seven to ten days of life. Infant weight were measured in grams and assessed daily during hospitalization. Dyads in which the infant has RWL on day three were assigned to the control group.

Excessive Weight Loss (EWL): Infant weight loss $\geq 8\%$ of the birth weight in the first week of life; considered a pathological response to extra uterine life. The nadir of weight loss is usually day two to three of life. Infant weights were measured in grams and assessed daily during hospitalization. Dyads in which the infant has excessive weight loss on day three were assigned to the case group.

Exclusive Breast Milk: A feeding method whereby the infant receives breast milk only from his or her mother. The infant may also receive drops and syrups (vitamins, minerals, or medicines) as needed

Predominant Breast Milk: A feeding method whereby 75% or more of the infant diet is breast milk from his or her mother. The infant may also receive water and infant formula. Feeding category will be determined at 24, 48, and 72 hours of age as well as cumulatively at 72 hours of age.

Maternal Hypotension: A systolic blood pressure reading of 90 millimeters of mercury (mm Hg) or less and/or a diastolic blood pressure of 60 mm Hg or less

accompanied by one or more of the following symptoms: dizziness, nausea, vomiting, diaphoresis, pallor, faintness, and/or fetal distress.

Data Analysis

All statistical analysis was done using SPSS Statistics Version 21 (SPSS, Incl., Armonk, NY). Descriptive statistics were run on all quantitative variables to summarize distribution, outliers, missing values, and data entry errors. The means, medians, standard deviation, and range of minimum and maximum values were calculated. The case and control groups were compared for similarities. For each categorical variable, the distribution of the variable was summarized using the frequency distributions. Categorical variables of interest were then compared using the Chi-Square Test of Independence. For each continuous variable a scatter plot or histogram was used to examine the normality of their distribution. Independent-Samples *t*-test were utilized to compare the means of these variables in the case and control groups. The odds ratio of the primary variables of interest were calculated to determine the likelihood of EWL. A conventional confidence interval of 95% was utilized for all hypothesis testing.

Resources

The cost of this study was approximately \$1,815 (Appendix E). The student investigator, Diane Thulier, PhD(c), assumed all associated costs. A \$500 award from the Dean's Fund, College of Nursing, URI and \$1,200 from the Nursing Foundation of Rhode Island provided the financial backing to complete this study.

Chapter V

Results and Analysis of the Data

The purpose of this study was to investigate if breastfed infant exposure to large amounts of maternal IV hydration and epidural anesthesia while in utero were associated with an increased occurrence of EWL on the third day of life. A sample of 272 mother/infant dyads were assigned to one of two groups; infants who had \geq 8% loss of birth weight (cases) on the third day of life and infants who had < 8% loss of birth weight (controls) on the third day of life. This chapter describes the background characteristics and demographics of the subjects and reports and compares the findings.

All entries noted in the hospital birth log from July 2010 to December 2010 were reviewed. The birth log provided preliminary screening information for eligibility requirements including maternal age, type of birth, singleton or twin delivery, and the gestational age of the infant. A total of 1019 potential dyads in the birth log met these initial eligibility requirements. After a chart review, 551 infants and 196 mothers failed to meet the enrollment eligibility criteria (Appendix C). The 272 mother/infant dyads that remained were assigned to either the case (day three weight loss \geq 8%) or control (day three weight loss < 8%) group.

Analyses of the Data

Data were analyzed using the statistical software program SPSS Version 21.0 (SPSS, Incl, Armonk, NY). The Independent-Samples *t*-test was utilized to compare the means of continuous variables in the case and control groups. The output provided the basic descriptive statistics including the sample size, mean, and standard deviation. Results of the *t*-test included the value of *t*, the degrees of freedom, and the significance

level. Categorical variables were compared using Chi-Square Test of Independence. The data were presented as sample number (n) and percent (%). The odds ratio of the primary variables of interest were calculated to determine the likelihood of EWL. Pearson correlation coefficient was used to determine the strength of the relationship between birth weight and the percent of infant weight loss on day three of life. Spearman correlation coefficient was used to determine the strength of the relationship between the amount of maternal IV fluid and the percent of infant weight loss on day three of life. The statistical hypotheses were tested at p < .05 level of significance.

Missing data were related almost exclusively to the date and time of mother/infant discharge. Two hundred and thirteen dyads (78%) were discharged on day four of life. Fifty nine dyads (22%) were discharged on the third day of life; 30 were in the case group, and 29 were in the control group. Day four weights, feedings and outputs are missing for all infants discharged on day three of life. One infant in the control group did not have a recorded weight for day one and day two of life. All other data were complete. The data that were generated and analyzed are presented as follows: (a) demographic characteristics of the mothers and their infants; (b) clinical characteristics of the mothers and infants; (c) analyses of the data as related to the two hypotheses; and (d) a summary of the data analyses.

Demographic variables. The maternal demographic characteristics from both the EWL and no EWL groups are shown in Table 2. There were no significant differences between the two groups in maternal age. The majority of the women in both groups were white and married. More women in the EWL group had private insurance (p = 0.03).

The neonatal demographic characteristics from both groups are shown in Table 3. More females were likely to experience EWL although this did not reach significance (p = 0.06). There was a significant difference based on gestational size. Infants in the EWL group weighed significantly more than infants who did not have EWL (p = 0.001). A Pearson correlation coefficient was calculated for the relationship between infants' birth weight and percent of weight loss on day 3. A strong positive correlation was found (*r* (270) = 0.218, p < 0.01), indicating a significant linear relationship between the two variables. Heavier infants tended to lose more weight and to be in the EWL group. Gestational age did not differ between groups.

Clinical variables. The maternal clinical variables are shown in Table 4. Parity was higher in the group without EWL. There were no significant differences between the EWL and no EWL groups regarding the number of hours of IV therapy, hypotension, fever, and CS (planned or unplanned). Women who experienced an induction of labor were significantly more likely to be in the group without EWL (p = 0.01).

There were no significant relationships noted between weight loss groups regarding the presence of fetal distress in labor (p = 0.17) or 5 minute Apgar scores (p = 0.21). Other neonatal clinical variables are shown in Table 5. All infants in both groups lost some percentage of their birth weights. On day two, three and four there was a significant difference between groups in regards to percent of birth weight lost (p = 0.001). It is important to note that on day three of life, the mean weight loss for all 272 infants in the study was 7.34% (Figure 1). In addition, more than half of all the infants in the study (54%) experienced $\geq 8\%$ weight loss by day three of life (Figure 2).

By day four of life, five infants in the group without EWL had gained more than their birth weight while no infants in the EWL group had done so. On day four of life, although it did not reach significance, there was a difference in weight gain between groups with the infants without EWL continuing to gain more weight (p = 0.08) (Table 5).

There was an increase in voids among the EWL group on day 1 of life (p = 0.09) (Table 5). On day four of life, infants in the group without EWL had significantly more voids (p = 0.003). There was no significant difference between groups in regards to number of stools on day 1 (p = 0.94). Infants in the group without EWL did have a significantly increased stools on day two, three and four of life (p = 0.03; day three p = 0.001; day four p = 0.03)

The neonatal feeding variables are shown in Table 6. Infants in the group without EWL had a significantly higher (or better) LATCH score (p = 0.001). No significant differences were found in the number of infant feedings on day one and two of life. On day three (p = 0.04) and day four (p = 0.005), infants with EWL fed significantly more often.

In terms of feeding categories, or what infants were actually fed, there was significant differences between the groups on day two, three, and four (Table 6). On day two, more infants with EWL were exclusively breastfed compared to infants without EWL (p = 0.01). This changed dramatically on day three (p = 0.003) and four (p = 0.001) when significantly more infants without EWL were exclusively breastfed compared to infants to infants with EWL (Figure 3). On day three of life, many infants with EWL started receiving increased amounts of formula supplements.

Analyses of the Data as Related to the Primary Outcome Variables

The two null hypotheses were used for statistical purposes and are presented in consecutive order. Data were analyzed using the Independent-Samples *t*-test, Chi-square (Table 7) and odds ratios (Table 8).

Hypothesis 1. The null hypothesis stated that there would be no statistically significant difference between the occurrences of EWL in term infants born to mothers who receive large amounts of IV fluids (\geq 3000 mls) during labor and birth as compared to term infants born to mothers who receive less IV fluids (< 3000 mls) during labor and birth. The null hypothesis was accepted. Chi-square test analysis revealed that the occurrence of excessive weight loss was similar between groups. A Spearman *rho* correlation coefficient was calculated for the relationship between maternal IV fluid volume and percent of infant weight loss on day 3 of life. A weak correlation that was not significant was found (r (270) = 0.032, p > .05) which indicated that maternal IV fluid volume was not related to infant weight loss on day 3 of life. The odds ratio analysis is also less than 1 which indicated that infants born to mothers who receive \geq 3000 mls of IV fluid are not at an increased risk of experiencing EWL (Table 8).

Hypothesis 2. The null hypothesis stated that there would be no statistically significant difference in the occurrence of EWL in term breastfed infants born to mothers who receive epidural anesthesia as compared to mothers who receive spinal anesthesia. The null hypothesis was accepted. Chi-square test analysis revealed that the occurrence of EWL among infants was similar between groups. The odds ratio analysis was less than 1 which indicated that infants born to mothers who receive epidural anesthesia are not at an increased risk of experiencing EWL (Table 8).

Summary

Data for 272 mothers and their full-term infants were generated by conducting a case-control research study. Data sources included the hospital's birth and delivery log from July, 2010 – December, 2010 as well as neonatal and maternal electronic medical records.

The maternal demographic variables were similar between groups. The only significant difference was that more infants in the EWL group had mothers with public insurance. The infant demographic data were also similar between groups, with the exception that infants who were large for gestational age were more likely to be in the EWL group. There were more female infants in the case group but this did not reach significance.

Women who underwent induction of labor were more likely to have infants in the control group. There were differences between groups regarding hours in hospital, hours of IV therapy, hypotension, fever, medical indications for cesarean section, and augmentation of labor.

There were several differences in the neonatal clinical variables between the groups. Infants in the case group had a significantly higher birth weight. On day two, three, and four there was a significant difference between groups in regards to percent of lost birth weight; infants in the case group lost more weight each day. On day four of life, significantly more infants in the control group had gained more than their birth weight compared to the case group. Infants in the case group also had a significantly increased number of stools on day two, three, and four of life and significantly more voids on day four. There was no difference between groups regarding the presence of fetal distress in

labor or Apgar scores. On day three of life, the mean weight loss for all 272 infants was 7.34%; more than half of all the infants in the study (54%) experienced \geq 8% weight loss by day three of life. Of interest, a total of 50 infants (18%) lost \geq 10% on day three of life.

There were differences between groups in regards to the infant feeding variables. Infants in the control group had a significantly higher LATCH score. On day three and four, infants in the case group fed significantly more often. A significant relationship was also found regarding how much breast milk infants were fed. On day two, three, and four the rate of exclusive breastfeeding in the case group decreased from 96%, to 67%, and to 53%, respectively. This compares to the more stable exclusive breastfeeding rates in the control group of 86%, 84%, and 80% on day two, three, and four of life.

Null Hypothesis One was accepted. Using chi-square test and odds ratio analysis, it was found that there were no statistically significant differences between the occurrences of EWL in term infants born to mothers who receive \geq 3000 mls of IV fluids during labor and birth as compared to term infants born to mothers who receive less IV fluids during labor and birth. Null Hypothesis Two was also accepted. Chi-square and odds ratio analysis revealed that there was no statistically significant difference in the occurrence of EWL in term breastfed infants born to mothers who receive epidural anesthesia as compared to mothers who receive spinal anesthesia.

Chapter VI

Discussion, Conclusions, and Implications

Maternal hydration and infant weight were the focus of this case-control study in breastfeeding infants delivered by CS. This chapter will review the theories used to support this work. A summary of the study purpose, procedure and sample, data analysis, and the findings will be provided. A discussion of the findings as they relate to the hypothesis and unanticipated findings will also be reviewed. This discussion will include the impact of infant output, labor induction, and insurance on infant weight as well as an examination of infant feedings in the case and control groups. It will also include how these findings contribute to the current body of literature on infant weight and feeding. Finally, the limitations of the study, conclusions, and recommendations for future research will be presented.

Theoretical Framework

The Post Modern Feminist Theory provided a highly useful theoretical framework. The major belief of this theory is that key assumptions of reason, truth, and progress that are embedded in nursing practices must be questioned and critiqued. The goal is to reveal whose knowledge has dominated and whose knowledge has been suppressed. A historical review of the development of obstetrical care in the US revealed that male knowledge and power has greatly shaped the development of childbirth practices over time. During the 19th and 20th century, women's knowledge and power were largely suppressed. It was not until the latter part of the 20th century that women were slowly able to be heard and gain some influence over their own childbirth experiences. This history provides insight into how and why common medical

interventions such as IV therapy and epidural anesthesia remain an integral and daily part of modern day childbirth practice.

Several physiologic principles were examined to demonstrate an empirical link between maternal hydration and infant weight. Changes that occur with pregnancy and birth may place laboring women at increased risk for acute hydration. These changes include expanded body water and plasma volume, increased secretion of antidiuretic hormone, and slower excretion of excess body fluid. When fluid overload occurs in pregnant women, parallel changes may be expected in the neonate. During labor, fluid may transfer to the neonate and result in an inflated infant birth weight. Over the next several days, the newborn will lose weight by natural diuresis, a process which may result in excessive weight loss.

When infants experience EWL, the cause is often thought to be ineffective breastfeeding and formula supplementation is frequently given to treat this weight loss. The cause of EWL however, may be related to medical interventions that occur during childbirth. The purpose of this research study was to examine the impact of selected medical interventions on the weight of the breastfed infant on the 3rd day of life. Specifically this study sought to determine the impact that maternal IV hydration and anesthesia have on neonatal weight.

The study used a case-control research design to determine the relationship between maternal IV fluid intake and excessive infant weight loss. It was conducted at a large level III maternity hospital in the northeast region of the US. From a larger sample of 1019 potential subjects, a sample of 272 women and their full-term infants (dyads) was selected meeting the study's inclusion criteria. These dyads were assigned to either a

case (\geq 8% loss of birth weight) or control (< 8% loss of birth weight) group depending on the infants weight on the 3rd day of life. The primary variables were the amount of IV fluid the mother received before birth and the type of anesthesia she received.

Data were collected from the hospital birth log, maternal, and infant electronic medical records. There were minimal missing data. Data were analyzed using the statistical software program known as SPSS Version 21.0 (SPSS, Inc., Armonk, NY).

Two hypotheses were tested. Hypothesis One was tested using chi-square tests of independence, odds ratio, and Spearman correlation. The chi-square test was used to determine if the amount of maternal IV fluid and infant weight loss were independent of each another. The odds ratio was used to determine if there was an increased probability of EWL in the infant when mothers had more or less IV fluids during labor. The Spearman correlation coefficient was used to determine the strength of the relationship between maternal IV fluid and the percent of infant weight loss on day 3 of life. Hypothesis Two was also tested using the chi-square test of independence and odds ratio. Chi-square analysis tested if the type of anesthesia and infant weight loss were independent of each other. The odds ratio tested if there was an increased probability of EWL for the infant when mothers had different types of anesthesia. Multiple categorical variables of interest were also analyzed using the Chi-square test of independence. Continuous variables of interest were tested using the Independent-Samples *t*-test to compare means between the case and control groups.

Data for 272 mothers and their full-term infants were collected. There were two significant differences found in the maternal and infant demographic variables. More infants in the case group had mothers with private insurance and more infants in this

group were larger at birth. Infant gender neared significance with more females in the case group (p. = 0.06).

Regarding the two main hypotheses, there were no significant differences found between the case and control groups in regards to the amount of maternal IV fluid or type of anesthesia received by mothers. However, there were several incidental findings of clinical significance. Infants whose mothers underwent induction of labor were more likely to be in the control group. There was also a trend in the control group where women had higher parity (p = 0.07). As expected, infants in the case group lost more weight daily compared to the control group. There was a trend toward increased voids on day one in the case group (p = 0.09). There were more stools on all subsequent days and more voids on day four for infants in the control group. More than half (54%) of the infants in the study lost $\geq 8\%$ of their birth weight, and 18% of the infants lost > 10%. Infants in the control group had a higher LATCH score. On day three and four, infants in the case group fed more often. By the 4th day of life the exclusive breastfeeding rate in the case group had decreased to 53%, while in the control group the exclusive breastfeeding rate was 80%.

Hypothesis One stated that term breastfed infants born to mothers who receive large amounts of IV fluids (\geq 3000 mls) during labor and birth will have a higher occurrence of EWL compared to term infants born to mothers who receive less IV fluids (< 3000 mls) during labor and birth. The null hypothesis was accepted. There was no statistically significant differences between the occurrences of EWL in the case and control groups.

Four studies have examined maternal IV fluid and infant weight (Chantry et al., 2011; Lamp & Macke, 2010; Mulder et al., 2010; Watson et al., 2012). The results of this body of research are contradictory. In 2010, Mulder et al. suggested that infants with a substantial weight loss might be experiencing a large diuresis due to large amounts of maternal IV intake during labor and birth. The following year, Chantry et al. concurred. They found that the prevalence of excessive weight loss was significantly related to maternal intrapartum IV fluid intake. However, Lamp and Macke (2010) reported that neonatal weight loss was not significantly related to intrapartum maternal fluid intake. Watson et al. also found no significant differences in infant outcomes related to maternal IV intake. Further analysis of the data presented by Watson et al., however, did reveal that infants whose mothers received > 2500 mls of IV fluid in labor lost significantly more weight during the first 48 hours of life (p = 0.03).

Data from this study of maternal hydration and infant weight revealed that the amount of maternal IV intake did not significantly impact infant weight. It is important to note, however, that few subjects in this work received large amounts of IV fluid (\geq 3000 ml). A total of 159 (58%) women underwent a planned cesarean section, and these women received 1,500 mls or less of IV fluid prior to delivery. This volume was much less than what has been reported in the literature. Lamp and Macke's reported (2010) that women who have a planned CS receive a mean volume of 2,759 mls of IV fluid prior to birth.

Lamp and Macke (2010) also reported that women who experienced labor and unplanned CS received a mean volume of 5,014 mls. This was also not consistent with the amount of IV fluid that women received in this study of maternal hydration and

infant weight. All subjects received considerably less IV fluid prior to birth. Only 69 (25%) of women received \geq 3000 mls of fluid prior to delivery. Furthermore only 20 women received a volume of \geq 4000 mls of fluid. An exploratory analysis of this sub group of 20 dyads demonstrated that 14 (70%) of the infants in this group experienced EWL. This indicates a trend toward EWL when fluid volumes \geq 4000 mls are given. Interestingly, this finding is consistent with the finding of the exploratory analysis done by Watson et al. (2012). Those researchers also found that 51 infants whose mothers received > 2500 mls of fluid lost significantly more weight during the first 48 hours of life (p = 0.03).

The type of facility may impact why women in this study of maternal hydration and infant weight received less IV fluid volume than is reported in the literature. As a tertiary care center with a Level III nursery, providers and nurses in the Labor and Delivery unit of this hospital may have been more cognizant of the potentially negative impact of IV fluid overload on high risk labor patients and preterm infants. This more conservative delivery of IV fluid volume may impact the amount of fluid received by all patients, including low risk labor patients.

Hypothesis Two stated that term breastfed infants born to mothers who receive epidural anesthesia will have a higher occurrence of EWL compared to term infants born to mothers who receive spinal anesthesia. The null hypothesis was accepted. There was no statistically significant differences between the occurrences of EWL in the case and control groups.

A limited number of studies have explored the impact of maternal anesthesia on infant weight. In an exploration of factors associated with infant weight loss in the first

few days of life, Martens and Romphf (2007) found that infants whose mothers had epidural anesthesia lost more weight. Lamp and Macke (2010) also noted that neonates who had a vaginal birth with an epidural lost about 1¾ % more of their birth weight than those who had a vaginal birth without epidural. Every infant in the study conducted by this investigator received either spinal, epidural, or a combination of epidural/spinal anesthesia. This suggests that all types of regional anesthesia have the same potential effect on infant weight; the epidural did not have more or less of an impact.

An important unanticipated finding of this study was that more than half (54%) of the enrolled infants lost $\geq 8\%$ of their birth weight. The mean weight loss for all 272 infants was 7.34% on the third day of life. This frequency and degree of infant weight loss has not previously been reported. Watson et al. (2012) found that 46% of infants lost > 7% of their birth weight prior to hospital discharge at two to four days of life. In addition, the study by this investigator found that 18% of all infants lost \geq 10% of their birth weight on the third day of life which supports similar findings of Chantry et al. (2011).

The guidelines by the AAP (2012), the Academy of Breastfeeding Medicine (2009), and International Lactation Consultant Association (2005) recommend that infants should not lose \geq 7% of their birth weight in the first week of life. By this definition, more than half of all the healthy, term, infants born by CS in this study had breastfeeding difficulties as determined by these professional organizations. This figure is alarmingly high and leads one to question the accuracy of the 5-7% expected weight loss as "normal". It is also necessary to discuss the other factors in this study which may have impacted infant weight; including infant output, induction of labor, and insurance

type. The differences in exclusive breastfeeding rates among the infants in the case and control groups will also be discussed.

Infant output. The variable that is most closely associated with maternal IV intake is infant voiding, especially in the first one to two days of life. Studies have demonstrated a positive relationship between neonatal output and percentage of newborn weight loss (Mulder et al., 2010; Noel-Weiss, Woodend, Peterson, Gibb & Groll, 2011). Lamp and Macke (2010) found that in babies with excess weight loss, the numbers of stools decreased from day one into day two but the number of wet diapers increased. These results point to a pattern of diuresis that impacts infant weight. The findings of this investigator corroborated with Lamp and Macke's findings. For infants in both the case and control groups, the number of voids increased from day one to day two of life. There was also a trend toward increased voids on day one in the case group (p=.08). This suggests that while all infants experience a diuresis, those infants in the case group experienced a larger diuresis and resultant impact on their weight.

The pattern of infant stooling over the course of four days reveals that infant feeding behavior likely impacted infant weight. There was no difference in number of stools in either group on day one. It is important to note that the case group had fewer stools on all subsequent days, and fewer voids on day four. The laxative effect of colostrum is well known and an increased intake of colostrum results in increased stooling. The amount of voiding by day four is also a direct result of colostrum or milk intake; at this point in time maternal IV intake would no longer affect diuresis. This is an important finding that suggests that infants in the control group were feeding more

effectively than infants in the case group. This finding is supported by the LATCH score which was significantly higher in the control group.

Induction of labor. One of the more interesting findings of this study showed that women who underwent induction of labor were more likely to have infants in the control group. Induction of labor in the US has reportedly increased from 9.5% in 1990 to 23% in 2008 (Martin et al., 2010). In 2007 Lothian (2007) reported induction rates as high as 34%. Induction of labor may or may not be medically indicated. Medical indications for labor induction include gestational diabetes or hypertension, intrauterine growth restriction, premature rupture of membranes, chorioamnionitis, post term pregnancy, and fetal demise (American College of Obstetricians and Gynecologists, 2009). In contrast, inductions not medically indicated (elective) may be done for maternal fatigue and/or discomfort, suspected macrosomia, prior pelvic floor injury, post term pregnancy, and psychiatric issues (ACOG, 2009). In this study, 34 women had a scheduled induction of labor. Three women (8%) had a medically indicated induction, all for post term pregnancy. The remaining 31 inductions were elective.

In consideration of why women who experienced induction were more likely to have infants with less weight loss, the gestational age at birth may be the most important factor. In this study, the mean gestational age for infants born to women who underwent labor induction was 40.7 weeks. These infants were significantly older than the other infants in the study (40.7 versus 39.3 weeks, p = 0.001). It is possible that the more mature gestational age of these infants may have resulted in more mature neurological development which positively impacted their feeding behavior. The vast majority of studies on infant feeding behaviors and gestational age have focused on the premature or

late preterm infant. Premature infants often have breastfeeding difficulties due to their physiological and neurological immaturity (Demirci, Sereika, & Bogen, 2013). Little attention has been paid to the gestational age of term infants who have often been considered capable of feeding well if born after 37 weeks gestation. Yet evidence is surfacing that suggests that differences in gestational age beyond 37 weeks may matter. In 2013, Zanardo completed a study of 2296 term infants (≥ 37 weeks) and explored their breastfeeding outcomes after elective caesarean delivery. The results demonstrated that lower gestational age was an independent predictor of formula feeding at hospital discharge.

Insurance. Analysis of the demographic data revealed that more infants in the case group were large for gestational age, female, and had private insurance. It has been previously established that infants who are LGA and/or female initially lose more birth weight (Martens and Romphf, 2007; Lamp & Macke, 2010). Much less information is known about the potential impact of the type of insurance. Most studies that have been done on infant health outcomes and type of medical insurance have focused on the preterm infant. In a review of studies published between 1989 and 2009, Anum, Retchin, and Strauss (2010) examined the preterm birth outcomes of women on Medicaid and those with private insurance. The results indicated that birth outcomes were not different between groups. Ounpraseuth et al. (2012) also found that there was no difference in the risk of 1-year mortality between very low birth weight infants born to woman with public versus private insurance. None of the available literature has examined the relationship between maternal insurance type and weight loss in healthy, term infants.

The results of the current study demonstrated that infants of mothers who use public insurance have less weight loss on day three. These results are not consistent with the results of the previously mentioned studies. This outcome is likely due to an increased inclination of mothers with public insurance to use supplemental formula in the early days of life. Indeed it is well established that women in lower socio economic groups, women who utilize the Special Supplemental Nutrition Program for Women, Infants, and Children, and younger women are all more likely to use formula supplementation (Thulier & Mercer, 2010). Statistical analysis did show that subjects with public insurance were exclusively breastfeeding less than those with private insurance on the 3rd day of life (p = 0.005). One must also consider whether interactions with health care workers are different for women with public insurance. It is unknown whether or not women with public insurance receive the same amount of breastfeeding encouragement and or support compared to women with private insurance.

Feeding behavior. In both the groups, day one represented a rather "slow start" to breastfeeding with all infants averaging six feedings in the first 24 hours. To ensure adequate milk production, it is typically recommended that breastfed infants feed 8-12 times in a 24-hour period. The low number of feedings that occurred in the first 24 hours for both groups was likely due to several factors. On the first day of life, after an hour or two in a wakeful state, most infants enter a deep sleep for up to ten hours, waking only one to two times during that period for feedings (Academy of Breastfeeding Medicine, 2009). Infants born by CS often have increased respiratory secretions which may decrease their likelihood of feeding well (Yeekian, Jesadapornchai, Urairong, Santibenjakul, Suksong, & Nuchprayoon, 2013). Mothers immediately postoperative

may not feel well and may be less motivated and/or capable of nursing their infants well in the first 24 hours. Finally, it is a common assumption among health care workers that infants do not need to feed well on the first day of life; that they are born with adequate glucose stores to sustain them through the first day. As a result, staff may be less inclined to encourage frequent feedings on day one, especially if the baby is sleepy and/or the mother does not feel well.

By the second day of life, infants in both groups were feeding about eight times in a 24 hour period. On the second day of life, infants are often more wakeful and display more hunger cues compared to the first day of life. On day three and four, infants in the case group fed significantly more often. While one would expect that infants feeding more often would gain more weight, this was not demonstrated. The increased number of feedings occurred after the weight loss was documented. Every morning, pediatricians typically discuss with parents the infant's health status and weight. Once made aware that their infant is losing too much weight, parents often respond by increasing the number of feedings. This pattern of behavior was clearly seen in this study.

Pediatricians are provided with infant daily weights upon their early morning arrival to the newborn nursery. They then examine the infants and visit the parents using the current recorded weight in mind. The AAP (2012) recommends that infants who lose > 7% should be evaluated for poor breastfeeding management. It is likely that many pediatricians expressed concern to the mothers in this study when the infants' weight loss was $\geq 8\%$. It is unknown, however, what kind of feeding directions were provided to the mothers. Some pediatricians may have supported continued breastfeeding without formula supplementation and provided a referral to a lactation consultant. Others may

simply have suggested that the infant's weight was a concern, while adopting a wait and see attitude. Finally, other pediatricians may have directly advised mothers to supplement with formula to avoid further weight loss and dehydration. The evidence clearly shows an alarming pattern of increased formula supplementation among mothers of infants in the case group on and after day three. For many of these mothers and infants the likelihood of a long and successful breastfeeding experience plummeted, before they had even been discharged from the hospital.

Limitations

The purpose of this research study was to examine the impact of IV hydration and epidural anesthesia on the weight of the breastfed infant on the third day of life. The hypotheses were not supported. The volume of maternal IV hydration and epidural and/or spinal anesthesia did not significantly impact neonatal weight. There were several limitations which may have influenced these outcomes.

Most of the study limitations were related to the design. First, infants were weighed on different scales and at the same time daily no matter their time of birth. This resulted in variation in infant ages at the time of the daily weights. In order to obtain accurate and comparable weights among groups, infants would ideally be weighed on the same scale and at 24, 48, and 72 hours of life. Second, the number of infant feedings and outputs were counted and recorded by the nursing staff. As a result, some feedings may have been missed if not reported by the mother. Outputs may also have been missed if the mother did not report a diaper change, or if longer periods of time elapsed between diaper changes by the nursing staff. Providing the mother a bedside checklist would be the most consistent and accurate way to count the number of feedings. Weighing all dirty

diapers would be a more accurate method of collecting the amount of output. Third, the LATCH score on many babies varied depending on the subjective assessment of the nurse. There would be much greater reliability in the scores if the assessment were to be done by one trained observer. Fourth, the amount of breastfeeding support offered by the pediatricians to the mothers was likely varied and unknown. The retrospective design of the study did not allow for more accurate methods of data collection. In future studies, a prospective, longitudinal design would allow for more accurate and reliable methods of data collection and well as the provision of consistent breastfeeding support. In addition, only 69 women (25%) received \geq 3000 mls of IV fluid prior to delivery. This small number did not adequately represent the population under study and did not allow for adequate data collection to support the hypothesis.

Conclusions

The results of this study contribute to the available literature; however, the impact of maternal IV fluid volume on infant weight remains undetermined. This study lacked sufficient subjects who received large amounts of IV fluid. Despite the null hypothesis, two findings did support a link between maternal IV fluid and infant weight. Infants in the case group had more voids on day one which suggests that they experienced a larger diuresis. In addition, 70% of infants whose mothers received \geq 4000 mls of IV fluid volume were in the case group. The second hypothesis was also null and demonstrated that epidural anesthesia was not associated with infant weight loss compared to spinal or epidural/spinal anesthesia. What cannot be determined from this study is whether or not the epidural has an impact on weight when compared to infants of mothers who do not have any other kind of anesthesia. Data analysis did reveal other variables that may

impact infant weight and warrant further investigation, in particular maternal insurance type and the induction of labor.

In addition, what this study clearly demonstrated is that more than half of all term, healthy singleton infants born by CS lose a significant amount of weight after birth. This study also demonstrates that infants who are exclusively breastfed are more likely to lose greater amounts of weight in the first two days of life. These infants are all more likely to receive formula supplementation prior to discharge and are therefore at much greater risk of decreased breastfeeding duration.

Obstetrical care as it exists today is the product of cultural views of women and the dominant biomedical model of care. Medical interventions, in particular the use of obstetrical anesthesia, are not likely to decrease in the near future. Evidence has suggested that a physiological relationship may exist between infant weight and various medical interventions. All variables that potentially impact infant weight must be systematically explored. If infant weight loss is associated with a routine medical intervention then this must be recognized and acknowledged.

Multiple professional organizations have suggested that infants should not lose > 7% of their birth weight in the first week of life (AAP, 2012; Academy of Breastfeeding Medicine, 2009; ILCA, 2005). The practice guidelines published by these organizations clearly indicate that weight loss greater than 7% may not be 'normal'. All three organizations recommend further breastfeeding evaluation for infants who lose > 7% and suggest that for these infants, formula supplementation may be needed. If the normal infant weight loss of 4-7% is not representative of breastfeed infants, this must be acknowledged. Research is needed to accurately identify the expected range of weight

loss for the breastfed infant after birth. Breastfeeding is one of the most important disease preventing and health sustaining acts that a mother can do for her infant. In order to support breastfeeding, practitioners must have accurate information about the impact of medical interventions on infant weight and about the normal and expected weight loss patterns of breastfed infants.

Implications and Recommendations for Future Research

1. Studies are needed to compare the weight loss patterns of infants whose mothers receive large amounts of IV fluid (> 3000 mls) and infants whose mothers do not receive any IV fluid. A community based hospital may prove to be a better setting than a tertiary care center for this kind of research. Community based hospitals and/or birth centers have increased numbers of low-risk patients. Providers and nurses in these settings may be less conservative in regards to administering large volumes of IV fluid.

2. Mulder et al. (2010) described how voiding and stooling frequencies are often touted as signs of effective breastfeeding and is used by clinicians in teaching protocols for parents during the first two days of life. The findings of the current study suggest that the increased number of voids on day one of life should not be viewed by parents or practitioners as evidence of effective breastfeeding. Increased voids on day one may indicate that the infant is at increased risk of weight loss due to a larger diuretic effect. Studies need to more closely examine output patterns and infant weight. Ideally these studies would be prospective in design and allow for the collection and weighing of all outputs for increased accuracy.

3. It remains undetermined whether or not maternal anesthesia impacts infant weight loss. Research with larger population samples is needed that compares the weight

loss patterns of infants whose mothers receive anesthesia versus infants of mothers who do not receive any anesthesia.

4. Expected weight loss patterns for healthy term infants born by vaginal delivery and cesarean section must be researched and compared. In order to move forward, it is necessary to re-examine the previous works upon which the 4-7% guidelines were established. Attention must be focused on the study designs. It is unclear if the results were generated from studies in which infants were breastfed, formula fed, or given both breast milk and formula. If these studies do reveal that the 4-7% expected weight loss was based on findings from formula fed infants, new studies must be completed to determine the true percentage of expected weight loss for exclusively breastfed infants.

5. The rate of elective cesarean section is rising. The majority of elective cesarean sections are at or near 39 weeks gestation. Evidence is beginning to show that term infants born at lower weeks' gestation (\geq 37 - < 39 weeks) may have poorer breastfeeding outcomes (Zanardo, 2013). More studies are needed to examine breastfeeding duration for these infants.

6. Qualitative research is needed to help gain an understanding about the attitudes and/or beliefs of pediatricians and nurses in regards to infant weight loss, breastfeeding, and formula supplementation. This kind of work can help to determine what kind of feeding support pediatricians and nurses are providing, and if certain populations of women and infants receive more or less support than other populations.

Maternal Demographics by Weight Loss Group

Variables	EWL	No EWL	p value
	>8% weight	< 8% weight	
	loss day 3"	loss day 3	
	(n = 146)	(n = 126)	
Maternal age, years	31 <u>+</u> 5	30 <u>+</u> 5	.31
	(20-40)	(18-44)	
Ethnicity			
White	119 (81%)	98 (78%)	.09
Black	6 (4%)	8 (6%)	
Hispanic	4 (3%)	11 (9%)	
Other	17 (12%)	9 (7%)	
Marital Status			
Married	120 (82%)	94 (75%)	.13
Insurance			
Private	123 (84%)	93 (74%)	.03

N (%) or mean \pm SD, (range); EWL = Excessive weight loss

Variables	EWL	No EWL	p value
	>8% weight	< 8% weight	
	loss day 3"	loss day 3	
	(n = 146)	(n = 126)	
Birth weight, grams	3582 <u>+</u> 449	3388 <u>+</u> 418	.001
	(2565 - 4740)	(2420 - 4450)	
Gestational Age,	39.4 <u>+</u> .88	39.6 <u>+</u> .97	.37
weeks	(38 - 41)	(38 - 42)	
Gender, Male	74 (51%)	78 (62%)	.06
Gestational Size			
AGA	119 (82%)	116 (92%)	.01
LGA	27 (18%)	10 (8%)	

Neonatal Demographics by Weight Loss Group (n = 272)

N (%) or mean \pm SD, (range); EWL = Excessive weight loss; AGA = Average for gestational age; LGA = Large for gestational age

Variables	EWL	No EWL	p value
	> 8% weight loss day 3"	< 8% weight loss day 3	
	(n = 146)	(n = 126)	
Parity	1.0 (median)	2.0 (median)	.07
	(1 – 4)	(1 - 5)	
HourIV	6.2 <u>+</u> 7.9	6.6 <u>+</u> 8	.67
	(.5-44)	(1-48)	
Hypotension			
Yes	30 (20%)	34 (27%)	.21
Maternal Fever			
Yes	6 (4%)	6 (5%)	.79
Planned CS			
Yes	90 (62%)	69 (55%)	.25
Induction			
Yes	11(8%)	23 (18%)	.01
No	135 (92%)	103 (82%)	

Maternal Clinical Variables by Weight Loss Group (n = 272)

N (%) or mean \pm SD, (range); EWL = Excessive Weight Loss; CS (cesarean section); HourIV (# of hours of IV therapy before birth)

Neonatal Clinical Variables by Weight Loss Group	Neonatal Clinical	Variables by	Weight Loss	Group
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Variables	EWL > 8% weight loss day 3" (n = 146)	No EWL < 8% weight loss day 3 (n = 126)	p value
Weight Loss Day Two, %	6.9 ± 1.4 (3 - 11)	5.1 <u>+</u> 1.3 (1 - 7)	.001
Weight Loss Day Three, %	9.1 <u>+</u> 1.4 (0 - 13)	5.2 <u>+</u> 1.7 (0 - 7)	.001
*Weight Loss Day Four, %	8.25 <u>+</u> 2.2 (3 - 14)	4.21 <u>+</u> 2.2 (0 - 10)	.001
Weight Gain Day Three, %	0 (0)	.02 <u>+</u> .3 (0 - 3)	.28
*Weight Gain Day Four, %	0 (0)	.143 <u>+</u> .86 (0 - 8)	.08
Voids Day One	3.3 <u>+</u> 1.7 (0 - 8)	3.0 <u>+</u> 1.6 (0 - 10)	.09
*Voids Day Four	3.85 +1.9 (1 - 10)	4.66 + 2.1 (1 - 12)	.003
Stools Day Two	3.1 <u>+</u> 1.5 (0 - 6)	3.5 <u>+</u> 1.9 (0 - 9)	.03
Stools Day Three	2.77 ± 2 (0 - 8)	3.9 ± 2 (0 - 11)	.001
*Stools Day Four	3.4 + 2.1 (0 - 11)	4.1 + 2.2 (0 - 10)	.03

N (%) or + SD, (range); EWL = Excessive weight loss; *Data missing due to discharge on Day 3: Day 4 Weight Loss and Gain, Day 4 Voids and Stools (Case group n = 116; control group n = 97)

Variables	EWL	No EWL	p value
	>8% weight	< 8% weight	
	loss day 3"	loss day 3	
	(n = 146)	(n = 126)	
Latch Score	8 (median)	9 (median)	.001
	(2 – 10)	(4 – 10)	
Feeds Day three	9.4 <u>+</u> 2.4	8.9 <u>+</u> 2	.04
	(3 – 17)	(4 – 13)	
*Feeds Day four	9.3 <u>+</u> 3.2	8.2 <u>+</u> 2.5	.005
	(2 – 17)	(1 – 16)	
Feeding Category			
EB Day one	133 (91%)	108 (86%)	.42
EB Day two	140 (96%)	108 (86%)	.01
EB Day three	98 (67%)	106 (84%)	.003
*EB Day four	62 (53%)	81 (80%)	.001

Neonatal B	reast Feeding	Variables by	Weight Loss	Groups

N (%) or mean \pm SD, (range); *Data Missing Day 4 Feeds and Feeding Category (Case group n = 116; control group n = 97); EWL = Excessive weight loss; EB = Exclusive breast milk feeding # = number of feedings

Variables	EWL > 8% weight loss day 3" (n = 146)	No EWL < 8% weight loss day 3 (n = 126)	p value
Anesthesia			
Spinal	95 (65%)	77 (61%)	. 73
Epidural	47 (32%)	44 (35%)	
Epi/Spi	4 (3%)	5 (4%)	
IV Volume			
< 3000 mls	111 (76%)	92 (73%)	.57
≥3000 mls	35 (24%)	34 (27%)	

Primary Outcome	Variables by	Weight Loss	Group	(n = 272)

Note. EWL = Excessive weight loss

N (%) or + SD, (range)

Odds Ratio for Clinical Variables by Weight Loss Group

E337	
EW	L NO EWL
IV Volume 35	34
≥ 3000 mls	
IV Volume 111	92
< 3000 mls	

IV Volume:

n = 146 n = 126

OR = 35 (92) / 111 (34) = 3220 / 3774 = 0.85

Type of Anesthesia:

	EWL	NO EWL
Epidural	47	44
No	99	82
Epidural		

N = 146 n = 126

OR = 47 (82) / 44(99) = 3854 / 4356 = 0.88 Note. OR = Odds ratio; EWL = Excessive weight loss

Appendix A

Feeding Practice	Requires the Infant Receive	Allows the Infant to Receive
Exclusive breast milk	Breast milk only (from mother, wet nurse or donor)	Drops, syrups (vitamins, minerals, medicines)
Predominant breast milk	Breast milk (>75% of diet)	Water, juice, formula, or solid food
Mixed feeding	Breast milk (25 – 75% of diet)	Water, juice, formula, or solid food
Predominant formula	Formula (> 75% of diet)	Water, juice, breast milk, or solid food
Exclusive formula	Formula only	Drops, syrups (vitamins, minerals, medicines

(Thulier, 2010)

Appendix B

Institutional Review Board Approval





OFFICE OF RESEARCH COMPLIANCE 70 Lower College Road, Suite 2, Kingston, RI 02881 USA p:401.874.4328 f:401.874.4814 uri.edu/research/tro/compliance

DATE: TO: FROM:	December 17, 2012 Debra Erickson-Owens, PhD University of Rhode Island IRB	
STUDY TITLE:	[401027-1] Maternal Hydration and Infant Weight: A Case-Control Study in Breastfeeding Infants Delivered by Cesarean Section	
IRS REFERENCE#: SUBMISSION TYPE:	HU1213-076 New Project	
ACTION: APPROVAL DATE: EXPIRATION DATE: REVIEW TYPE: REVIEW CATEGORY:	APPROVED December 17, 2012 December 16, 2013 Expedited Review Expedited review category # 5	

Thank you for your submission of New Project materials for this research study. University of Rhode Island IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office. Please note that all research records must be retained for a minimum of three years. Based on the risks, this project requires Continuing Review by this office by December 16, 2013. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact us by email at compliance@ds.uri.edu. Please include your study title and reference number in all correspondence with this office.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document unless the signature requirement has been waived by the IRB.

Women & Infants

Project No. 12-0104 INSTITUTIONAL REVIEW BOARD SUBCOMMITTEE FOR EXPEDITED & ANNUAL REVIEW REPORT ON COMMITTEE ACTION

PRINCIPAL INVESTIGATOR: Diane Thulier, RN, Doctoral Student URI

PROTOCOL TITLE: MATERNAL HYDRATION AND INFANT WEIGHT: A CASE-CONTROL STUDY IN BREASTFEEDING INFANTS DELIVERED BY CESAREAN SECTION

The committee appointed to review proposals for clinical research and other investigations involving human subjects has reviewed the application identified above.

DATE OF REVIEW: 11/19/2012

COMMITTEE ACTION: Approved study through 11/18/2013. Approved protocol dated 10/24/2012.

Signature applied by Juan Sanchez-Esteban on 11/23/2012 01:30:30 PM EST

Signature applied by Paul DiSilvestro on 11/26/2012 09:52:39 AM EST

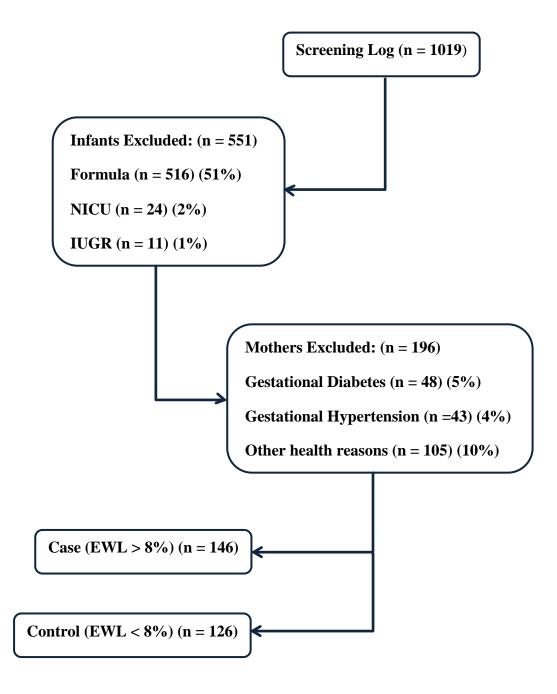
CC: James Padbury, MD

Date issued: November 20, 2012

WOMEN & INFANTS HOSPITAL OF RHODE ISLAND A CARE NEW ENGLAND HOSPITAL 101 DUDLEY STREET PROVIDENCE RHODE ISLAND 02905 401-274-1100 FAX 401-453-7666 WWW.WOMENAND INFANTS.ORG AFFILIATED WITH THE WARREN ALBERT MEDICAL SCHOOL OF BROWN UNIVERSITY

Appendix C

Enrollment Flow Chart



Appendix D

	0	1	2	Totals
L Latch	Too sleepy or reluctant No sustained latch or suck achieved	Repeated attempts for sustained latch or suck Holds nipple in mouth Stimulate to suck	Grasps breast Tongue down Lips flanged Rhythmical sucking	
A Audible Swallowing	None	A few with stimulation	Spontaneous and intermittent (< 24 hours old) Spontaneous and frequent (>24 hours old)	
T Type of Nipple	Inverted	Flat	Everted (after stimulation)	
C Comfort (Breast/Nipple)	Engorged Cracked, bleeding, large blisters or bruises Severe discomfort	Filling Reddened/small blisters or bruises	Soft Non-tender	
H Hold (Positioning)	Full assist (staff holds infant at breast)	Minimal assist Teach one side, mothers does other Staff holds and then mother takes over	No assist from staff Mother able to position and hold infant	

LATCH Breastfeeding Assessment

(Schlomer, Kemmerer, & Twiss, 1999)

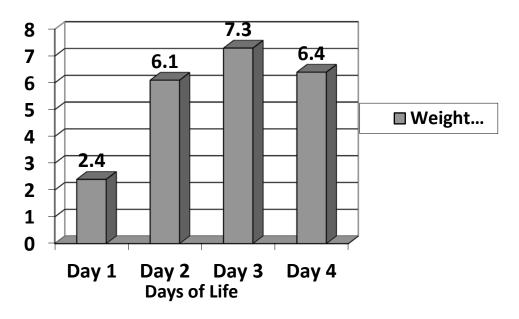
ITEM / SUPPLIES	QTY	COST	SUBTOTAL	TAX	TOTAI
DELL Computer	1	\$600		\$42	\$642
IBM SPSS Statistics Version 18	1	\$250	\$250	\$17	\$267
Flash Drive	4	4 x \$20	\$80	\$6	\$86
Toner	6	6 x \$30	\$180	\$12	\$192
Printer	1	200	\$200	\$14	\$214
TRAVEL					
	12 x 60 miles	720 x .4	\$288		\$288
GAS	36 gallons	36 x \$3.50	\$ 126		\$126
TOTAL					\$1815

Appendix E

Budget

Figure 1

Infant Weight Loss % (n = 272)





Percent of Weight Loss Day Three of Life

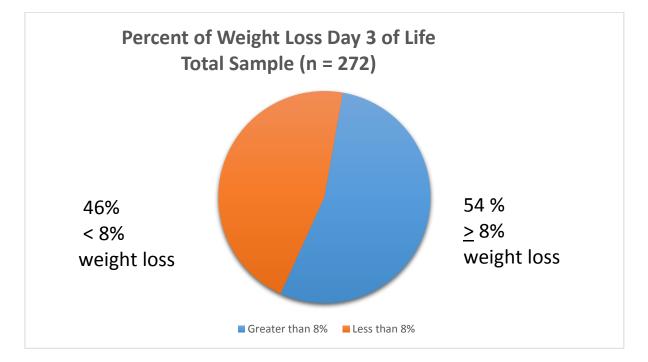
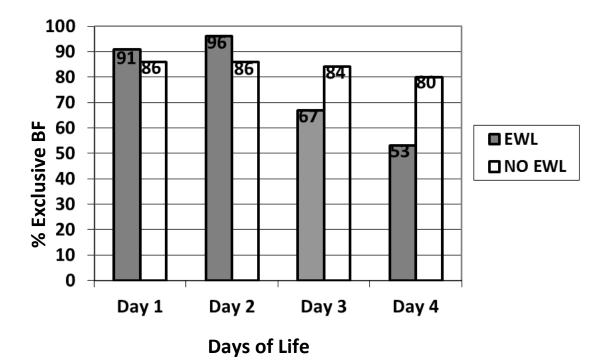


Figure 3

Percent of Exclusive Breastfeeding

EWL versus NO EWL Groups, Days 1-4



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