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**FACULTY OF GRADUATE AND
POSTDOCTORAL STUDIES**

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**Relationship Between Intravenous Fluids Given to Women During Parturition and Their Breastfed
Newborns' Weight Loss**

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**RELATIONSHIP BETWEEN
INTRAVENOUS FLUIDS GIVEN TO
WOMEN DURING PARTURITION AND THEIR
BREASTFED NEWBORNS' WEIGHT LOSS**

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Thesis submitted to the
Faculty of Graduate and Postdoctoral Studies
In partial fulfillment of the requirements for the
Degree of Doctor of Philosophy in Nursing

School of Nursing
Faculty of Health Sciences
University of Ottawa



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Your file *Votre référence*
ISBN: 978-0-494-74228-0
Our file *Notre référence*
ISBN: 978-0-494-74228-0

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Abstract

Neonatal weight measurements are used as a key indicator of breastfeeding adequacy. The purpose of this study was to explore non-feeding factors that might be related to newborn weight loss. The relationship between the intravenous (IV) fluids women receive during parturition (the act of giving birth including time in labour or prior to a cesarean section) and their newborn's weight loss during the first 72 hours postpartum was the primary interest.

Three hypotheses guided the thesis. Specifically, the hypotheses stated that in the first 72 hours postpartum, there is a positive association between: (a) the amount of IV fluid given to a woman during parturition and the amount of weight her infant loses; (b) the amount of IV fluid given to a woman during parturition and the amount her infant eliminates; and (c) the amount an infant eliminates and the infant's weight loss.

In an effort to clarify patterns of weight loss, a systematic review was completed to determine reference weight loss, and the results are reported in this thesis. Additionally, the issue of who should consent for neonates in lactation and breastfeeding research studies was raised during the ethics review, and the results of an examination of the underpinning principles for such consent are presented in this thesis.

A prospective observational cohort study was conducted to explore associations between maternal fluids during parturition, neonatal output, and newborn weight loss. During labour or before a cesarean section, maternal IV and oral fluids were recorded. Participants weighed their newborns every 12 hours for 72 hours, then weight was measured daily from Day 4 to Day 14. Parents weighed all output (i.e. diapers) in the first 72 hours.

Results of the systematic review show that the 7% maximum allowable weight loss recommended in four clinical practice guidelines appears to be based on mean weight loss and does not account for standard deviation. Although we

determined patterns of weight loss, causes of weight loss and implications for morbidity and mortality were not established. Completing the systematic review clarified assumptions about how birth weight is used as the baseline for calculating weight loss and how clinical decisions are based on the percentage of loss from birth weight.

The three hypotheses were supported. At 60 hours postpartum (point of maximum weight loss), mean loss was 237.2 grams (SD 98; $n = 96$, range 70-467 grams) and the percentage lost was 6.57 (SD 2.51; $n = 96$, range 1.83-13.06%). There was a positive relationship between maternal IV fluids from admission to birth and neonatal weight loss in grams ($r(83) = .199$, $p = .035$). Mean neonatal output for the first 24 hours was 83.04 grams (SD 47.81; $n = 107$, range 0-314 grams). There was a positive relationship between maternal IV fluids given in the final 2 hours before birth and neonatal output at 24 hours ($r(17) = .426$, $p = .044$) which explained 18% of the variability in weight loss. On Day 1, there was a positive relationship between output and weight loss ($r(96) = .341$, $p < .0001$) which explained 12% of the variability in weight loss. When groups, based on maternal fluids, were compared (≤ 1200 mls [$n = 21$] versus > 1200 [$n = 53$]), newborns lost 5.51% versus 6.93% ($p = 0.03$). A hierarchical regression analysis indicated gestational age and birth weight were additional predictors of weight loss. It appears neonates experience diuresis in the first 24 hours with a related weight loss.

Overall, the results indicate that maternal IV fluids before birth are related to weight loss in the early postpartum period. It appears neonate's experience varying degrees of diuresis, and consequent weight loss, in the first 24 hours is a correction. Clinicians (e.g. nurses, lactation consultants, and physicians working with breastfeeding women) should reconsider using birth weight as baseline when assessing newborn weight loss. These findings support using weight measured at 24 hours postpartum as the baseline for assessing newborn weight loss.

Acknowledgements

Over the past three decades, I learned from teachers and colleagues and, most especially, from the women and babies with whom I have had the privilege to work. Unfortunately, I cannot name each person who added to my learning, mentored me, or helped me along my journey. Please know how much I appreciate your contribution to my work.

At this time, I would like to acknowledge the individuals who contributed most directly to this thesis. I would like to thank my thesis supervisor, Kirsten Woodend, members of the thesis committee, Bill Gibb, Dianne Groll, and Wendy Peterson, and my co-authors Genevieve Courant and Sonya Kujawa-Myles.

To the mothers and fathers who participated in the study - thank you. You amazed me with your generous contributions, your interest in research to help breastfeeding mothers and babies, and your careful data collection.

Sheryl Hamilton, Maureen Kennedy, Nancy Labelle-Bourassa, Pamela Tkach, and Penny Webster worked as research assistants. Many friends and family took road trips with me to pick up scales and drop off pamphlets. I thank you for your time, energy, and encouragement. I also thank Kathleen Donovan, a special internet colleague, who prompted me to a clearer articulation of this work.

I would like to acknowledge staff and managers from the five hospitals. Recruitment, data collection, and the ultimate results could not have happened without their gracious support and contributions. I feel blessed to work with these wonderful professionals.

Special thanks to the Ottawa Valley Lactation Consultants and to the individuals who donated baby scales so I could fulfill my research goals.

To my classmates in the PhD program - merci.

Last, but not least, I would like to thank my family. My mom and sisters have cheered me on with each step, and they constantly reminded me that the only way to eat an elephant was one bite at a time.

Kate and Rachel, my beautiful daughters, have grown into women I am proud to know. They taught me so much, and they continue to support me from their own very busy lives. Our pact to never quit on a bad day saw me through many challenges. I enjoy my time with them. They make me laugh and treat me like a princess - how lucky can a woman get? The wee Gavin, my first grandbaby, began his life about the time I started this project and, as I finish this work, he is able to walk and talk. I would say his progress was much surer and faster than mine.

It has been a long journey. Ben was there at the beginning and supported me to the end. Of course, he's just lucky to have me.

Relationship Between Intravenous Fluids Given to Women During Parturition and Their Newborns' Weight Loss

Chapter One - Introduction

Appropriate lactation (i.e. to make milk) and breastfeeding (i.e. to give milk) assessments in the early days and weeks are required to maintain infant health and to ensure optimal breastfeeding support. Because neonatal weight measurements are used as a key indicator of breastfeeding adequacy, nurses need to understand the factors that affect neonatal weight loss: (a) to account for weight loss that requires no intervention; (b) to prevent unnecessary weight loss; and (c) to recommend appropriate interventions when required due to weight loss.

Background

Clinical Issue

Breastfeeding offers many benefits to mothers and their infants, yet early weaning (e.g. before six months) is common for Canadian women and their babies. Women who breastfeed have decreased incidences of premenopausal breast cancer, ovarian cancer, and osteoporosis (Bernier, Plu-Bureau, Bossard, Ayzac, & Thalabard, 2000; Labbok, 2001; Lawrence & Lawrence, 1999). Breastmilk provides the nutrients, growth factors, and the immunological components that a healthy term infant requires (Bachrach, Schwarz, & Bachrach, 2003; Duffy et al., 1997; Labbok, Clark, & Goldman, 2004; McNiel, Labbok, & Abrahams, 2010; Oddy et al., 2003; Scariati, Gummer-Strawn, & Fein, 1997; Young et al., 2002). Benefits appear to be dose related; the longer a woman breastfeeds or the longer an infant is breastfed, the more protective the benefits (Labbok, 2004; Oddy et al., 2003; Shantakumar et al., 2007).

The World Health Organization (2002) and Health Canada (2004) recommend exclusive breastfeeding for the first six months of life and continued breastfeeding with appropriate complementary foods for two years and beyond. In Canada, approximately 88% of women who give birth initiate breastfeeding, but one quarter of these breastfeeding infants are weaned by one month of age (Statistics Canada, 2010). By six months, 46% of Canadian mothers who initiated breastfeeding have weaned (Statistics Canada, 2010). Initiation rates suggest more women are choosing to breastfeed their infants at birth (e.g. compared to 25% initiation in the 1960s; McNally, Hendricks, & Horowitz, 1985), but duration rates suggest women need additional support to continue breastfeeding for the optimal period of time.

Problem Statement

Maternal perceptions of lack of milk and the use of formula supplementation seem to be related to beliefs that neonates have lost excessive amounts of weight (i.e. greater than 7 or 10%). Infant weight gain is an indicator of effective breastfeeding and milk transfer, and when excessive weight loss is identified by health care providers, inadequate milk production or intake is assumed, and management techniques, including supplementation, are then recommended (Academy Of Breastfeeding Medicine [ABM], 2009; American Academy of Pediatrics, [AAP] 2005; International Lactation Consultants Association [ILCA], 2005; Registered Nurses Association of Ontario [RNAO], 2003). Supplementation contributes to early weaning (Casiday, Wright, Panter-Brick, & Parkinson, 2004; Declercq, Labbok, Sakala, & O'Hara, 2009; Hill, Humenick, Brennan, & Woolley, 1997; Sheehan, Krueger, Watt, Sword, & Bridle, 2001). Additionally, the number one reason given by women for weaning before six months postpartum is

inadequate milk supply (Millar & Maclean, 2005). It is difficult to determine from the available data how much the neonates' weight loss contributes to the mothers' perceptions of inadequate milk supply. It may be that concerns about neonatal weight loss influence maternal perceptions and, ultimately, decisions to wean.

The neonate's weight loss might not be due to a lack of milk or a lack of feeding. It is possible the weight loss is the result of non-feeding factors. It is also possible that the weight loss is a physiological correction and not due to pathology. Evidence is needed to ensure accurate breastfeeding assessment and to prevent inappropriate supplementation and maternal perceptions of a lack of milk.

Conceptualization of the Phenomena

What babies are fed and how much weight they lose have potential health implications. Optimum infant health requires adequate breastfeeding, and inadequate breastmilk intake poses hazards for the infant which might include dehydration, hypernatremia, or hyperbilirubinemia (Bertini, Dani, Tronchin, & Rubaltelli, 2001; Livingstone, Willis, Adbel-Wareth, Thiessen, & Lockitch, 2000; Oddie, Richmond, & Coultard, 2001).

At the same time, there are risks associated with the feeding of artificial breastmilk substitutes (i.e. formula supplementation) such as exposure to foreign proteins, disruption of gut flora, and premature weaning (Casiday et al., 2004; Hill et al., 1997; Rubaltelli, Biadaoli, Pecile, & Nicoletti, 1998; Sheehan et al., 2001; Walker, 1993; Zetterström, Bennet, & Nord, 1994). Proper assessment is needed to ensure adequate and appropriate feeding and to avoid unnecessary interventions. To this end, nurses and other

health care providers need research evidence about neonatal weight loss to practice effectively.

When infants are born, they are usually weighed within minutes of birth and then they are fed frequently and weighed over the following few days (see Figure 1). Weight loss, determined as a change from the first weight measured and calculated as a percentage, appears to be common in most healthy full term neonates. Interventions, ranging from extra assessments to supplementation, are recommended with weight loss in excess of 7% of birth weight (ABM, 2009; AAP, 2005; ILCA, 2005; RNAO, 2003). Informally, from observations in hospital postpartum units, a 10% loss from birth weight is often the level for interventions. Given these practices and recommendations, clinicians seem to hold a number of assumptions about neonatal weight change: (a) weight measured within minutes of birth is an accurate baseline; (b) weight loss is due to insufficient intake; and (c) weight loss past a certain threshold requires intervention.

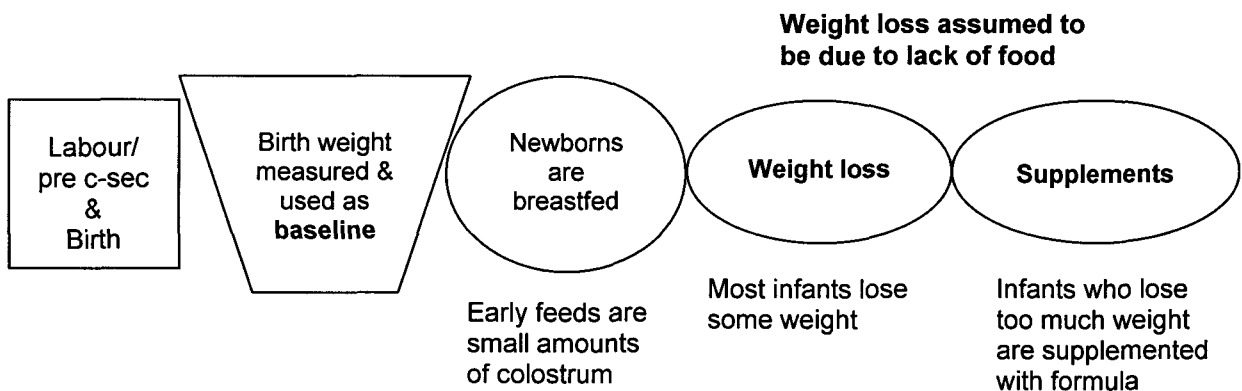


Figure 1. Conceptualization of the phenomena of how weights are measured and evaluated possibly resulting in supplementation.

These assumptions raise several questions: (a) When should the baseline weight be measured?; (b) What non-feeding factors during parturition (the act of giving birth including time in labour or prior to a cesarean section) and in the immediate postpartum affect weight loss?; (c) What is a safe weight loss?; and (d) When are supplements appropriate?

Research Question and Hypotheses

The Research Question

Researchers have identified several non-feeding factors that affect neonatal weight loss (Bystrova et al., 2007; Martens & Romphf, 2007; Merry and Montgomery, 2000; Muskinja-Montanji, Molnar-Sabo, & Vekonj-Fajka, 1999). Some factors are demographic or physiological (e.g. girls lose more than boys and feeding type [breastfeeding versus formula feeding]; Martens & Romphf, 2007), and some are iatrogenic (defined as caused by medical intervention; e.g. epidurals; Merry & Montgomery, 2000). The main variable of interest for this study is the intravenous (IV) fluid women receive prior to their infants' birth. Other moderating and mediating variables identified from the literature were also tracked during the study (see Figure 2).

The impetus for this thesis was observations of the boluses of IV fluids that women received when they had epidurals. Fluids and electrolytes move freely between mother and fetus via the placenta (Brace, 1998; Brace, 2004; Rosenfeld, 2004; Sibley, & Boyd, 2004). It is possible that when a woman receives IV fluids before the birth of her baby that the fetus takes on extra fluids. The neonate's weight loss may not be due to a lack of intake, but may be the result of increased neonatal output. It is possible that some infants are born with a fluid overload and the resulting diuresis contributes to weight loss.

The research question is, "What is the relationship between the intravenous fluids administered to a woman during parturition (childbirth) and her infant's weight loss during the first 72 hours postpartum?"

Research Hypotheses

1. There is a positive association between the amount of IV fluids given to a woman during parturition and the amount of weight her infant loses during the first 72 hours postpartum.
2. There is a positive association between amount of IV fluids given to a woman during parturition and the amount her infant eliminates during the first 72 hours postpartum.
3. There is a positive association between the amount an infant eliminates and the infant's weight loss during the first 72 hours postpartum.

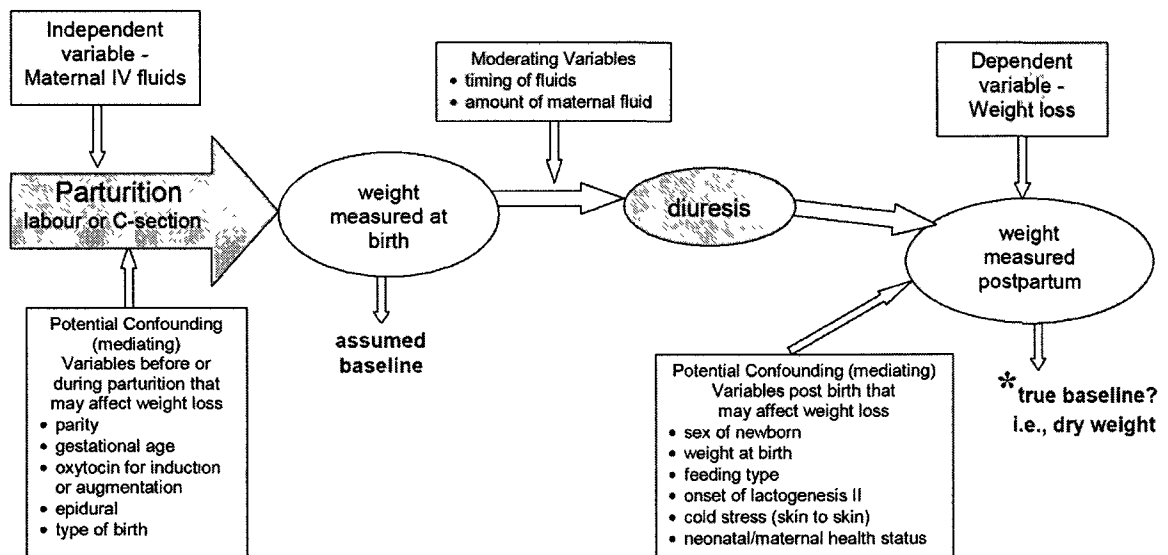


Figure 2. Conceptual framework for thesis includes potential mediating and moderating variables and questions which neonatal weight measurement should be baseline.

Potential Contribution to Nursing Knowledge

Supporting breastfeeding women and assessing infant feeding patterns are within a nurse's scope of practice. In this case, identifying a fluid shift is of interest to nurses if the result of the fluid shift is measurable in infant weight loss, and the interpretation of the weight loss results in increased formula supplementation.

Whether in the hospital or in the community, nurses are usually the first point of contact for breastfeeding women and their infants. A clear understanding of what to teach women about breastfeeding and when to raise a "red flag" is required for nurses to work effectively. To properly assess lactation and breastfeeding, nurses need appropriate and accurate evidence. This study attempts to provide such evidence.

Organization of the Thesis

This thesis consists of seven chapters. To facilitate timely publication of the results, it is a manuscript-based format with three chapters written as journal articles. Each chapter has its own running head, reference list, and its own abstract and appendices when appropriate. All chapters maintain continuous page numbering. Due to the article-based nature of this thesis, there is some overlap of information.

Chapter One - Introduction

This chapter introduces the topic and the thesis format. The introduction includes background, the research question, and the hypotheses.

Chapter Two - First Article

This chapter is a published article, and it is presented in its published form. It is a systematic review that was completed to determine the reference weight loss for neonates in the first two weeks post birth.

Chapter Three - A Review of the Literature

This section is written in the style of a monograph chapter. It identifies the gap in literature and provides the background and rationale for the study.

Chapter Four - Methodology and Methods

This section is also written in the style of a monograph chapter. Prefaced with a description of the approach and research design, it is a detailed description of the techniques used for this research study.

Chapter Five - Second Article

This chapter is a published article presented in its published form. It is a discussion, initiated by this study, of the principles underlying decisions about whether one or both parents should consent for neonates in breastfeeding studies.

Chapter Six - Third Article

This chapter is a manuscript for submission to the *Journal of Human Lactation* and it is formatted using the intended journal's instructions to authors. This paper presents the research study including the results and conclusions. For each chapter to be able to stand on its own, there is some repetition of information.

Chapter Seven - Conclusions and Recommendations

This chapter concludes the thesis with an overall discussion of the research study and recommendations for use of the results.

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**Relationship Between Intravenous Fluids Given to Women
During Parturition and Their Newborns' Weight Loss**

Chapter 2 - First Article

Physiological weight loss in the breastfed neonate: a systematic review

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Competing interests: None declared.

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Abstract

Background: Healthy, full-term, exclusively breastfed infants are expected to lose weight in the first days following birth. There are conflicting opinions about what constitutes a normal neonatal weight loss, and about when interventions such as supplemental feedings should be considered.

Objective: To establish the reference weight loss for the first 2 weeks following birth by conducting a systematic review of studies reporting birth weights of exclusively breastfed neonates.

Methods: We searched 5 electronic databases from June 2006 to June 2007: the Cochrane Database of Systematic Reviews; MEDLINE (from 1950); CINAHL (from 1982); EMBASE (from 1980); and Ovid HealthSTAR (from 1999). We included primary research studies with weight loss data for healthy, full-term, exclusively breastfed neonates in the first 2 weeks following birth.

Results: Eleven studies met the inclusion criteria. Definitions, types of measurements, and reporting styles varied among studies. In most studies, daily weights were not measured and measurements did not continue for 2 weeks. Mean weight loss ranged from 5.7% to 6.6%, with standard deviations around 2%. Median percentage weight loss ranged from 3.2 to 8.3 with the majority around 6%. The majority of infants in these eleven studies regained their birth weight within the first 2 weeks postpartum. The second and third days following birth appear to be the days of maximum weight loss.

Discussion: Methods used to report weight loss were inconsistent, using either an average of single lowest weights or a combination of weight losses. The 7% maximum allowable weight loss recommended in 4 clinical practice guidelines appears to be based on mean weight loss and does not account for standard deviation. Further research is needed to understand the causes of neonatal weight loss and its implications for morbidity and mortality.

Introduction

Infant weight measurement is one of the tools most frequently used to assess breastfeeding adequacy. Neonates receive only small amounts of fluids in the first days following birth,¹ and they tend to lose weight before they begin to gain weight.² Excessive weight loss or inadequate weight gain can be indications of low milk production or of insufficient milk transfer. To ensure adequate intake and, at the same time, to avoid inappropriate supplementation, parents and professionals need evidence to assess patterns of neonatal weight change and to make decisions about infant feeding.

Expert opinions and guidelines disagree about what constitutes a normal neonatal weight loss. How much weight loss should be considered a red flag? What is the upper limit that indicates intervention is required? We did a systematic review to answer the question, "What is a normal physiological weight loss for full-term exclusively breastfed infants in the first 2 weeks following birth?"

We made 3 assumptions. First, neonatal weight loss in the first days following birth is expected, and we therefore refer to such weight loss as *physiological* weight loss. Second, to define abnormal or pathological weight loss, we need evidence of what would be considered a normal or reference weight loss. Third, we expected to find observational studies (e.g., cohort, case-control) rather than randomized controlled trials (RCTs) in our search. The nature of the research question and the implications of the answer for the care of breastfed infants require a rigorous methodology. Therefore, we chose to complete a systematic review even though we sought evidence for parameters of weight loss and not for optimal interventions.

Methods

Search methods. Two of us (JNW, GC) completed separate database searches through our respective university libraries. We searched 5 electronic databases from June 2006 to June 2007: the Cochrane Database of Systematic Reviews, MEDLINE (from 1950); CINAHL (from 1982); EMBASE (from 1980); and Ovid HealthSTAR (from 1999). Boolean searches using alternative spellings of key words were run multiple times (see Textbox 1). Boolean searches were also completed using Google and Scirus search engines. We identified relevant clinical practice guidelines (CPGs) and used their reference lists to ensure a thorough search. We did not restrict our search by dates, study design (all research methods were considered), language, or country of origin.

Inclusion criteria. We included only primary research studies that reported data about weight loss occurring in the first 2 weeks following birth. We defined primary research as research undertaken by the authors, and we included systematic reviews and secondary analyses of data sets. The "primary research" criterion allowed for the inclusion of research studies that collected data about weight loss as part of their protocol, even if their research was not intended to be about weight change patterns. We excluded cited research, narrative reviews, and reports that did not measure and report individual weight loss.

We included studies of healthy, full-term, singleton, breastfed babies. We defined full-term as a gestation of more than 259 days (36 6/7 weeks),³ and we defined breastfeeding (i.e., exclusively breastfed) as fed only breast milk, whether at breast or by bottle, with no other food or liquids, including water, with the exception of medicines, vitamins or minerals.⁴ We excluded studies of infants fed or supplemented with formula,

and preterm, near-term, or multiples (e.g., twins, triplets), unless data for full-term, singleton, exclusively breastfed infants were reported separately.

Data abstraction and analysis. We conducted separate searches and abstractions. First, articles were screened and retrieved based on their titles and abstracts (see Fig. 1 for methodological steps). In the next step, 2 of us (JNW, GC) used an abstraction form developed for this systematic review to analyze screened studies to determine eligibility for inclusion. Results were compared to reach a consensus. Six authors were contacted for clarification.⁵⁻¹⁰

We constructed tables and examined key aspects of each study: research design, population size, types and timing of data collection, methods for measurement, definitions of breastfeeding, and elements of reporting. We used descriptive statistics from the studies. In one case, to answer the research question, we had to re-analyze data in order to pool the study subjects to obtain an average for the whole group.¹¹

Results

Eleven studies met the inclusion criteria (see Table 1).^{6-8, 11-18} Ten of the studies were observational. One study, an RCT,¹² provided data from the control arm that we used. With one exception, all were prospective studies in which data were collected on the basis of a research question. The one exception was a secondary analysis of data.¹⁴ Six of the 11 studies researched non-weight topics but provided data about weight change patterns. Nine of the studies were reported in English, one in French, and one in Croatian. Studies were conducted in Bangladesh, France, India, Italy, Jamaica, Scotland, Serbia, Spain, Sweden, and the United States.

Authors of the included studies reported the amount and timing of weight loss using a variety of descriptive statistics (see Table 1, under Study Results). None of the studies provided morbidity or mortality statistics. Examples of excluded studies and rationales for their exclusion are provided (see Table 2).^{5,9,10,19-29}

Appraisal of included studies. The studies included in this review represented several different cultures. In all studies, measurements started from birth. The populations were comparable in age, but the length of time for and frequency of weight measurements were not comparable across studies. Sample sizes varied from 21 to 937, with a median of 120. All but one study had more than 40 subjects. Most studies had convenience, not random, samples.

Measurement bias occurred in many of the studies that met the inclusion criteria. The frequency of weighings was inadequate. Most of the studies weighed the infants daily while they were in hospital, but not after discharge. The lack of measurements makes it impossible to determine the lowest weight or patterns of weight loss. The fact that most of the research studies were not primarily intended to study weight explains some of the variations. In one study, researchers completed a secondary analysis of data and reported maximum weight loss, even though infants were weighed only twice over a 2-week period.¹⁴ With only 2 weights measured in 2 weeks, it is not possible to determine the lowest weight, or when it was reached.

Definitions for breastfeeding and weight loss, as well as inconsistencies in approaches and reporting methods for descriptive statistics, were problematic. Most studies did not specify a definition of breastfeeding. In 1 case, the term "exclusively breastfed" was used, but later in the report we found that infants who received water or

glucose water were included.¹⁰ Neonates frequently had substantial weight loss, in which case supplementation might be expected, but researchers rarely identified when the infants received supplemental feeding. Without a clear definition of breastfeeding, and without clear reporting of supplementation, it is difficult to discern supplemented from exclusively breastfed neonates (i.e., nothing by mouth except breast milk and, possibly, medicines or vitamins). We contacted authors to establish the definition of breastfed infants in their studies, and we only included study data that met our definition.

Definitions of weight loss varied. Maximum weight loss for an infant could be the lowest single weight or it could be an average of the daily losses. Furthermore, a mean loss for the study group could be each infant's one lowest weight, pooled and averaged, or all of the infants' weight losses averaged for the group. The size of the sample often varied within a study (e.g. smaller sample on day 3 than on day 1) due to attrition and this fact complicates calculations of mean weight loss.

There are some inconsistencies as to whether the day of birth was counted as day 0 or day 1, a detail that may cause confusion with regard to expectations as to when infants should begin to gain weight. Health status and the infants' status as singletons or multiples were often not clear; we contacted authors for clarification on these points when necessary. If the subjects were referred to as dyads (i.e., mother and infant) we presumed the neonates to be singletons; we assumed infants to be healthy if they were discharged to home.

Among the 11 studies included in this review, 1 study stands out. The study by MacDonald et al.¹⁵ followed infants for 14 days. The infants were weighed daily while in hospital but intermittently after discharge. The researchers took this factor into account

by reporting changes as medians. Based on the results of this study, it appears that weight loss of up to 12% of birth weight is experienced by about 95% of neonates.¹⁵ Within a range, the first day to begin regaining weight is around day 4, and infants regain their birth weight around day nine.¹⁵ Although the longer follow-up period of this study is a strength, the lack of daily weights weakens the findings.

Amount of weight change. Weight loss patterns were described in terms of amount and timing, and the wide range of data descriptions made it difficult to compare or combine study results. In 10 of the 11 included studies, weight change was measured as amounts of weight; the 11th study reported weight patterns based solely on the timing of changes.⁶ In the 10 studies that reported the amounts of weight change, 8 types of descriptive statistics are used to express the amount of weight change: (1) mean weight loss;^{8,11,12,18} (2) median weight loss;^{8,15,16} (3) range of weight change;^{11,14,16} (4) number of subjects over or under a percentage;^{11,13,14} (5) amount in grams or kilograms lost or gained;^{7,12,18} (6) percentile data;¹⁵ (7) mean change;¹⁴ and (8) weight change by parity or birth type.¹⁷

Mean weight loss ranged in the studies from 5.7% to 6.6%, with standard deviations hovering around 2% (see Table 1).^{8,11,18} Whether mean percentage represented the average of maximum daily weight loss measurements (i.e., 1 measurement per neonate) or an average of all weights taken is not clear. Manganaro et al.¹¹ divided their subjects into 2 groups (< 10% and ≥ 10%); pooling the results, we determined that the average for the group as a whole was 5.9%. Median percentage weight loss ranged from 3.2% to 8.3%, with the majority of reported medians around 6%.^{8,15,16}

The authors who reported the range of weight change had collected data for 72 hours to 24 days, and the range in these studies varied from a loss of 14.3% to a gain of

15.3%.^{24,26,28} Authors of 3 papers grouped subjects according to the percentage of weight change. For example, DeMarzo et al.¹⁴ report that 8.7% of infants lost more than 7% of their birth weight, whereas Bhat et al.¹³ found 6.8% lost more than 10% of birth weight, and Manganaro et al.¹¹ found 7.7% lost more than 10% of birth weight. The choice of 7% or 10% for grouping the sample appears to be an arbitrary demarcation for substantial weight loss.

Jolly et al.,⁷ Martin-Calama et al.,¹² and Muskinja-Montanji et al.¹⁷ report the number of kilograms or grams neonates lost or gained. Martin-Calama et al.,¹² describe mean weight losses that peaked at 48 hours, afterwards mean gains begin. Muskinja-Montanji et al.¹⁷ report weight loss in grams by parity; and the days that most infants lost weight were day 2 and 3. Contrary to the other studies showing weight loss in the first 2 days, Jolly et al.⁷ report substantial weight gains, with 90% of the study infants averaging a gain of 230 grams by the third day.

Three authors were unique in their reporting of weight changes. DeMarzo et al.¹⁴ report the mean change between 2 weights (around day 5 and day 10) measured at post-discharge clinical visits. MacDonald et al.¹⁵ demonstrate the upper limit of weight loss in their study, by stating that the 95th percentile is 11.8%. Rodriguez et al.,¹⁸ in their study of body composition, report average weights for 3 days, but do not provide data about the change.

Timing of weight change. Some of the researchers looked at the day on which the lowest weight (i.e., the nadir) was reached and the day on which neonates regained their birth weight. Five approaches were used to describe the timing of weight change: (1) the day the infants regained their birth weight;^{6,15} (2) the percentage of infants who gained or lost

on a particular day;^{13,14} (3) the day of lowest weight;¹⁷ (4) weight change by parity or birth type;¹⁷ and (5) median for both number of days losing weight and days to regain birth weight.¹⁵

In the studies that report the amount of time it took for infants to regain their birth weight, the majority of infants regained their birth weight within the first 2 weeks. Hossain et al.⁶ found 91.57% had regained initial weight by day 14, and DeMarzo et al.¹⁴ state that 88.7% infants were back to birth weight by the second clinic visit (average day 10).

The day of lowest weight is reported by Michel et al.⁸ as day 1 and 2, and by Muskinja-Montanji et al.¹⁷ as day 2 and 3. In each study, the 2 combined days account for about 90% of the sample. The discrepancy seems to be a matter of counting the day of birth as day 0 or day 1 and then the second 24 hours as day 1 or day 2.

Hossain et al.⁶ and Jolly et al.⁷ identify the day infants began to gain weight, with very different results: 56.25% by day 5 and 90% on day 3, respectively. This discrepancy is an outstanding feature; with only 2 studies describing weight change in this manner, it is difficult to determine which is the outlier.

Two authors have unique methods of reporting. MacDonald et al.¹⁵ report the median number of days of weight loss and the median day to regain birth weight as 2.7 and 8.3 respectively. Manganaro et al.¹¹ note that infants in their study who were born vaginally reached their lowest weight between day 3 and 4, and infants delivered by cesarean section reached their lowest weight between day 4 and 5.

Review of clinical practice guidelines. Clinical practice guidelines (CPGs) are defined as "systematically developed statements [based on best available evidence] to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."³⁰ Four key CPGs, among others, were found during searches for this systematic review.³¹⁻³⁴ Three of the guidelines³¹⁻³³ are about overall breastfeeding, and 1 deals specifically with supplementation.³⁴

These CPGs on breastfeeding advise against supplementation (i.e., replacement breastfeeds) as a standard or casual practice, and they recommend outer limits for weight loss. The American Academy of Pediatrics³¹ states: "Weight loss in the infant of greater than 7% from birth weight indicates possible breastfeeding problems and requires more intensive evaluation of breastfeeding and possible intervention to correct problems and improve milk production and transfer." The International Lactation Consultant Association³² and the Registered Nurses' Association of Ontario³³ specify that a loss of more than 7% of birth weight, continued loss after day 3, or failure to regain birth weight within a minimum number of days (i.e., 10 days³⁴ or 2–3 weeks,³³ respectively) are signs of ineffective breastfeeding. The Academy of Breastfeeding Medicine³⁴ advises "Possible indications for supplementation in term, healthy infants [include] weight loss of 8% to 10% accompanied by delayed lactogenesis (day 5 or later)."

These guidelines presume that some weight loss is expected and too much weight loss is a sign of inadequate milk intake due to low milk supply or ineffective milk transfer. The consensus indicates a weight loss in excess of 7% is cause for further assessment and possible intervention. Several of the studies screened for this review are referenced in these CPGs.

Discussion

We found insufficient evidence to answer the question, "What is a normal physiological weight loss for full-term breastfed infants in the first 2 weeks following birth?" We found gaps in relevant data collection and reporting. For instance, weights were not measured daily after discharge and sample size varied within a report due to attrition.

Two difficulties arise when CPGs propose a single, absolute number as the maximum weight an infant can safely lose. First, an absolute number does not take ranges into account. A recommendation based on observations of a mean loss of 7% of birth weight, assuming such recommendations are derived from samples with normal distributions, needs to take standard deviations into account. For example, a mean weight loss of 6.9% with a standard deviation of 3.07, as Maisels et al.²⁴ report in their study, indicates that about 68% of all infants would experience a weight loss of between 4.0% and 9.8%, and that about 95% of all infants would experience a weight loss of between 1.0% and 12.7%.

Second, when distinguishing a physiological from a pathological weight loss, an absolute number may cause health care professionals to miss red flags. For example, a 3-day-old infant with a 7%–10% weight loss is probably reaching his or her lowest weight before gaining, and this child would be in a different situation than a 5-day-old infant who weighs 10% less than his birth weight. Not only has the 5-day-old infant lost weight, but he or she has not regained and is therefore further behind than the 3-day-old infant. An absolute number in this case is deceptive.

Strengths and limitations of the systematic review. The strengths of this review include adherence to a rigorous methodology. For example, 2 researchers independently completed literature searches and abstractions, and follow-up collaboration ensured that the articles were analyzed multiple times. Our group includes experienced clinicians familiar with current lactation research and the issues involved with breastfeeding (e.g., definition of breastfeeding, significance of supplementation) and experts in statistical analysis.

An important limitation of our study was that our research question did not take into account morbidity and mortality. Given the research question and the inclusion criteria established for this systematic review, no studies were specifically sought to provide evidence suggesting a point, by weight or time measurement, when weight loss presents a health risk. We did find that weight loss did not always have clinical indicators. For example, substantial weight losses were not always paired with hypernatremia.^{11,13,22,29}

Identifying what appears to be a normal weight loss leaves the reader with the question, "So, what if weight loss is outside of normal parameters?" It also became apparent as we analyzed the included studies that not all weight loss is physiological: there are demographic and iatrogenic factors that affect weight loss, including feeding and non-feeding factors. The research question and the inclusion criteria for articles sought in this systematic review do not illuminate these factors.

Recommendations for further research. Future research should include measures of morbidity and mortality and consider factors affecting weight loss. Morbidity and mortality rates and their relationship to weight loss must be established to determine the

point when interventions are required to prevent illness and protect health. Assessment of effective breastfeeding and decisions about supplementation must be based on more than weight loss. The underlying assumption is that weight loss is directly related to inadequate intake, due to either a lack of milk supply or ineffective milk transfer. There appear to be confounding factors (e.g., factors that are not natural or biological imperatives), as evidenced by the variations in mean weight losses.

We found evidence of patterns of weight loss, but we did not identify a relationship with morbidity or mortality. The data we found did not provide information about the implications of a 7% weight loss or a 10% weight loss. Recognizing weight change patterns helps clinicians identify red flags, but assessment cannot stop there. The implications of the weight loss must be understood. Such evidence would ensure that interventions such as supplementation are not based solely on maintaining an infant's weight within pre-established norms.

Research is also needed to determine if weight loss is due solely to inadequate intake. There appears to be iatrogenic weight loss, since we found studies that demonstrate that birthing practices, hospital routines, and birth experiences are associated with the amount of weight lost. Researchers should consider the amount of stooling and voiding that might also contribute to neonatal weight loss. For instance, there is some evidence that infants born to mothers who received IV fluids during parturition experience greater weight loss, and excess neonatal diuresis could be the reason.^{35,36} Studies are needed to understand such factors and how they might affect weight loss.

This systematic review was completed to determine the reference weight loss in the first 2 weeks following birth. Although there is some strong, consistent evidence

regarding weight loss patterns in the first few days, the results of our systematic review suggest that further questions need to be answered before a normal range for neonatal physiological weight loss can be established and indications for interventions can be determined.

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Textbox 1: Basic search string for this systematic review

1. (infant or neonate or newborn or baby or neonatal).mp. [mp=ti, ot, ab, nm, hw]
2. (breastfeeding or breast-feeding or breast feeding).mp. [mp=ti, ot, ab, nm, hw]
3. (full-term or fullterm or term).mp. [mp=ti, ot, ab, nm, hw]
4. (weight or weight loss or "birth weight" or birth weight).mp. [mp=ti, ot, ab, nm, hw]
5. (postnatal or post natal).mp. [mp=ti, ot, ab, nm, hw]
6. weight.m_titl.
7. 4 or 5 or 6
8. 1 and 2 and 3 and 7

note: "mp." indicates it was searched as a key word (including ti = title, ab = abstract; nm = name of substance word, etc.); whereas "m_titl." indicates it was searched for in titles only

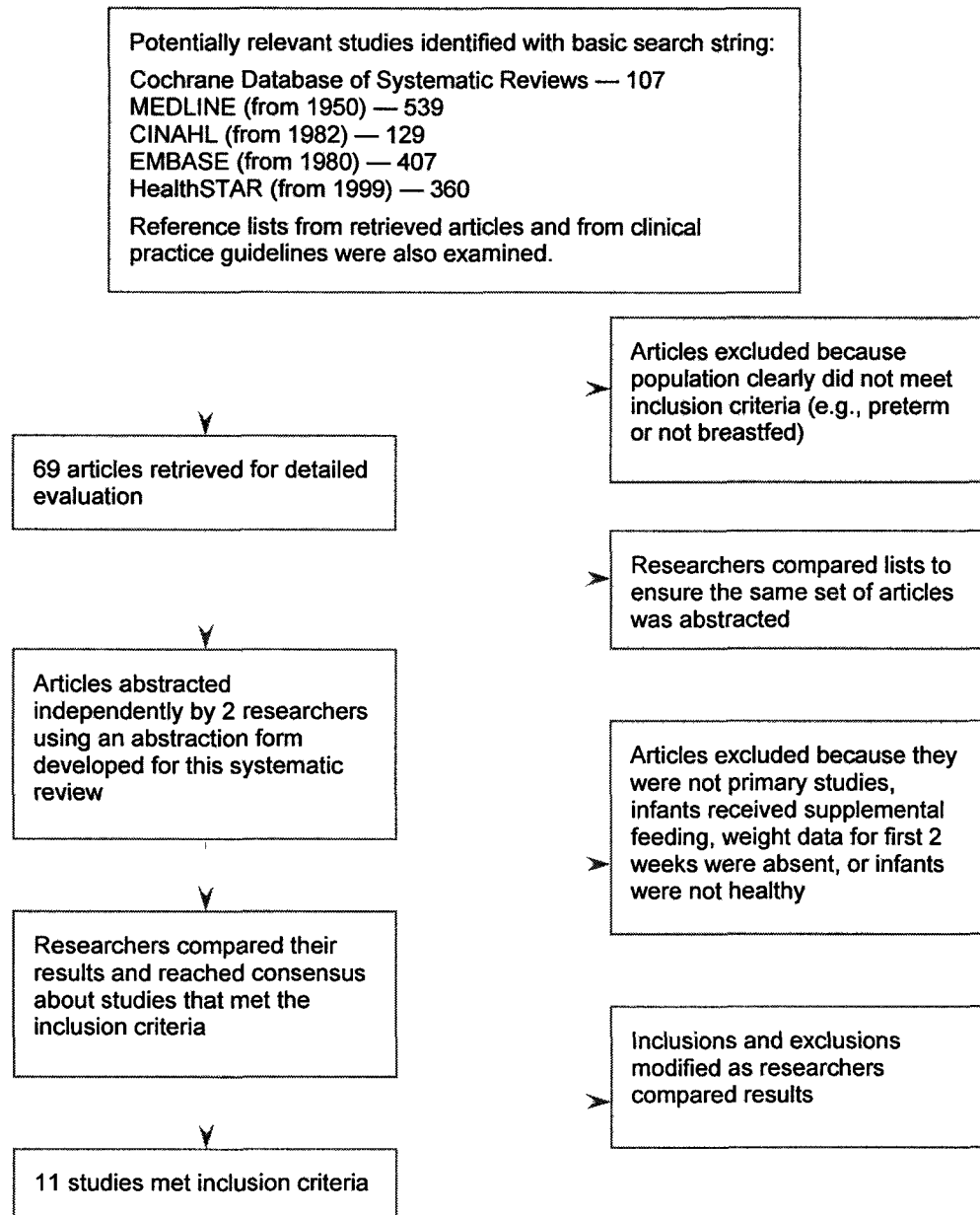
**Figure 1: Methodological steps**

Table 1: Studies that met the inclusion criteria

Reference	Methodology	Purpose	Intention to study weight change	Sample size	Measurements	Results
Bhat et al. ¹¹ India	Prospective observational study conducted for 6 m	To determine incidence of significant WL, dehydration, hypernatremia and hyperbilirubinemia in exclusively breastfed, term healthy neonates and compare incidence in warm versus cool months	No	496 infants of a possible 832 births	Daily weights Birth to discharge (3–8 d) Reports: (1) % infants by WL group Note: significant WL defined as > 10% and/or > 5% in a 24-h period	(1) % infants in WL group: > 10% WL = 06.8% > 05% WL in 24-h period = 24.7% WL considered NS for 68.4% of infants
DeMarzo et al. ¹⁴ United States	Secondary analysis of data	To explore patterns of initial WL and return to BW among healthy, term, breastfed infants and specifically the validity of the clinical criterion of 10% as an acceptable WL	Yes	264 neonates (236 were exclusively breastfed at day 10)	BW, then 1st weight at mean of 5 d and 2nd weight at mean of 10 d Reports: (1) % weight change from BW to 1st weighing, including range, mean, median and SD (2) % infants whose WL exceeded 7% at 1st weighing (3) % infants above BW at 2nd weighing (n = 236)	(1) Range = -14.3 to +15.3% Mean = -1.8% Median = -1.8% SD = 4.2 (2) > 7% WL at ~day 5 (first weighing) = 8.7% of infants (3) Regained BW by 2nd visit = 88.7%
Hossain et al. ⁶ Bangladesh	Prospective observational study conducted for 6 m	To determine postnatal weight change in early neonatal period in relation to gestational age and BW.	Yes	48 full-term infants of 185 births (includes 3 low BW babies)	Daily weight until infant regained BW Reports: (1) number of d before beginning to regain weight (2) time in d to regain birth weight	(1) 56.25% began to regain by day 5; 43.75% began to regain by day 10 (2) Regained BW. 1–10 days = 56.16% 11–14 days = 35.41% 15–21 days = 8.33% > 21 days = 2.08%
Jolly et al. ⁷ Jamaica	Prospective	To examine weight change of exclusively breastfed infants through the first 24 d following birth and to evaluate the effect of breastfeeding factors and maternal characteristics on early weight change in the infants	Yes	21 neonates	Weights on day 1 (day of birth) and days 3, 7, 10, 17, 24 Reports: (1) mean and median amounts of weight gained in kg (2) % infants who gained weight on d 3, 7, 24	(1) Change of weight from birth in kg Mean (SEM): Day 3: 0.23 kg (± 0.06) Day 7: 0.56 kg (± 0.09) Day 24: 1.22 kg (± 0.14) Median: Day 3: 0.16 kg Day 7: 0.49 kg Day 24: 1.16 kg (2) % infants who gained. Day 3: 90% Day 7: 95% Day 24: 100%

Macdonald et al. ¹⁹ Scotland	Prospective observational cohort study	To define the range of neonatal WL in a population relative to feeding method.	Yes	937 infants: 45% breastfed (n = 420), 42% formula-fed, 13% combined	Weighed at birth, at discharge (~48 h), ~day 5, 7, 10, 14 (weighing stopped when BW regained) Reports: Median for (1) % WL (2) timing of maximum WL in d (3) d to regain birth weight (4) percentile data of above	(1) % WL (n = 420) median = 6.6 (6.3–6.9); 95th percentile 11.8 (11.2–12.9) (2) Timing of loss (d) (n = 420): median = 2.7 (2.5–2.8); 95th percentile 9.1 (7.7–10.2) (3) Regain BW (d) (n = 395): median = 8.3 (7.7–8.9); 95th percentile 18.7 (16.7–20.8)
Manganaro et al. ¹⁷ Italy	Prospective observational study	To verify the incidence of hypernatremic dehydration in exclusively breastfed, term infants and identify possible maternal and/or infant factors that interfere with successful breastfeeding.	No	686 infants of 782 births ≥10% WL (n = 53) <10% WL (n = 633) No supplements first 3 d 26% received formula supplement due to WL (≥ 10%)	Daily weights in hospital and at home on day 5 (vaginal birth) and on day 10 (both vaginal and cesarean) Reports: By group (≥ 10% and < 10% WL) (1) mean % WL and range of % WL for those who lost ≥ 10% (2) range of days of maximum WL for type of birth	% subjects: ≥ 10% WL = 7.7% < 10% WL = 82.3% (1) Mean WL ≥ 10% group = 11.3 ± 1.1 (range 10%–14.8%) < 10% group = 5.5 ± 1.2 (no range stated) (2) vaginal: lowest weight at 3–4 d cesarean: lowest weight at 4–5 d
Marchini et al. ¹⁸ Sweden	Prospective observational study	To investigate whether plasma leptin was related to BW or WL during the neonatal period	No	120 infants during first 4 d 4 groups (n = 30 each) according to timing of blood work	Daily weights Reports: (1) % median WL with range	(1) % WL median (range) Group 1: 3.2 (0.4–5.7) Group 2: 6.0 (2.1–8.2) Group 3: 6.4 (0.1–12.6) Group 4: 5.7 (0.3–15.7)
Martin-Calama et al. ²² Spain	RCT with control arm of exclusively breastfed infants	To compare the use of glucose water and exclusive breastfeeding on WL, serum glucose level, temperature and breastfeeding duration	No	87 infants in the exclusively breastfed group followed for 72 h	Weights at 6, 12, 24, 48, and 72 h Reports: (1) WL in grams (2) WL as % birth weight	(1) WL, g (SD) 6 h: 46.4 (± 19.1) 12 h: 86.4 (± 30.4) 24 h: 140.6 (± 42.4) 48 h: 197.8 (± 73.2) 72 h: 141.9 (± 89.1) (2) % BW lost 6 h: 1.4% 12 h: 2.6% 24 h: 4.2% 48 h: 5.9% 72 h: 4.2%

Michel et al. ⁶ France	Prospective descriptive study	To identify incidence and risk factors for breastfeeding difficulties in maternity ward using 3 indicators: excess neonatal WL, delayed onset of lactation, and suboptimal infant breast- feeding behaviour	No	118 infants of whom 94 were exclusively breastfed 20.3% received formula supple- ments	Daily weights while in hospital Reports: (1) WL as a mean (2) n that lost < 10%	(1) WL: mean = 6.62 (SD±1.84) in ex- clusively breastfed infants (shown in text, not table) (2) 3 of 94 (~3%) lost more than 10% (clarified by email)
Muskinja-Montanji et al. ⁷ Serbia	Prospective descriptive study	To determine effect of rooming-in on initiation of lactation, and on physiological WL.	No	200 infants: 100 in nursery and 100 in Baby Friendly Hospital Initiative™ (BFHI) hospital (rooming-in)	Daily weights Reports: (1) average WL in g by parity (P) (2) day of lowest weight (3) % of WL by parity	(1) Average WL (g) for nursery / BFHI: P1: 205.00 / 191.70 P2: 178.82 / 171.95 P3: 190.00 / 178.00 (2) Day of lowest weight (combined to form %, n = 200) Day 1: 2 Day 2: 93 Day 3: 90 Day 4: 14 Day 5: 1 (3) % WL by parity for nursery / BFHI: P1 = 6.00% / 5.50% P2 = 5.20% / 5.00% P3 = 5.34% / 5.04% P4 = 7.27% / 5.66%
Rodríguez et al. ⁸ Spain	Prospective observational study	To investigate nature of weight changes (i.e., fluid versus solid) that accompany early physiological WL	No	43 neonates	Multiple anthropometric variables in- cluding weight at birth and days 1, 2, 3 Reports: (1) mean weight in g (2) mean WL	(1) Mean BW: 3297.7 +/- 381.4 Mean daily weight (SD): Day 1: 3252.1 g (± 389) Day 2: 3146.7 g (± 380) Day 3: 3111.4 g (± 371) (2) Mean WL (SD) = 5.7% (±1.98)

BW = birth weight, NS = non significant, SEM = standard error of the mean; WL = weight loss, d = day, h = hour; g = gram; kg = kilograms, m = month

Table 2: Examples of studies excluded from systematic review

Reference	Rationale for consideration for abstraction	Study details and reason for exclusion after abstraction
Avoa et al. ¹⁹	Used as reference in clinical practice guideline Appears to provide information about WL	Study to determine the effect of a breastfeeding education session provided in labour and delivery on infant WL. Supplemented and "low-birth-weight infants" (not defined) infants are pooled with exclusively breastfed infants
Benson ²⁰	Title suggests relevant weight data would be part of study.	Study of breastfeeding patterns during first 60 h. No data about weight.
Bystrova et al. ²¹	Abstract says infants were weighed daily as part of study.	Aim was to study effects of different combinations of ward routines: skin-to-skin vs clothed, rooming-in vs. nursery, and swaddling vs. loosely dressed. Lack of data for weight change patterns of exclusively breastfed infants.
Çağlar et al. ²²	Title suggests primary study about weight loss.	Aim of study was to identify risk factors for WL. No primary data regarding WL.
Dewey et al. ²³	Title and abstract identify neonatal weight loss as a variable.	To determine the incidence of and risk factors for suboptimal infant breastfeeding behavior, delayed onset of lactation, and excess neonatal weight loss. Not all infants were exclusively breastfed.
Livingstone et al. ¹	Abstract identifies weight loss parameters and normal weight loss is stated on first page of article	Retrospective study of neonates with hypernatremia. States: "It is normal over the first week of life for the neonate to lose as much as 7% of its birth weight through normal diuresis. Neonates should start to gain weight within a few days and regain their birth weight by the tenth day of life. Either rapid weight loss or loss greater than 7% of birth weight is a cause for concern" (p. 647). No primary data regarding WL No references or data to support 7% WL limit statement
Maisels et al. ²⁴	Used as a reference in a CPG.	Compares a group of infants with jaundice (n = 147) with a control group of infants (n=147) randomly chosen from a pool of 2269 healthy infants. States "breastfed infants lost an average of $6.86 \pm 2.97\%$ of their birth weight" (p. 508). Only 46.9% were breastfed. Retrospective chart review for data about weight patterns Insufficient detail about breastfed infants to meet inclusion criteria for systematic review
Merlob ²⁵	Used as a reference in a CPG. Title and abstract indicate topic is about weight loss in the first days following birth	Weight loss on the third day was the criteria for forming study groups to determine predictability for breastfeeding duration. Data about infant weights were not provided.
Powers et al. ²⁶	Used as a reference in a CPG.	Clinical information intended for pediatricians. Suggests a weight loss of 8%–10% accompanied by delayed lactogenesis is a possible indication for early supplementation. No primary data regarding weight loss. No references or data to support 8%–10% weight loss limit statement.

Shrago ⁹	Used as a reference in a CPG.	Conference proceeding States: "Normal weight loss in breastfed neonates should not be > 7% of birth weight." Not primary data. Used secondary citations to establish normal weight loss.
Shrago ¹⁰	Abstract states the participants were exclusively breastfed and weighed daily.	Study did not meet definition of "exclusively breastfed." Under methods, authors state, "An infant who received water or glucose water or expressed breast milk was not excluded from the study" (p.197).
Tjon et al. ²⁷	Abstract suggests relevant weight data would be part of study.	Study to determine the percentage of weight lost by Basotho infants following birth and the time to regain birth weight, n = 814 neonates over a 4-year period. Daily weights for up to 7 d or as long as in hospital, reports: 1) mean % of birth weight over 6 d 2) d to regain BW Only 289 of 814 infants were assessed for gestational age. Results included data for pre-term and small-for-gestational-age infants pooled together with data for term infants.
Wright et al. ²⁸	Title suggests relevant weight data would be part of study.	To determine maternal socioeconomic factors that affect infant weight gain or faltering. Only 51% of the neonates were breastfed. Exclusively breastfed data were not reported separately.
Yaseen et al. ²⁹	Used as a reference in a CPG.	To identify the clinical presentation of dehydration related to failure of lactation in exclusively breastfed term infants Control group of 58 healthy, term infants aged 4–7 days. Only 74% of control group were exclusively breastfed, and data were pooled.

Relationship Between Intravenous Fluids Given to Women During Parturition and Their Newborns' Weight Loss

Chapter 3 - A Review of the Literature

Newborn weight loss was explored in this thesis, and it was hypothesized that intravenous (IV) fluids women receive during parturition (i.e. the act of giving birth including time in labour or prior to a cesarean section) affect their newborns' weight. The current literature about patterns of normal physiological weight loss patterns is presented in the article in Chapter 2, and factors that affect weight loss in the breastfed and support the hypotheses are presented in this chapter.

Methods

For this summary of literature, nursing and medical literature was reviewed for evidence about neonatal weight loss, supplementation, and early weaning and for evidence about non-feeding factors that might affect neonatal weight loss in the first two weeks of life. Maternal fluids during labour and prior to a cesarean section are the primary factors of interest, therefore, the use and potential effect of IV fluids during parturition; physiology of fetal fluid regulation; potential effect of IV fluids on newborn weight loss are reviewed.

Computerized searches of the research literature were completed using MEDLINE, CINAHL, EMBASE, and the Cochrane Library databases between October 2006 to May 2010. Although more consideration was given to studies from the past 10 years, dates, languages, and research methodologies were not restricted.

All searches were completed with Boolean operators using the terms: infant or neonate or newborn or baby or neonatal; breastfeeding or breast-feeding or "breast feeding"; weight or "weight loss" or "birth weight" or birthweight; full-term or fullterm or term. Both subject and title search features were used.

Factors related to neonatal weight loss in the first days and up to two weeks postpartum were included. Inclusion criteria were healthy fullterm newborns, and studies about preterm or ill infants were excluded. The factors are often described in terms of weight loss, but the factor could also be described in terms of weight gain. Although the main interest is the breastfed infant, all feeding methods were considered.

Neonatal Weight Loss, Supplementation, and Early Weaning

Currently, professional practice guidelines recommend that an infant should not lose in excess of 7% of birth weight (Academy Of Breastfeeding Medicine [ABM], 2009; American Academy of Pediatrics, [AAP] 2005; International Lactation Consultants Association [ILCA], 2005; Registered Nurses Association of Ontario [RNAO], 2003). These professional guidelines use weight loss as an indicator for effective breastfeeding and adequate milk production and transfer. When excessive weight loss is identified, it is assumed that infants have experienced inadequate intake. Management techniques, including supplementation, are then recommended (ABM, 2009; ILCA, 2005).

Supplementation in the early postpartum period is defined as the use of fluids other than breast milk and it is recognized as a substitution for, not a complement to, breastfeeding (Breastfeeding Committee of Canada [BCC], 2006). Glover (1995) found both mothers and nurses believed supplementation would prevent dehydration, hypoglycemia, hyperbilirubinemia, and newborn weight loss. Gagnon, Leduc, Waghorn, Yang, and Platt (2005) explored the frequency and reasons for in-hospital supplementation and found 47.9% of infants in their study were supplemented while in hospital. More than half of the nurses interviewed cited weight loss as one of the reasons for supplementing

(Gagnon et al., 2005). Gagnon et al. state that nurses also reported breastfeeding problems, infant behaviour, and maternal fatigue as reasons for supplementing.

Many factors contribute to early weaning and the primary reason given by Canadian women is a lack of milk (Millar & Maclean, 2005; Sheehan, Krueger, Watt, Sword, & Bridle, 2001). Other factors include nipple pain and damage and a perceived lack of breastfeeding information or familial support (Cerandas, Noceda, Barrera, Martinez, & Garsd, 2003; McLeod, Pullon, & Cookson, 2002). There is also strong evidence that postpartum maternal confidence is positively correlated to breastfeeding success (Blyth et al., 2002; Chezem, Friesen, & Boettcher, 2003; O'Campo, Faden, Gielen, & Wang, 1992).

Supplementation is also correlated with early weaning (Casiday, Wright, Panter-Brick, & Parkinson, 2004; Declercq, Labbok, Sakala, & O'Hara, 2009; Hill, Humenick, Brennan, & Woolley, 1997; Sheehan et al., 2001). Although a correlation is confirmed in these studies, causality is not clearly established. The issues that contribute to early weaning (for example, sore nipples or a lack of maternal confidence) may also contribute to supplementation. In a randomized controlled trial (RCT), Martin-Calama et al. (1997) demonstrated that infants randomized to an intervention group receiving supplements of glucose water by bottle in the first three days were subsequently supplemented with twice as much formula in the first month and were weaned earlier than the control group.

The strong correlation between early supplementation and early weaning along with the results of Martin-Calama et al.'s RCT substantiate calls to decrease the use of supplements, especially in the first few days after birth. There are dissenters and supporters for this policy. Szajewska, Horvath, Koletzko, and Kalisz (2006), in their systematic

review of the effects of brief exposures to supplements, conclude that one RCT is insufficient evidence. On the other hand, the WHO/UNICEF Baby-Friendly™ Hospital Initiative acknowledges the importance of avoiding supplementation by stipulating that 80% of mothers need to be exclusively breastfeeding to meet the minimum standard for Baby-Friendly™ status (BCC, 2004).

Non-feeding Factors Related to Neonatal Weight Loss

Amounts of intake and type of feeding affect neonatal weight loss or rate of weight gain. For example, type of feeding (i.e. breastfeeding versus formula feeding) and timing of lactogenesis II (i.e. the onset of a full milk supply) have been related to weight loss in the newborn (Dewey, Nommsen-Rivers, Heinig, & Cohen, 2002; Lamp & Macke, 2010; Martens & Romphf, 2007).

While insufficient caloric intake leads to weight loss or lack of weight gain, there is also evidence that non-feeding factors influence neonatal weight loss. Dewey, Nommsen-Rivers, Heinig, and Cohen (2003), in a prospective study (n = 280), determined higher maternal BMI, parity (primiparous), type of birth (cesarean), and use of regional anesthesia were correlated to excessive neonatal weight loss. Martens and Romphf (2007), in a retrospective chart audit (n = 812), found higher birth weight, infant sex (female), lower gestational age, epidural use, and increased length of hospital stay were positively related to newborn weight loss. The number of wet diapers was a predictor of weight loss in two recent studies (Lamp & Macke, 2010; Mulder, Johnson, & Baker, 2010). Macke and Lamp (2010) also found sex was a strong predictor of weight loss during the first 48 hours after birth. Lamp and Macke (2010) found no correlation

between maternal fluid prior to birth and neonatal weight loss in the first 48 hours postpartum.

Iatrogenic factors might affect neonatal weight loss including the use of synthetic oxytocin (Chou, DiGiovanni, Mejia, Nielsen, & Knepper, 1995) and timing for cutting the umbilical cord (Levy & Blickstein, 2006). Merry and Montgomery (2000) showed that mothers who received epidurals had babies who weighed more at birth and lost more weight in the first 24 hours than babies of women who had not received epidurals. Odent (1990) found one third of infants born at home ($n = 100$) did not lose weight. Other researchers demonstrated that hospital routines were associated with weight loss (Bystrova et al., 2007; Muskinja-Montanji, Molnar-Sabo, & Vekonj-Fajka, 1999).

The effects of labour might be considered, especially the effects of labour on the unborn infant's lungs (Jain & Eaton, 2006). A shift to intracellular fluid and an overall decrease in the percentage of fluid in the fetus in the days prior to birth results in a decrease in the amount of fluid in the unborn infant's lungs (Brace, 2004). It is possible that excess weight loss in the first three days can be attributed to additional insensible loss from fluids blown off in respiration or from excess mucus coughed up by infants born by cesarean section.

Ensuring infant health is a priority for nurses and lactation specialists working with breastfeeding women and their infants. The goal is to provide infants with adequate and appropriate nutritional intake. To achieve this goal, infants need to be fed enough and to be fed their mother's milk. Research is needed to determine whether infant weight changes are an appropriate measure of adequate feeding in the first days of life and if birth practices create excess weight loss that is mistakenly labelled as inadequate feeding.

Use of Intravenous Fluids During Parturition

Physicians order IV fluids during parturition for surgical procedures (e.g. Caesarean sections), to rehydrate women, and to maintain hemodynamics (Keppler, 1988).

Intravenous fluids are also used while providing IV medications, especially for induction or augmentation of labour with oxytocin (Keppler, 1988). Issues of hemodynamics during parturition usually centre on the use of spinal and epidural anesthesia which can contribute to maternal hypotension and result in reduced blood flow to the fetus (Cyna, Andrew, Emmett, & Middleton, 2006; Hofmeyer, Cyna, & Middleton, 2004).

Clinical indications for using IV fluids prophylactically to prevent hypotension might depend on whether the woman is receiving an epidural in labour or a spinal anesthetic for a Caesarean section. In a Cochrane review, "Prophylactic Intravenous Preloading for Regional Analgesia in Labour", Hofmeyer et al. (2004) conclude that IV preloading prior to high-dose local anesthetic blocks for healthy labouring women may be beneficial, but they question if preloading is necessary with low-dose epidurals. In a separate Cochrane review, Cyna et al. (2006) analyzed studies that had used IV fluids, medications, and leg compressions to prevent maternal hypotension during anesthesia for Caesarean sections. They concluded that complete prevention of hypotension is not possible, but interventions including IV fluids may decrease the frequency and severity of adverse symptoms.

The use of IV fluids to prevent hypotension has been challenged (Kinsella, Pirlet, Mills, Tuckey, & Thomas, 2000; Shannon & Ramanathan, 1998), and several studies looked at the types of IV fluids used during parturition, the effect of IV fluids on duration of labour, and decision-making around using IV fluids. There is a debate in the literature

about the optimal type of IV fluid for use during childbirth. The key factors to consider are colloid versus crystalloid solutions and whether solutions should contain sodium.

Crystalloid solutions (e.g. 0.9% saline, dextrose 5% in water [D5W], Ringer's Lactate, Hartmann's Lactate) contain water and electrolytes and pass freely through a semipermeable membrane, whereas colloid solutions (e.g. Dextran) do not dissolve into a true solution and do not pass freely through a semipermeable membrane (Shami & Davidson, 1997). To prevent maternal hypotension during spinal anesthesia, Cyna et al. (2006) determined that colloids were more effective than crystalloids and crystalloids were more effective than no fluids. Dahlgren et al. (2005) compared Ringer's lactate and Dextran and found that the protective effect of colloid solutions increased with the severity of the hypotension.

Eslamian, Marsoosi, and Pakneeyat (2006) determined that increased IV fluid intake shortened the course of labour in nulliparous women. Garite, Weeks, Peters-Phair, Pattillo, and Brewster (2000) also determined that increased fluids shortened the length of labour. Both studies were randomized controlled trials where the control group received 125 ml per hour, while the intervention group received 250 ml. of Ringer's Lactate hourly. The participants in Garite et al.'s study were given additional boluses of IV fluids if the woman received an epidural. Eslamian et al.'s participants did not have epidurals. While shortening labour is a worthwhile goal, the potential for maternal complications from the use of IV fluids, including hyponatremia, pulmonary edema, and neurological changes, must also be considered (Borcherding & Ruchala, 2003; Fraser, & Arieff, 1997; Singhi, Chookang, Hall, & Kalghatgi, 1985).

Tourangeau, Carter, Tansil, McLean, and Downer (1999) implemented a practice change regarding use of IV fluids (i.e. with the revised protocol, IVs were started based on need rather than as routine practice upon admission), and they found that less than a third of labouring women required IV fluids under their new protocol. The majority of women in their study did not receive IV fluids and no adverse effects were reported. Sommer, Norr, and Roberts (2000) determined that the role differences between Certified Nurse-Midwives (CNMs) and Registered Nurses (RNs) seemed to be most important in determining whether a woman had an IV started. In particular, the RNs were more concerned than CNMs about having IVs in place in case of an emergency situation. The results of these studies raise questions about the routine use of IV fluids.

Neither provincial nor national statistics on amounts of IV fluids used during parturition were found. An average of 62% of women experiencing a vaginal birth in Ontario had epidurals (Ontario Perinatal Programs Partnership [OPPP], 2009). The rate is assumed to be 100% for the 28.4% of cesarean births. For first-time mothers, the average for epidurals is 72.4% and for multiparous women the average is 50.2% (OPPP, 2009). Small community hospitals have the lowest epidural rates for vaginal births (35.4%), possibly due to a lack of availability of anesthetists (OPPP, 2009). Level 2 and Level 3 hospitals, where more complicated cases are treated, have higher rates (61% and 75.5% respectively; OPPP, 2009). Given the epidural rates, it appears the majority of women, especially nulliparous women and women in Level 3 hospitals receive IV fluids.

Maternal-Placental-Fetal Physiology and Fetal Fluid Regulation

During the 266 days of gestation, a human fetus grows rapidly from a single cell to an embryo then a fetus and finally a newborn (Bolender & Kaplan, 2004). Unique

anatomy and physiology support this growth. A mother and her unborn baby maintain separate circulatory systems and often different blood types, and these separate systems intersect at the placenta where water and electrolytes move freely between both systems; nutrients and oxygen tend to move from mother to fetus; and carbon dioxide and fetal metabolic waste are transferred to the mother (Battaglia, 1960; Sibley & Boyd, 2004).

The placenta develops from the trophoblast cells. A low resistance, high-flow vascular bed is formed by the basal plate on the maternal side. The chorionic villi on the fetal side are separated from the basal plate by the intervillous space (Kaufmann & Frank, 2004). Fetal blood approaches the placenta via two umbilical arteries which arise from the internal iliac arteries, and it leaves via a single umbilical vein; the three vessels are imbedded in the umbilical cord (Adamson, Myatt, & Byrne, 2004). At term, maternal uterine blood vessels have formed 100 to 200 spiral arterioles that bathe the placental microvilli in the maternal blood (Rosenfeld, 2004; Woelkers, 2004). Primarily oxygen and nutrients move from mother to unborn baby, and waste products move away from the fetus.

The embryo's heart begins beating around 22 days after fertilization with some circulation of fluids within a day afterwards (Bolender & Kaplan, 2004). From conception to birth, the fetus goes through many changes in fluid balance. At the beginning of the fetal period, the fetus is about 95% water with the percentage of fluids decreasing to about 70% at birth, and this contrasts with adult humans who consist of about 45-50% water (Brace, 1998). The fluid spaces transition throughout gestation with more fluid in the extracellular spaces at first, and a shift to an increased proportion of intracellular fluid closer to birth (Brace, 1998). Throughout fetal life, the proportion of

fluid in the intravascular space remains constant, and the goal of fetal fluid balance may be the maintenance of optimal blood volume (Brace, 1998).

There are key differences between fluid balance in the human fetus and the human adult. In addition to the differences in percentage and placement of fluids, a fetus transports fluid at a much faster rate relative to body weight when compared to adults (Brace, 1998). The placental connection to its mother and the presence of amniotic fluid also affects fluid balance in the fetus (Brace, 1998). As the fetus grows, it swallows and "breathes" the amniotic fluid and, in doing so, voids and "exhales" into the amniotic fluid (Beall, van den Wijngaard, van Gemert, & Ross, 2007). These exchanges alter the amniotic fluid and are key regulators of fetal fluid balance.

Fetal fluid balance is a combination of diffusion, hydrostatic pressure, and osmotic pressure (Faber & Anderson, 2010). In the short term, the key mechanisms for fluid homeostasis are transcapillary fluid movements (Brace, 1998). In the long term, transplacental fluid movements are fundamental to fluid balance (Brace, 1998). The kidney plays a bigger part in fluid balance following birth. Fetal kidneys receive about 2% of cardiac output; whereas, a newborn, aged 2-36 hours, processes about 10% of cardiac output (Lumbers, Gibson, & Stevenson, 2004).

Maternal Intravenous Fluids and Neonatal Weight Loss

Studies have been undertaken to determine the effects of maternal IV fluids on the newborn with regards to jaundice (Akinyinka, Omigbodun, Akanmu, Osanyintuyi, & Sodeinde, 1995; Singhi Chookang, & Hall, 1984); tachypnea (Singhi & Chookang, 1984); and hypoglycemia (Kenepp et al., 1982). Overall, these reports support the proposition that

there is a relationship between IV fluids given to women and the effects experienced by infants.

Several studies have shown that women who receive IV fluids during parturition experience varying degrees of hyponatremia, usually without symptoms, and that their infants subsequently have decreased cord serum sodium levels (Altstatt, 1965; Singhi & Chookang, 1984; Spencer, Mann, Smith, Woolfson, & Benson, 1981; Suvonnakote, Toongsuwan, & Prijavudhi, 1986; Tarnow-Mordi, Shaw, Liu, Gardner, & Flynn, 1981). For example, in a retrospective study of the relationship between IV administration of 5% dextrose and oxytocin to labouring women and cord serum sodium levels, Dahlenburg, Burnell, and Braybrook (1980) found the sodium levels were significantly lower for infants in the intervention group compared to the control group. Additionally, the babies of mothers who had IV fluids lost more weight than the babies of mothers who only had oral fluids. Discovering that infants of mothers who received fluids had lost more weight than the infants not exposed to IV fluids during parturition was secondary to the original study purpose (Dahlenburg et al., 1980). This research supports the hypothesis that birth weight is affected by IV fluids given to women during parturition.

Descriptions of fetal physiology and fluid balance and studies of the effects of maternal IV fluids support the hypothesis that a newborn can be born overhydrated and subsequent diuresis contributes to neonatal weight loss. These studies do not establish a relationship between IV fluids, neonatal output (e.g. urine excreted in the first days after birth), and neonatal weight loss in the first 72 hours postpartum. A prospective study to establish correlations among these factors could help clinicians understand the relationship between maternal fluids and neonatal weight loss in the first few days postpartum.

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Relationship Between Intravenous Fluids Given to Women During Parturition and Their Newborns' Weight Loss

Chapter Four - Methods

Study Design

This research study was a prospective observational single cohort design. It followed a self-selected group of participants from parturition (the act of giving birth including time in labour or prior to a cesarean section) through to two weeks postpartum, and it was designed to collect data about factors that might influence neonatal weight loss (see Figure 1). The aims of this observational study were to describe associations between: (a) maternal IV fluids during parturition and neonatal weight loss; (b) maternal IV fluids during parturition and neonatal elimination; and (c) neonatal elimination and neonatal weight loss during the first 72 hours postpartum.

Observational studies encompass descriptive, cohort, cross-sectional, and case-control study designs, do not involve manipulation of a variable, and they are useful when studying incidence, causes, and prognosis (Mann, 2003). Establishing a correlation between two variables does not prove causation, on the other hand, causation cannot be established without a correlation (Aldrich, 1995). In a prospective cohort study events are recorded in chronological order, providing an opportunity to distinguish cause from effect.

The research question determines the best research design (Sackett & Wennberg, 1997). In this study, the goal was not to determine optimal treatment, but to assess if the participants developed the outcome of interest (weight loss). It was decided that the most suitable research design would follow the natural developments during parturition and early postpartum to ascertain correlations between variables and confirm predictors of neonatal weight loss.

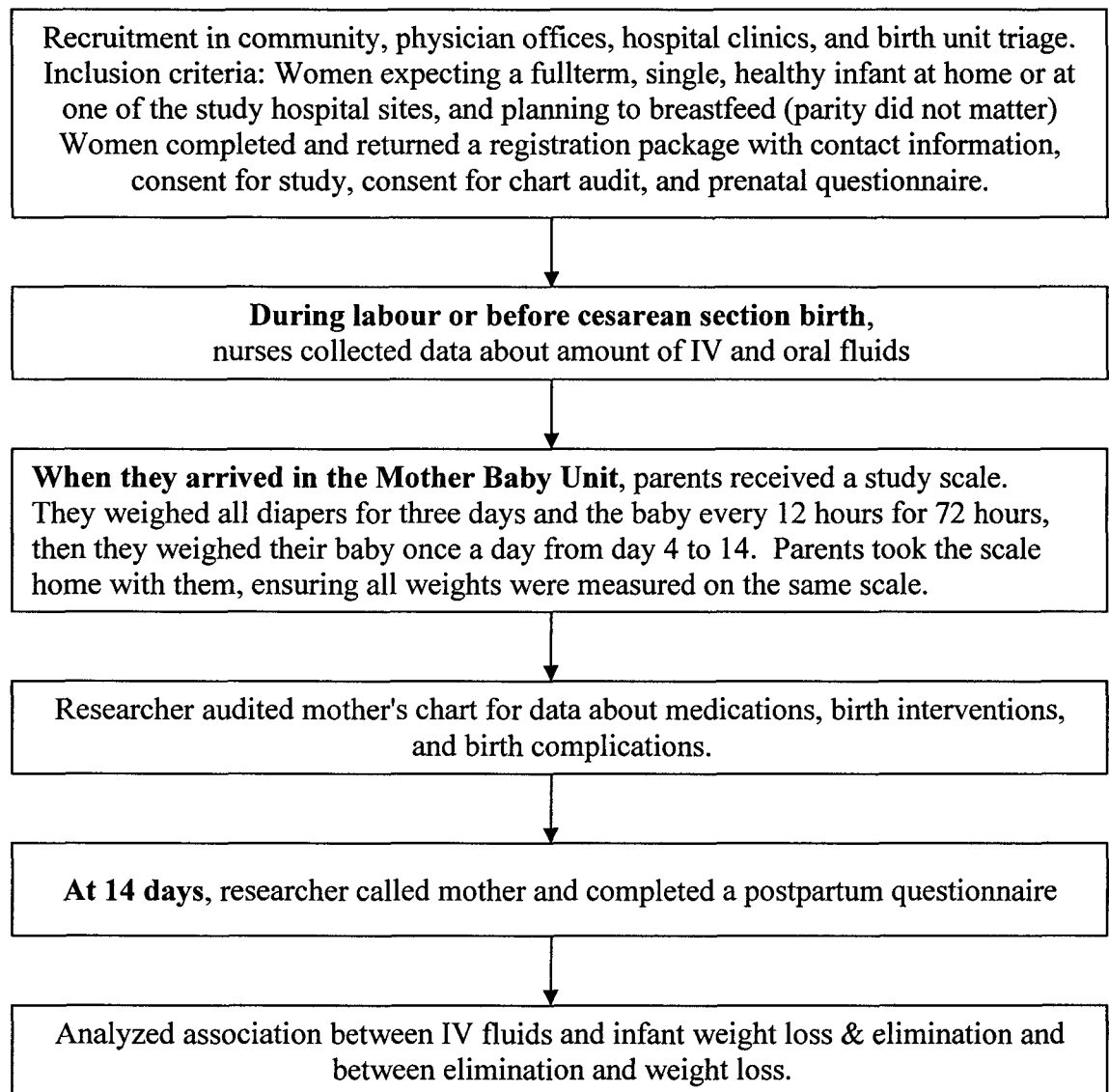


Figure 1. Schematic of research study describes inclusion criteria, steps and timing for data collection, and aspects of analysis.

Setting

Data were collected through four hospitals at five different locations (one hospital has two campuses) near and in a mid-sized Ontario city. Data collection began in September 2008 and was finished in June 2010. The researcher reasoned that different hospitals could provide different birth practices, the three community hospitals had low risk patients, and

there would be at least one large hospital with a high census. Two research assistants, both registered nurses, were willing to volunteer in the smaller towns, thereby making the choice of hospitals feasible.

Participants

Inclusion Criteria

Eligible participants were women of any parity, who gave birth to a single, full term infant either at home or in one of the participating hospitals and who were planning to breastfeed. Birth could be either vaginally or by Caesarean section and full term was defined as more than 36 6/7 weeks (Engle, 2006). Participants needed to be able to read, write, and speak English, and they required a telephone to be able to complete postpartum questionnaires.

Mother and infant had to be discharged at the same time and both had to be healthy enough to breastfeed without restriction. Babies who were supplemented remained in the study. Francophone participants who were willing to join an English study and complete questionnaires in English received the patient information sheet and consent forms in French.

Sample Size

Originally, an a priori sample size calculation determined the sample size needed was 250 participants. The rationale was that there were 20 variables being considered; therefore 200 participants were required when allowing for 10 participants per variable for analysis (Norman & Streiner, 2008). Approximately 25% was added to allow for attrition. As the study progressed and with further reflection, the researcher realized that several of the variables affected breastfeeding duration and exclusivity and not necessarily weight loss. Eleven variables relevant to weight loss were kept for analysis.

This change reduced the required sample size to 110. Correlations required a sample of 64 subjects to detect a moderate (.30) correlation at an alpha of 0.05 with a power of 0.80 (Faul, Erdfelder, Buchner, & Lang, A-G., 2009).

Protection of Human Rights

This research study conformed to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, 1998). The thesis committee approved the thesis proposal (see Appendix A). The research ethics boards of the University of Ottawa and participating hospitals provided research ethics approvals for the study and subsequent amendments (see Appendices B and C).

Procedure

The sample was a convenience sample. Participants could sign up at any time before or during admission to the hospital, although the researcher avoided asking anyone who was less than 20 weeks gestation; to ensure a stable pregnancy and to avoid attrition.

The study was advertised with posters and pamphlets (see Appendices D and E). Initially, the researcher expected to recruit participants when women preregistered for the hospital. Unfortunately, such a preregistration does not take place at area hospitals. Research ethics amendments allowed for recruitment in the community (at prenatal classes and a baby show/trade fair), at clinics, and in midwives' and physicians' offices. During the final four months of data collection, recruitment also took place in triage at one of the hospitals. Hospital or office staff approached potential participants and told them about the

study. If the woman agreed, the researcher or a research assistant would explain the study. Women could take the registration package home to discuss it with their families.

The registration package included a patient information sheet (PIS), two consent forms, a contact information sheet, and a prenatal questionnaire (see Appendices F, G, H and I). Copies of the PIS, the consent forms, and the instructions for use of the baby scale (see Appendix J) were given to the participants to keep. Participants returned signed, dated copies of the consent forms and the contact information sheet and prenatal questionnaire to the researcher.

During labour or before a cesarean section, fluid information was recorded by nurses and the parents (see Appendix K). After the baby was born (and usually following transfer to the Mother Baby Unit), parents were given a cart with a study scale and an envelope with the data collection sheets (see Appendices L, and M). Parents were responsible for measurements following birth. Parents took the scale home with them, and the researcher arranged to pick it up from their home after the newborn was two weeks old.

The researcher audited the participant's hospital chart (Appendix N). At two weeks postpartum, participants were called and they completed a postpartum questionnaire by telephone which included an algorithm about feeding categories (see Appendices O and P).

Measurements

Maternal Fluids During Parturition

Amounts of oral and intravenous fluids were recorded from admission to birth in millilitres. In the original proposal, the researcher planned for IV information to be collected hourly. Nurse managers stated this would be onerous for nurses. Since most nurses work 12-hour shifts, nurses on the floor said that accuracy would be best with 12-hour shift

amounts. Therefore fluid data were collected for all participants in 12-hour intervals. During the last three months of data collection, the researcher asked nurses to also estimate the amount of IV fluids in the two hours before birth.

Newborn Weights

The Ultrascale MBSC-55 Digital Scale was used for the study. It is an electronic scale with precision to within 2 grams under 500 grams (e.g. the diapers) and to within 10 grams over 500 grams (e.g. the baby). For safety reasons, the scales ran on batteries. Each scale was sanitized and tested using a standardized stone before it was wrapped for use by a participant. Parents took the scales home when discharged, so all weights were measured on the same scale for internal consistency.

Neonates were weighed at birth, then every 12 hours for 72 hours, followed by daily from day 4 to 14. Most infants reach their nadir of weight loss around day 3 (Noel-Weiss, Courant, & Woodend, 2008). Any fluid shift was expected to happen within 24 to 48 hours post birth (Brace, 1998). Given these patterns, the protocol was set up for more frequent weight measurements in the first 3 days to try to detect any shifts in weight.

Since the newborn was weighed at birth on a hospital scale, and it was less intrusive to provide the baby scale in the Mother/Baby Unit, the first weight on the hospital scale counted as birth weight for the study. Parents began weighing their baby at 12 hours. For one hospital, parents checked off on the data collection sheet when the security clamp (a device attached to the infant set to alarm if infant is taken off the ward) was intact, and the researcher subtracted the 22 grams from the baby's recorded weight. Newborns were weighed without diapers or clothing.

Most infants regain their birth weight by 14 days (Noel-Weiss et al., 2008). Parents continued weighing their infants once a day from day 4 to 14 to determine if weight loss patterns in the first 72 hours continued or if the weight loss was isolated to the first few days.

Neonatal Output

Diapers were weighed for three days and recorded on the data collection sheet provided with the study scale. The rationale for three days was also based on the nadir and timing of the possible fluid shift. The protocol was built to minimize effort from parents. Each diaper was weighed and the full weight was recorded. The weight of a dry diaper was also recorded, and the researcher subtracted the amount before entering the data into the database. Parents noted any lost output (i.e., voids and stools not in diaper).

Infant Feeding

At two weeks postpartum, infant feeding patterns were established during a telephone questionnaire by asking if babies were supplemented in hospital and by using an algorithm. The algorithm was used to establish which of seven feeding categories the neonate fit (e.g. exclusively breastfed versus weaned; see Appendix P).

Data Collection

Developing Data Collection Sheets

Two questionnaires, an algorithm to determine feeding category, and measurement sheets were developed for this study. The principal researcher used similar forms in a previous study (Noel-Weiss, Rupp, Cragg, Bassett, & Woodend, 2006). Questionnaires were vetted for content by nurses and lactation consultants with clinical experience working with breastfeeding women and appropriate changes were made to key questions. The feeding category algorithm was built from the current literature (Breastfeeding Committee of Canada,

2006; Labbok & Krasovec, 1990; Noel-Weiss et al., 2006) and four lactation consultants trialed the algorithm by doing a "think aloud" exercise as they read the algorithm for the first time. By thinking aloud, they identified awkward wording and challenging formatting. Their feedback helped in the editing of the algorithm.

Nurse managers, nurse educators, and nurses were consulted about the data sheets and changes were made to fit each site. For example, only one hospital had security clamps on the babies (an alarm sounds if someone tries to leave with the baby). The baby weight sheet for that hospital was adjusted to indicate if the baby had the clamp on.

The data collection sheets were included with the scale, and all directions were on the sheets. The specific times for measurements, a request for the weight of one dry diaper, and key instructions that might be easy to forget were written on the sheets. Also, parents were advised to put diapers in a plastic bag if they could not weigh it immediately, so the diaper would not dry out (Oddie, Adappa, & Wyllie, 2004).

Data Collection

The first participants at each hospital were treated as pilot cases to modify forms if needed. Originally, mothers were asked to record feedings, but this task proved onerous and the sheet was subsequently removed.

Data were collected through four hospitals at five different locations, and each hospital had its own logo and research ethics board-approved forms. To ensure the correct pamphlets, posters, and registration forms were used, each hospital was assigned its own colour. Posters, pamphlets, crates to hold the registration forms, and file folders for collected data sheets matched each hospital's colour.

Data collection materials included (a) a registration package with contact information, consent forms, and the two-page prenatal questionnaire; (b) measurement sheets: maternal fluid sheet, diaper weight sheet, and baby weight sheet; (c) a two-page postpartum questionnaire and feeding category sheet; and (d) a chart audit sheet. Four of the data collection sheets were colour coded. Initially only the diaper weights (yellow) and baby weights (pink) were coloured. Later, the maternal fluid sheet was changed from white to blue. This change appeared to bring the sheets to the nurses' attention and more sheets were completed and returned. All data sheets were kept in the same order. The order and coloured sheets facilitated data entry. There were three data collection periods: (a) a prenatal registration, (b) data collection at birth, and (c) a two-week follow up (see Appendix Q for steps).

Managing the Data

Ensuring data were assigned the correct participant number was essential to managing data. Chart audits sheets had a paper strip with the mother's name on it and the sheet had the corresponding participant number. Once the chart had been audited at the hospital (with several checks that the name matched the chart), the corresponding number was added to the blue fluid sheet (when the sheet was available). Subsequently, the name was cut off the blue sheet and the paper strip was removed, both were deposited in the shredding box.

The researcher used similar paper strips with participant name, dates for birth and two weeks postpartum, and telephone number to prepare a postpartum questionnaire. After a postpartum questionnaire was completed the participant's number was added to all sheets and the strip was removed.

Quality Assurance

Controlling for Bias

Controlling for measurement bias was essential, since reliable results require precise measurements. The researcher's goal was to optimize accurate and complete measurement of maternal fluids, infant weight loss, and neonatal output. To that end, measurement protocols were simplified, prospectively collected when feasible, and data collection protocols were pilot tested. A simple, workable system to accurately weigh babies and all soiled diapers was established.

Precision scales (Ultrascale MBSC-55 Digital Scale) were purchased and provided to women for two weeks postpartum. A stone was used to establish a scale's accuracy before the scale was provided to a family. If the scale did not agree with the stone, the researcher performed a full recalibration, according to manufacturer directions, using a 10 kilogram weight. Because birth weight was the first weight measured by the nurses on the hospital scale, the same stone was used with hospital scales to ensure uniformity.

Data about amounts and types of IV and other fluids were collected prospectively and separately from usual charting practices to ensure completeness and accuracy. Data about patterns of parturition and medications were obtained retrospectively from patient charts and from a telephone questionnaire with participants at 14 days postpartum.

The Chart Audit

Ensuring IV information was collected was expected to be difficult. Recording fluids for the study was an additional step that nurses were asked to perform and the fluid sheet needed to follow the mother to the postpartum unit and eventually to the researcher. To add a second opportunity for obtaining the information, a chart audit was conducted. The audit

form was short, but the maternal chart audit ensured back up information for the IV fluids and a means to retrieve the fluid sheet if it was left on the chart.

The chart audit included information about maternal drugs, length of the first and second stages, and any interventions during birth. Although this information is generally known by the mother (and the same questions were asked during the postpartum questionnaire), it helped to have the information from the chart to fill in gaps.

The chart audit included information about birth weight, gestational age, and baby's sex. In the case of confusion about the identity of participant (e.g. if more than one chart was audited, and there was concern about the participant number being switched), the data could be matched to other data collection sheets to be certain the data were given the proper identification number.

Inservices and Information for Nurses

Nurses actively participated in the study in both the Birth Units (BU) and the Mother/Baby Units (MBU). Without their participation, data could not be collected. BU nurses collected the fluid data and called the researcher to advise her when the participant was in labour or preparing for her cesarean section. MBU nurses gave the mothers a cart and scale and often helped with weight measurements. Several strategies were used to inform the nurses. Initially, nurse managers at every hospital arranged inservices for the nurses. Posters with a summary of the study were posted (see Appendix R) and "gentle reminders" were handed out at shift changes (see Appendix S). The researcher built information folders for each unit with a summary of the steps in the study (see Appendix T) and copies of all documents.

Data Analysis

The amount of maternal fluids measured in millilitres was treated as a continuous variable (i.e. zero when the woman did not receive fluids). Baby weights and neonatal output (diaper weights including voids and stools) measured in grams were also continuous variables. A conversion chart was developed to convert any weights recorded in pounds and ounces, and this chart was comparable to conversion charts used at the hospital (see Appendix U).

Data was analyzed using SPSS 18. Univariate statistics (means, standard deviations, and frequencies) were used to describe the participants. Univariate statistics used to describe weight change included timing of lowest weight and frequency of percentage of change over time. Of particular interest was the percentage lost when baseline is set at 24 hours instead of using birth weight as the baseline.

Inferential statistics were used to test the hypotheses about associations. Pearson's correlation was run for normally distributed variables. In cases where the variable was not normally distributed, Spearman's Rho was used. All tests were one-tailed because we hypothesized positive associations.

A hierarchical multiple regression model, using 11 variables identified in the literature review, was built to determine predictors of neonatal weight loss. Regression diagnostics were completed prior to developing this model (e.g. missing data, outliers, normal distribution of residuals, independence of errors, linearity, homoscedasticity, and multicollinearity).

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**Relationship Between Intravenous Fluids Given to Women
During Parturition and Their Newborns' Weight Loss**

Chapter 5 - Second Article

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**Lactation and Breastfeeding Research Studies:
Who Should Provide Consent for the Neonate?**

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Received for review January 10, 2010; revised manuscript accepted for publication February 8, 2010.

Competing interest: none to declare.

J Hum Lact 26(2): 180-182

DOI: 10.1177/0890334410365068

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**Lactation and Breastfeeding Research Studies:
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Abstract

Research ethics guidelines do not provide sufficient direction for breastfeeding and human lactation studies. This article presents the principles of consent for research studies and discusses rationales for who should consent for infants in lactation and breastfeeding research studies.

Keywords: consent, research, parents, breastfeeding, lactation

The World Health Organization states, "All research involving human participants must be conducted in a manner that respects the dignity, safety, and rights of research participants and that recognizes the responsibilities of researchers."¹ Research ethics boards (REBs), also known as research ethics committees (RECs) or institutional review boards (IRBs), are usually responsible for reviewing and approving research studies involving human subjects.²⁻⁵ Generally, the REBs' mandates are outlined by governmental agencies, and an REB can be set up by any institution involved with research (eg, universities and hospitals). The REBs follow the standards set by the governmental agency.

Overall, REBs are responsible for protecting the rights of subjects and participants in research studies. Such protection includes, but is not limited to, ensuring: (1) potential harms are in proportion to potential benefits; (2) risk is minimized; (3) research methods are rigorous; and (4) consent is voluntary and informed.²⁻⁵ The purposes of this article are to (1) present general principles of consent for research studies, and (2) to specifically

discuss issues around 1 versus 2 parents consenting for infants who participate in human lactation (ie, to produce milk) and breastfeeding (ie, to provide milk) research studies.

General Guiding Principles for Consent

Consent should be sought from all research participants or subjects.³ The participant (or subject) is the person who is the focus of the research and the person from whom the data are collected.⁴ This definition does not include persons who collect data. For example, when researching a neonatal medication, the infant is the participant. The nurse or parent who administers the medication is not a participant. If the researcher wants to study someone's technique for giving medications, then the nurse or the parent would be the subject of the study.

Informed and voluntary consent of participants (or subjects) is foundational to ethical research.²⁻⁵ It reflects respect for human beings and is a requirement for REB approval. Informed consent requires that the participant have "adequate understanding of the purpose, methods, demands, risks and potential benefits of the research."⁵ Voluntary consent means consent without coercion or pressure, and participants should be assured that their consent may be refused or withdrawn at any time without reason or negative repercussions.²⁻⁵

Who consents and how consent is collected are not straightforward. Consent might be unwritten and only implied, as in the case of an anonymous survey that is handed in; the handing in implies consent.^{2,5}

Alternatively, consent may be sought after data collection, for example, when participants are studied covertly because awareness of being under study might change their behavior.^{2,5} When a person is not able to speak for him or herself, a third party is

required to provide consent on the person's behalf.²⁻⁵ In the end, the researcher must justify the means for consent and must conform to research ethics guidelines to receive REB approval.

Guidance for Consent from Existing Guidelines

Research ethics guidelines do not provide sufficient direction for breastfeeding and human lactation studies. We searched documents from Australia, Canada, the United Kingdom, and the United States²⁻⁵ that guide the research ethics approval process, and breastfeeding and human lactation are not specifically cited. Regarding the issue of whether 1 or both parents should consent for infants, only 2 of the guidelines provide direction for general parental consent for children and consent for fetuses and pregnant women.^{4,5} These directions could be applied to breastfeeding and lactation research studies.

The US Department of Health and Human Resources (HHR)⁴ spells out quite clearly what the expectations are for parental consent when human fetuses or neonates are involved. In the document, HHR states that if the research will benefit the fetus or neonate only, then the signatures of both parents are required. If the research might benefit both mother and infant, then only the mother needs to sign. This document seems to acknowledge that parents are equal when they are not participants or they are not in a position to benefit, but the mother has authority when she is equally involved with her infant in the study.

The current Australian guideline states that 1 parent may provide consent for a child unless the REB deems "the risks involved in a child's participation require the consent of both parents."⁵ Risk would be determined on a case-by-case basis. The

Canadian and UK policies recognize that research with individuals unable to consent for themselves is ethical, and third party consent must be provided in such cases.^{2,3} Parental consent, specifically if 1 or both parents should provide consent, is not addressed in these documents.

The rationales for 1 or 2 parental consents for neonates in lactation and breastfeeding research studies can be examined from several views. Elements to consider include viewing breastfeeding as a symbiotic relationship; comparing such consent with consent to treatment; considering the responsibility and authority of each parent or guardian; taking into account the population being studied; weighing risk and benefit; and allowing for the research process.

One-parent Consent

A breastfeeding woman and her infant are inextricably linked (similar but not identical to pregnancy). Breastfeeding is a relationship, and breastfeeding research requires both an infant and mother. Even lactation research (eg, testing milk supply or milk components), which seems to require only a lactating woman, might affect the infant if using breast milk for testing reduces the mother's supply available for her infant, or if milk needs to be pumped and measured before being fed to the infant. The results of such lactation studies may involve risk or benefit for infants.

Given the symbiotic relationship, all breastfeeding and lactation research can potentially benefit both mother and infant. Therefore, the argument can be made that only the mother of a breastfeeding baby, as an equal participant, needs to consent as stipulated in the United States guidelines.

One-parent consent meets the requirement for a third party to speak for infants, as described in the guidelines from Canada and the United Kingdom. It could be argued that research consent is similar to consent to treatment. Taking an infant to a physician for a vaccination is an example of such consent. One parent is the proxy for the infant's consent to treatment.

There is another philosophical aspect to consider. To seek the second parent's consent appears to ask for permission rather than consent. For many women, this permission might seem paternalistic. In other words, the second signature undermines the mother's authority—it suggests she needs her husband's approval. One could question whether the father would require the mother's permission if the research were about a father's interactions with his breastfed baby.

One should also consider the population involved in the study, as there may not be a second parent or involving the second parent might create a risk of verbal or physical violence for a woman considering participation. In the case of guardianship, if the infant is breastfed (eg, a fostering mother is nursing the baby, an infant is receiving donor human milk, or a baby is breastfed intermittently by the biological mother) and meets the inclusion criteria, 1 guardian would then likely have the authority to consent.

A final rationale for 1-parent consent is to simplify the process and possibly ensure successful recruitment. A requirement for 2 signatures may be an unnecessary step that impedes the process. Although easing the researcher's job is not an ethical rationale, setting up a procedure to ensure a successful study is ethically justified.

Two-parent Consent

Two-parent consent is specified in 2 of the guidelines. Research that is considered high risk would require 2-parent consent according to the Australian guidelines.⁴ If the research were deemed to be of benefit to the infant only, then the United States guidelines would also require 2 signatures.

Parents value their authority with regard to their infants' involvement in research studies.^{6,7} Requiring both parents' consent respects this authority. If invasive procedures are required (eg, neonate's blood will be drawn), permission from both parents might be appropriate. If the research requires the participation of the nonparticipant parents (eg, fathers taking measurements in a breastfeeding or lactation study), asking for their consent may encourage full participation.

On a separate note, in the wording of 2-parent consent, the population being studied should be considered. The term "second parent" would be inclusive of all family arrangements and might be preferred. *Husband* and *father* are role and sex specific and, in some cases, the second parent is not married to the mother or is another woman. To clarify consent, the form could leave the requirement for a second parent open-ended (eg, if a second parent is not available, please offer a reason).

Conclusion

The breastfed infant and mother form an intricate dyad. Any consent procedure for a breastfeeding or lactation research study should take into account the breastfeeding relationship. A search of 4 different research ethics guidelines demonstrates no specific directions for breastfeeding and lactation. Future work is required to rectify this situation.

It is important for the researcher to know the components of a consent form and their rationales. It is also important to appreciate the philosophy underlying such documents. When building a proposal for breastfeeding or human lactation research, researchers should decide carefully who will need to sign the consent, and they must provide a justification for their choice.

Lactation consultants also need to be aware of the rationales for consent used in research studies and to raise issues with researchers who may not be familiar with breastfeeding as a symbiotic relationship. Lactation consultants can highlight any potential benefits and risks to mothers or infants, particularly if the study is focused on only 1 of the 2 people involved or if the researcher views a mother's milk as disembodied from the mother. Ideally, the research team will include a lactation consultant who will be involved with development of the protocol, including the consent form.

This paper presents several issues to consider regarding parental consent for breastfeeding and lactation research studies. Breastfeeding and lactation are unique situations in which issues about who qualifies as a study participant (and therefore needs to consent) and who has authority to be proxy for the infant must be established for each research study. Whether 1 or 2 parents provide consent needs to be decided on an individual basis within the guidelines that apply to the researcher's work.

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**Relationship Between Intravenous Fluids Given to Women
During Parturition and Their Newborns' Weight Loss**

Chapter 6 - Third Article

Running head: NEWBORN WEIGHT LOSS STUDY

Maternal Fluids During Parturition, Neonatal Output, & Newborn Weight Loss:
An Observational Study to Determine Associations

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Abstract

Relationships among newborn weight loss, maternal fluids during parturition, and neonatal output are explored. Participants ($n = 109$) weighed newborns for 14 days and diapers for 3 days postpartum. At 60 hours (nadir of weight loss), mean loss was 6.57% (SD 2.51; $n = 96$, range 1.83-13.06). When groups, based on maternal fluids, were compared (≤ 1200 mls [$n = 21$] versus > 1200 [$n = 53$]), newborns lost 5.51% versus 6.93% ($p = 0.03$). During the first 24 hours, there are positive relationships between output and weight loss ($r(96) = .341$, $p < .0001$) which explained 12% of the variability in weight loss and between maternal IV fluids given in the final 2 hours before birth and neonatal output ($r(17) = .426$, $p = .044$) which explained 18% of the variability in weight loss. At 60 hours postpartum, there is a positive relationship between grams of weight loss and IV fluids from admission to birth ($r(83) = .199$, $p = .035$). A hierarchical regression analysis indicates gestational age and birth weight were predictors of weight loss. Because neonates experience diuresis in the first 24 hours, birth weight is not a reliable baseline measurement to assess weight loss. A weight measurement at 24 hours postpartum is recommended for baseline.

Summary statement

This study establishes correlations between maternal IV fluids, neonatal output, and newborn weight loss. The results suggest the baseline weight for determining weight loss should be changed from birth weight to the 24-hour weight measurement.

Key words - breastfeeding, newborn weight loss, neonatal output, IV fluids

Maternal Fluids During Parturition, Neonatal Output, & Newborn Weight Loss:
An Observational Study to Determine Associations

What do a planned cesarean section, fetal decelerations before birth, and an epidural late in labour have in common? All usually involve large amounts of maternal intravenous (IV) fluids (greater than 1000 mls.) administered within a few hours of birth.¹⁻³ The purpose of this research study was to analyze how maternal fluids in labour or before a cesarean section are related to neonatal weight loss in the first three days following birth.

It was hypothesized that there is a positive relationship between maternal IV fluids received during parturition (the act of giving birth) and 1) weight lost by the newborn; as well as 2) neonatal output during the first 72 hours post birth. It was further hypothesized that there is a relationship between neonatal output and newborn weight loss during the first 3 days. The question underlying these hypotheses is whether neonatal weight loss is due to a fluid shift rather than feeding or pathology (see Figure 1).

Newborn Weight Loss

Newborns are typically weighed within a few minutes following birth, and that measurement becomes the baseline for monitoring newborn weight loss. Health care professionals use the percentage of weight change from birth weight as an indicator of feeding adequacy.⁴⁻⁷ Excessive weight loss in the breastfed newborn, currently assumed to be 7% from birth weight, is usually attributed to inadequate intake due to either insufficient milk supply or ineffective milk transfer.⁴⁻⁷

Although some patterns for weight loss appear in the literature, there is a lack of evidence to explain the variation in early newborn weight loss and no indicators for morbidity and mortality related to a 7% weight loss during the first two weeks

postpartum. Instead, the weight loss patterns are used as the basis for clinical decisions about infant feeding.

Recently, researchers looked at non-feeding factors related to newborn weight loss.⁸⁻¹⁰ Martens and Romphf⁸ conducted a chart audit (n = 812) and determined that higher birth weight, female sex, epidural use, and longer hospital stay were positively related to newborn weight loss in hospital. With some variables, reverse causality might be in effect. For example, the longer hospital stay may be the result of weight loss not the cause of the loss. Lamp and Macke⁹ analyzed data related to maternal intrapartum fluid intake from admission to birth and neonatal weight, output, and feedings in the first 48 hours. They found the maternal fluids were not related to neonatal weight loss, but the number of diapers was predictive of neonatal weight loss. Mulder et al.¹⁰ also found total voids to be a significant predictor of neonatal weight loss.

Fetal Fluid Regulation

At the beginning of the fetal period, the fetus is about 95% water and this percentage decreases to about 70% at birth with the fluid transitioning from extracellular spaces to intracellular spaces closer to birth.¹¹ Throughout fetal life, the proportion of fluid in the intravascular space remains constant, and the purpose seems to be maintenance of a constant intravascular fluid level and system homeostasis with optimal blood volume.¹¹ As the fetus grows, it swallows and "breathes" the amniotic fluid and, in doing so, voids and "exhales" into the amniotic fluid.¹²

In the short term, the key mechanisms for fetal fluid homeostasis are transcapillary and transplacental fluid movement.¹¹ As early as 1960, Battaglia et al.¹³ demonstrated that pregnant women and their fetuses are inextricably linked via the

placenta, and that fluid and electrolytes move freely between the two separate bloodstreams. Fluid balance in the fetus is essentially maintained through mechanisms of diffusion, osmosis, and active transport.¹⁴ Along with the renal and circulatory systems processes for maintaining fluid balance, intramembranous fluid movements have been demonstrated in sheep and may be active in the human fetus.¹⁵ During the transition from fetal life, the newborn's kidneys begin to process about 10% of cardiac output in contrast to the 1.9% of cardiac output that fetal kidneys receive.¹⁶

Use of Intravenous Fluids During Parturition

Women who have a cesarean section and about 62% of women experiencing a vaginal birth in Ontario, Canada have spinal or epidural anesthesia.¹⁷ To maintain hemodynamics, IV fluids are used as boluses and continuously during parturition.¹ There are a few reports that speculate about or demonstrate links between maternal IV fluids given before birth and neonatal weight loss. Kepplar¹⁸ discussed the use of IV fluids in labour, and proposed the potential for excess newborn weight loss. Dahnberg¹⁹ showed that infants of mothers who received IV fluids had hyponatremia and lost 50% more weight than infants whose mothers only received oral fluids ($6.17\% \pm 3.36$ SD versus $4.07\% \pm 2.20$ SD, $p < 0.01$). Clinicians and researchers have recently questioned the effect of maternal fluids during parturition on neonatal weight loss.^{9,10} The hypotheses for the present study presuppose that women receive fluids for medical reasons, the fluids move freely from a woman to her fetus, the newborn is born overhydrated due to iatrogenic factors, and a correction in the newborn's fluid balance is a measurable weight loss.

Optimum infant health requires adequate breastfeeding; inadequate milk intake may create health risks for an infant.²⁰⁻²² At the same time, there are risks associated with

using artificial breastmilk substitutes (i.e. formula).²³⁻²⁹ Weight measurements are used as a key indicator of breastfeeding adequacy.⁴⁻⁷ Clinicians (e.g. nurses, lactation consultants, and physicians working with breastfeeding women) need to understand factors that affect neonatal weight loss to: (a) account for weight loss that requires no intervention; (b) prevent unnecessary weight loss; and (c) recommend appropriate interventions when required due to weight loss. To maintain infant health and optimize breastfeeding support, evidence is needed to ensure appropriate lactation and breastfeeding assessment.

Methods

This research study was an observational, prospective cohort design with a convenience sample of expectant women. It followed participants from labour or prior to a cesarean section to 2 weeks postpartum, and it was designed to collect data about factors that might influence newborn weight loss. The University of Ottawa Research Ethics Board and the research ethics boards of each hospital provided ethics approval based on the requirements of the Tri-Council Policy Statement.³⁰

Recruitment

The study was advertised through brochures and posters in the community, at ultrasound clinics, and in physicians' and midwives' offices. The study information was presented at hospital tours and prenatal classes. Active recruitment involved one-to-one explanations with pregnant women and their partners which took place in caregivers' offices, hospital clinics, a birth unit triage site, and at a parenting exposition.

Inclusion criteria included: expecting a fullterm (259 days),³¹ single, healthy infant at one of the participating hospitals or a home birth, and planning to breastfeed.

Healthy was defined as both mother and newborn discharged at the same time and able to breastfeed without restriction. All parities were included. Women completed and returned a registration package with a contact information sheet, consent for the study, consent for a chart audit, and a prenatal questionnaire before their baby's birth.

Measurements and Data Collection

For women in the study, oral and IV fluid data during labour or prior to a cesarean section were collected from admission to birth. Since most nurses work 12-hour shifts, fluid data were collected in 12 hour increments. For women who gave birth in the final three months of the study, nurses were asked to also estimate the amount of IV fluids administered in the final two hours before birth. The rationale was that fluids could resettle and move back from fetus to mother, therefore the fluid in the final two hours would be mostly likely to have an effect. Lamp and Macke's¹⁰ results supported this supposition. There was no other change in fluid data collection for these participants.

Following birth and recovery, women received a study baby scale when they arrived at the mother-baby unit or, in the case of home births, the scale was provided before the expected due date. The scale included two data collection sheets: one to record diaper weights and one for baby weights. Parents weighed and recorded all diapers (diaper weights including voids and stools) for 3 days. They weighed their newborns every 12 hours for 72 hours then daily from Days 4 to 14. All weights were recorded in grams or converted if parents used pounds and ounces.

This protocol was designed to minimize parental effort. Each diaper was weighed and the full weight was recorded. The weight of a dry diaper was also recorded, and the researcher subtracted the dry weight before totaling the day of diaper weights. For one

hospital, a neonatal security band was used and parents indicated whether the band was on. The researcher subtracted its weight (22 grams) when required.

Parents took the scales home when discharged, and all weights were measured on the same scale for consistency. The Ultrascale MBSC-55 Digital Scale was used for the study. It is an electronic scale with precision to within 2 grams under 500 grams (the diapers) and to within 10 grams over 500 grams (the baby). For safety reasons, the scales ran on batteries. The researcher sanitized each scale and tested it using a standardized stone. If there was doubt about its accuracy, it was recalibrated according to manufacturer's directions. Because birth weight was the first weight measured by the nurses on the hospital's scale, the same stone was used with the hospitals' scales to ensure uniformity.

Infant feeding categories were established by asking mothers if babies were supplemented in hospital and with the use of an algorithm.^{32,33} When the infant was two weeks old, questions from the algorithm determined how much the infant was breastfed using seven possible feeding categories (e.g. exclusively breastfed versus weaned).

At 14 days postpartum, the researcher called participants to complete the telephone questionnaire. Arrangements were made to pick up the baby scale and data collection sheets from their homes.

Analysis

Descriptive statistics and tests of significance were undertaken using SPSS 18. The intention was to describe the participants and patterns of newborn weight loss and to determine any correlations between the variables. All tests were run with one-tail because the hypotheses stated a direction. A regression analysis was completed to

determine predictors of neonatal weight loss. An a priori sample size calculation determined a minimum sample size would be 110 subjects based on 5-10 subjects per variable for a regression analysis with 11 variables.³⁴ Correlations analyses (i.e. Pearson's correlation and Spearman's rho) would require a sample of 64 subjects to detect a moderate (.30) correlation at an alpha of 0.05 with a power of 0.80.³⁵ Attrition was expected to be about 25%.

Supplemented babies remained in the study and were not treated differently from exclusively breastfed babies. This decision was based on the need to maintain generalizability as well as evidence that there is little difference in weight loss in the first days post partum.^{9,10} When the percentage weight loss at 60 hours (nadir of weight loss) for the supplemented versus non-supplemented newborns was compared, the mean losses were 6.8% and 6.5%, respectively. Using an independent samples t-test, there was no statistically significant difference ($p > .50$). In addition, the percentage of supplemented newborns was similar to the provincial average, so the results are generalizable when the supplemented infants are included in the analyses.

Results

Description of Setting and Sample

The study took place in eastern Ontario, Canada at five sites: two small community hospitals (~ 300-400 births per year each), a large community hospital (~ 2500 births per year), and a teaching hospital with two campuses (~ 6800 births combined sites).¹⁷ Fewer than five participants gave birth at home. One hundred and sixty-four women registered for the study, and 109 families completed data collection. Reasons for loss of registered participants included: 37% who intended to continue but

did not receive a baby scale; 23% stopped because of illness (e.g. infant's prematurity, unexpected cesarean section, postpartum hemorrhage); 17% changed their mind about the study or opted to bottle feed; and for 23% the exact reason is not known. The group that completed the study was comparable to the lost participants based on age, amount of breastfeeding, maternal education level, and family income (using an independent samples t-test and chi-squared, $p < .05$). There was a difference between the two groups based being in a committed relationship (100% versus 88% respectively, $p > .05$). Demographic characteristics of the participants, mothers and newborns, who completed the study are in Table 1a and 1b, respectively.

Onset of lactogenesis II (measured as the day women first noticed breast fullness, birth counted as Day 1) averaged 3.5 days (SD 1.1; range 1-7), and 5% of the participants did not notice the day of onset. Breastfeeding confidence was measured on a scale of 1 to 10 (not at all to very much). At 14 days, 9% stated confidence rates of 4 or less, and 71% stated 8 or more. Almost a third of the women (27.5%) stated they experienced no breastfeeding problems, 34% had a single issue, and 38.5% identified more than one issue. Problems identified by participants were: 30% sore nipples; 17% latching; 13% supply; 8% sore breast or mastitis; 8% tongue tie or thrush; 7% breast refusal; 5% engorgement; and 5% sleepy baby.

Weight Loss and Maternal Fluids

Tables 2a and 2b present the average weight loss from birth in grams and by percentage. Table 3 presents the amounts of maternal fluid intake during parturition.

Data about baby weights (including new variables of percentage/grams lost), IV fluids and totals of fluids from admission to birth, and output for Day 1 were normally

distributed; determined using a one sample Kolmogorov-Smirnov test. Amounts of oral fluids; neonatal output on Days 2 and 3; years of breastfeeding experience; rates of edema; and day of onset of lactogenesis II were not normally distributed.

The first hypothesis was that there is a positive association between the amount of IV fluids given to a woman during parturition and the amount of weight her infant loses during the first 72 hours postpartum. Correlations were statistically significant at 60 hours (also the time of maximum loss) and 72 hours (see Tables 4a & 4b). Because data for IV fluid during the last two hours were not collected from the start of the study, the sample sizes are smaller than for other fluid categories. Oral fluids alone were not significant but an increase in fluids is correlated to an increase in weight loss when IV fluids are combined with oral fluids.

Maternal Fluids and Neonatal Output

To determine neonatal output, all diapers were weighed with voids and stools counted. Details of neonatal output are presented in Table 5.

The second hypothesis was a positive association between amount of IV fluids given to a woman during parturition and the amount her infant eliminates during the first 72 hours postpartum. Discrete output (i.e. daily amounts) was correlated to the maternal fluid amounts. There was a positive relationship between amounts of IV fluid women received within two hours of birth and neonatal output during the first 24 hours (see Table 6 for results of correlational analysis). Other categories of fluids were not statistically significant.

Neonatal Output and Weight Loss

The third hypothesis stated that there was a positive association between the amount an infant eliminated and the infant's weight loss during the first 72 hours postpartum. Weight loss as a percentage for each 24 hour period was correlated to output for the same period in the analysis (see Table 7 for results).

For Day 1, there was a positive relationship between newborn weight loss and neonatal output. This result indicates that as output (i.e. diaper weight) increases, weight loss also increases during the first 24 hours. On Day 2, there was no relationship between the two variables. On Day 3, there was a statistically significant *negative* correlation between output and weight loss. Although the hypothesis does not hold, this serendipitous result suggests two possible developments: either output increased as weight gain increased ($\uparrow$ output = $\downarrow$ weight loss) or output decreased as weight loss increased ($\downarrow$ output = $\uparrow$ weight loss).

Further Analyses of Weight Loss

Following our initial analyses, we examined the data with three additional questions: (a) How was onset of lactogenesis II related to weight loss given the correlation of weight gain to output on Day 3?; (b) Are fluids and output predictors of newborn weight loss when other possible factors are considered?; and (c) Is the amount of weight loss clinically significant?; (d) If the baseline for weight loss is changed to 24 hours, what is the pattern of weight change?

Women were asked if they noticed the day their "milk came in" (i.e. the first day of fullness). There was a significant positive correlation between the number of days

identified (i.e. onset of lactogenesis II) and weight loss in the first three days ($r_s(97) = .354, p < .0001$).

In addition to the independent variables of interest, maternal fluids and neonatal output, several variables were identified in the literature as predictors of neonatal weight loss. The variables cited in the literature were used in the conceptual model (see Figure 1): parity,³⁶ gestational age,⁸ oxytocin [induction or augmentation] use,³⁶ epidural use,³⁷ type of birth,³⁸ sex of newborn,^{8,9} birth weight,^{8,9} feeding type (i.e. supplemented),^{8,9} timing of lactogenesis II,³⁹ and time with skin to skin.⁴⁰ With the exception of time skin to skin, the same variables were used in a hierarchical multiple linear regression model. There was inadequate data to include skin to skin.

The regression model was designed to introduce the variables that can be measured before and during parturition, followed by post birth variables. Overall, the regression model was significant (see Table 8 for details). Output remained strongly predictive of weight change throughout, and maternal fluids were a predictor until post birth variables were included in the model. Gestational age and birth weight were significant predictors of weight loss. Parity, oxytocin, epidural anesthesia, sex of newborn, birth weight, feeding type (i.e. supplemented), and timing of lactogenesis II were not significant predictors of weight loss at 72 hours in this model. Type of birth showed a trend to significance.

Using the variables in the first model (step 1) and holding neonatal output at 200 mls, we predict that 1000 mls of maternal fluids results in 6.66% weight loss; whereas, 2000 mls of maternal fluids results in 7.66% weight loss. Using all the variables in the first two steps of the regression model (model 2) and with neonatal output set at 200 mls,

parity = 1, gestational age = 1, oxytocin = 1, epidural = 1, and birth type = 1, we varied maternal fluids. With maternal fluids of 1000 mls, newborn weight loss is predicted to be 7.1%; whereas maternal fluids of 2000 mls predict a weight loss of 8.1%.

By forming two groups based on total amount of fluids received, we could compare the two groups and look for differences in amounts of newborn weight loss. We used the point of maximum weight loss (60 hours) and chose 1200 mls as the maternal fluid cut-point. Our rationale was that 1200 mls seems to be a moderate amount of fluid from admission to birth. For the mothers who had 1200 mls or less, the average percentage of newborn weight loss at 60 hrs was 5.51% (n = 21). Whereas the group with more than 1200 mls total fluids averaged newborn weight loss 6.93% (n = 53). The difference of 1.42% is clinically significant, and it was statistically significant (p = 0.03).

We ran descriptive and frequency analyses of percentage weight loss contrasting two possible baselines. With birth weight as baseline, the mean percentage weight change became a negative (i.e. a weight gain) on Day 8. With 24 hours as the baseline, the mean percentage weight gain begins on Day 4. At 60 hours (the nadir of weight loss), mean losses from the two baselines were 6.57% (SD $\pm$ 2.51, range 1.83 to 1306, n = 96) compared to 2.17% (SD $\pm$ 2.41 range -2.87 [a gain] to 8.58, n = 87), respectively.

Using the birth weight baseline, 12% had not regained birthweight by Day 14 (n = 102). When baseline is set at 24 hours, 98.9% of the newborns regain their baseline weight by Day 14 (n = 93). From a birth weight baseline, 33.3% lost between 7 and 10%, and 7.3% lost more than 10%. From the 24-hour baseline, 2.3% lost between 7 and 10%, and none lost in excess of 10% (see Table 9 for frequency of weight loss using both baselines).

Discussion

The results of the hypotheses tested in this study are clinically significant and changes in practice should be considered. Based on the correlations we found, 18% of the variability in neonatal output is related to maternal IV fluids given in the two hours before birth. In addition, 4% of the variability in weight loss is related to maternal IV fluids before birth and 6% of the variability in weight loss is related to all maternal fluids before birth. About 12% of the variability in weight loss is related to the neonatal output. Results from this study support findings from other studies that demonstrated associations between neonatal weight loss and newborn weight loss.^{10,11}

Generalizability

Overall, this convenience sample is comparable to Ontario, the provincial population of origin. In hospital, 27% of study participants supplemented their babies and the provincial rate of hospital supplementation is 28%.¹⁷ In 2007-08, 43% of women who gave birth in Ontario were first-time mothers.¹⁷ Likewise, 42.2% of the study participants are primiparous. The study participants also have similar rates of cesarean sections and epidural use when compared to Ontario provincial rates (25% versus 28.4% and 64% versus 62%, respectively).¹⁷

Comparisons of neonatal weight loss are difficult because some authors count birth as Day 1 and others treat the first post-birth day as Day 1 (i.e. birth = Day 0). The Day 1 weight for this study is birthweight (0-24 hours), and Day 2 was the weight taken at 24 hrs. Day 3 is 48 to 72 hours. Newborns in the study experienced weight losses comparable to reports in the literature. The percentage of weight lost peaked at 60 hours (i.e. 3rd day) with a mean 6.57% loss (SD 2.51, range 1.83 to 13.06, n = 96).

In a systematic review of early weight loss patterns, 11 studies demonstrated a mean loss of about 6% with a standard deviation of about 2 (median was also about 6%); the nadir (point of lowest weight) was the third day.⁴¹ MacDonald et al.⁴² completed a prospective study and found breastfed babies lost a median of 6.6% of birth weight (95 centile = 11.8%) within a median time of 2.7 days. Crossland et al.⁴³ developed a centile chart (n = 111) capturing weight loss in the first two weeks postpartum. They also showed that breastfed neonates average a loss of 6.4% of birth weight with the majority reaching the point of maximum weight loss on the third day.⁴³

Maternal Fluids

There is little information in the literature about the relationship between IV fluids and neonatal weight loss in the first week postpartum. In a recent study, Lamp and Macke⁹ found no relationship between intrapartum maternal fluids and neonatal weight loss. There are three main differences between their study and this study: (a) neonatal output data were collected for 48 hours versus 72 hours, respectively; (b) the amounts of fluids from admission to birth were quite different (2522.5 to 5013.75 mls.⁹ versus 0 to 7200 mls. for our study); (c) all fluids in Lamp and Macke's study were measured from admission to birth (i.e. they did not collect data about IV fluids specifically within 2 hours of birth). With this study, correlations between fluids and weight loss appear at 60 hours and 72 hours. The wider range of fluid amounts and longer data collection period may account for positive findings in this study.

The potential significance of timing (i.e. the fluids given within 2 hours of birth) was followed in the last months of data collection, and no other published studies consider timing. We found a significant relationship between the IV fluids given in the

final two hours before birth and neonatal output in the first 24 hours; although the relationship between weight loss and total IV fluids is not significant until 60 hrs postpartum. There may be immediate and long-term means of fluid balance. Perhaps fluids recently acquired and in the neonate's intravascular spaces are readily excreted, whereas fluids in extravascular spaces may take longer to correct.

Neonatal Output

Neonatal output in our study was significantly related to weight change. Day 1 output was positively related to weight loss. These findings corroborate results from two studies. Lamp and Macke⁹ observed that the number of wet diapers was predictive of weight loss, and Mulder et al.¹⁰ reported that total voids were a predictor of excessive weight loss (> 7%). Their findings differ from our results somewhat as we report the days separately and output as total weight of diapers.

It appears lactogenesis II affects output on Day 3. The relationship becomes negative; specifically, output is related to weight gain, suggesting that an increase in intake results in an increase in output. The correlation of onset of lactogenesis II to weight loss supports this conclusion. On Day 3, there was a positive correlation in number of days for onset and weight loss. In other words, the longer it took for onset, the more weight lost.

In the hierarchical regression model built from potential predictor variables, our results are comparable to Marten and Romphf's⁸ findings from a chart audit (n = 812) regarding gestational age and birth weight. Specifically, higher birth weight and lower gestational age result in higher percentage of loss. Given the correlation of output to weight loss, we question whether the higher birth weight is a result of overhydration.

Our finding that sex was not a predictor matched results published by Crossland.⁴³

Parity, epidurals, and birth type were not significant predictors in this regression model, although the model might have been underpowered.

The results of the hypotheses tested in this study provide an interesting picture. The IV fluids women received 2 hours before their babies' births are related to neonatal output, and neonatal output is related to newborn weight loss in the first 24 hours.

Further, weight loss at 60 hours shows a correlation to the amounts of maternal fluids from admission to birth whether the difference is measured as grams or percentage lost.

Reconsider Birth Weight as Baseline

Clinicians debate the limits of acceptable neonatal weight loss in the first days. Current clinical practice guidelines recommend interventions, including extra assessments or supplementation with formula, when weight loss exceeds 7%.⁴⁻⁷ Some authors identify a loss of $\geq 10\%$ as a sign of breastfeeding inadequacy.^{37,44} Weight loss in this case is the percentage of weight lost from the first weight measured (i.e. birth weight). There is little or no evidence to support these percentages as indicators of breastfeeding inadequacy or markers of increased risk of morbidity.⁴¹ Birth weight as a baseline against which to assess weight loss is a universal choice, but it lacks sufficient empirical evidence.

It appears that the neonates experienced diuresis in the first 24 hours as evidenced by the positive correlation of the 24-hour output to the maternal 2-hr prebirth IV fluids and to weight loss in 24 hours. With birth weight as baseline, an overhydrated newborn may have an artificially high reference point for weight loss. Resetting baseline to a point after the diuresis has occurred (i.e. the newborn's weight has stabilized) would be a

better gauge for assessment of the newborn. This premise is supported by van Dommelen et al.⁴³ who determined a 10% rule of thumb produces false positives (i.e. it is not a good indicator to detect hypernatremic dehydration).

Intuitively, clinicians and parents want to see the neonate return to birth weight. If birth weight is an inflated measurement, then the expectations for a return to birth weight in the first days are questionable. In the dialysis literature, the term "dry weight"⁴⁶ is used to describe a patient's weight without additional fluid, and it is the patient's post-dialysis goal weight. The neonates in this study appear to reach their dry weight around 24 hours, although the timing of this iatrogenic weight loss might depend on birth practices.

Strengths and Limitations

Strengths of this study include: (a) participants using the same scale to ensure internal consistency; (b) weight measurements every 12 hours for the first 72 hours which permitted detection of the nadir of weight loss; and (c) continued daily weight measurements from Day 4 to Day 14 which added valuable information.

The limitations are attributable to data collection issues. The late decision to collect additional data about fluids in the final two hours before birth meant a very small sample for this analysis. The first weeks following birth are an intense time for parents, and data were frequently missed. We did not attempt to input missing data regarding weights and fluids, because we could not be certain of the direction (e.g. should weight go up, down, or stay the same). Babies managed to void and stool when their diapers were off. Parents were asked to document missed output, and we estimated the loss. The study design did not permit precise determination of IV fluids until the cord was cut nor

amounts of insensible loss due to, for example, mucous a neonate might have expectorated or fluid exhaled from the lungs. Timing of the first bath might be a predictor of weight loss due to additional calories burned, but these data were not collected.

Future Research

Further research is needed to understand the effects of iatrogenic and modifiable factors such as maternal fluids during parturition. Evidence is needed to understand why and how timing of maternal fluid is a factor. The relationship between IV fluids administered in the two hours before birth and weight loss should be further studied.

A study with diaper weights every 12 hours might determine the peak of diuresis. It is possible that diuresis continues to 36 hours, but we could not analyze output and weight loss at 36 hours because the diapers were weighed in 24 hour increments.

Researchers who plan studies about neonatal weight loss need to be careful to use hours and not days for their protocols. For example, diapers for Day 1 can be interpreted many ways and stipulating from birth to 24 hours is clearer. Additionally, conditions for daily weight measurements should be consistent (e.g. weigh before feeds or in the mornings).

Conclusions

With this research, we found evidence that maternal fluids during parturition are related to neonatal output and newborn weight loss. We believe weight change data is a valuable assessment tool, but weight measurements should be only one tool for feeding assessment and not the basis for clinical decisions. A complete evaluation is needed, and

observations of neonatal behaviour, frequency and amounts of output, and feeding behaviours also contribute to breastfeeding assessments.

Clinicians should rethink how newborn weight loss is calculated and account for weight loss that requires no intervention (i.e. iatrogenic loss). For example, based on this study, we recommend a baseline of 24 hours to allow time for diuresis. With a change in baseline, the time and measurement of the lowest weight did not change, but the percentage of weight lost and the interpretation of that loss changed dramatically.

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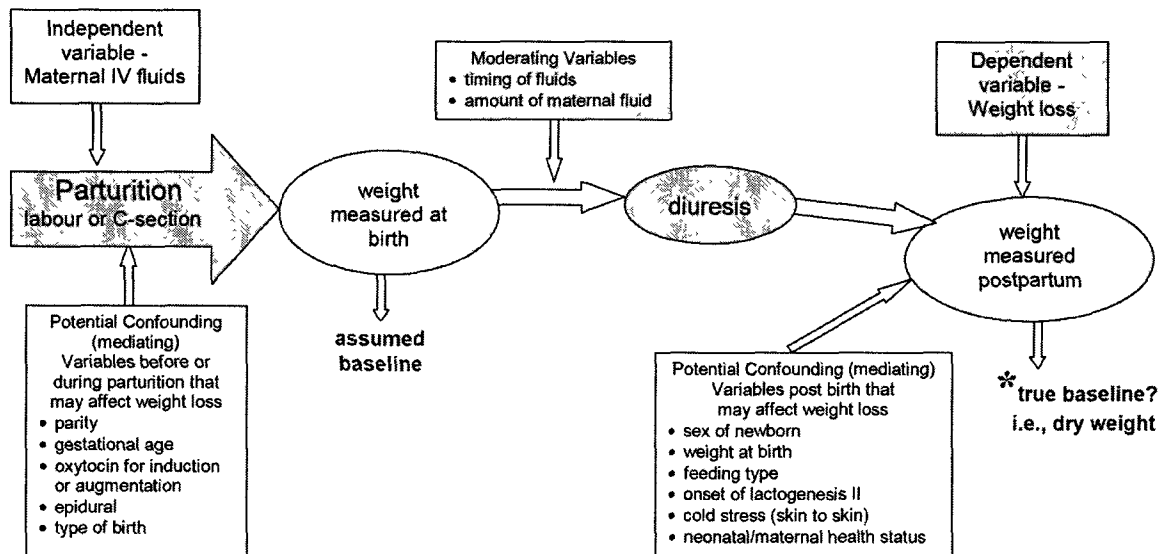


Figure 1. Conceptual framework for thesis includes potential mediating and moderating variables and questions which neonatal weight measurement should be baseline.

Table 1a. Demographic Characteristics of Mothers (n = 109)

<i>Characteristics</i>	
Maternal age (years) [$\bar{x} \pm SD(\text{range})$]	32 $\pm$ 4.3 (22-45)
Committed relationship (%)	100
Some post-secondary education (%)	97
Family income > 70K (CAN) (%)	91
Non-smoker (%)	91
Primiparous women (%)	42
Multiparous women's years of breastfeeding experience – all children [median (range)]	1 (0.10 - 5.30)
Decided to breastfeed before pregnant (%)	89
Planned to exclusively breastfeed for 6 months (%)	83
Planned to breastfeed for 1 year or more (%)	76
Gestation (weeks) [$\bar{x} \pm SD(\text{range})$]	39.8 $\pm$ 1.2 (37-42)
Care at birth (%)	
Obstetrician	82
Family physician	12
Midwife	6
Birth type (%)	
Vaginal	75
Planned cesarean	12
Unplanned cesarean	13
Intravenous (%)	78
Epidural for vaginal birth (%)	64
Oxytocin (%)	46
Spent time skin-to-skin post birth (%)	73

Table 1b. Demographic Characteristics of Newborns (n = 109)

<i>Characteristics</i>	<i>%</i>
Newborn sex (%) ^v	
Female	51
Male	49
Newborn birth weight (grams) [$\bar{x} \pm SD(\text{range})$]	3619 $\pm$ 502 (2185-4707)
Supplemented in hospital (%)	27
Treated for jaundice (%)	10
Feeding categories at 2 weeks (%)	
Exclusively breastfed (only breast milk from birth)	62
Totally breastfed (no supplements Days 7-14)	14
Predominant breast milk (1-2 supplements Days 7-14)	13
Partial or no breast milk (3+ supplements Days 7-14)	11

Table 2a. Average Weight Loss in Grams from Birth (N = 109)

<i>Timing</i>	<i>Sample Size</i>	<i>Mean $\pm$ SD</i>	<i>Range</i>
12 hours	95	2.34 $\pm$ 1.21	000 to 4.77
24 hours	97	4.45 $\pm$ 1.41	1.47 to 7.66
36 hours	98	5.94 $\pm$ 1.45	2.10 to 8.96
48 hours	105	6.55 $\pm$ 1.82	1.64 to 10.23
60 hours	96	6.57 $\pm$ 2.51*	1.83 to 13.06
72 hours	100	5.78 $\pm$ 2.58	(.53)** to 11.15

* Timing of maximum weight loss; ** Numbers in parentheses indicate weight gain

Table 2b. Average Percentage Weight Loss from Birth (N = 109)

<i>Timing</i>	<i>Sample Size</i>	<i>Mean $\pm$ SD</i>	<i>Range</i>
12 hours	95	2.34 $\pm$ 1.21	000 to 4.77
24 hours	97	4.45 $\pm$ 1.41	1.47 to 7.66
36 hours	98	5.94 $\pm$ 1.45	2.10 to 8.96
48 hours	105	6.55 $\pm$ 1.82	1.64 to 10.23
60 hours	96	6.57 $\pm$ 2.51*	1.83 to 13.06
72 hours	100	5.78 $\pm$ 2.58	(.53)** to 11.15

* Timing of maximum weight loss; ** Numbers in parentheses indicate weight gain

Table 3. Amounts of Maternal Fluids in Millilitres (N = 109)

<i>Category of Fluids</i>	<i>n</i>	<i>Mean (SD)</i>	<i>Median</i>	<i>Range</i>
IV fluids in last 2 hrs before birth	17	419 (397)	400	0 to 1200
IV fluids admit to birth	93	1578 (1215)	1500	0 to 5800
Oral fluids admit to birth	82	-	400	0 to 3000
All fluids admit to birth	81	2129 (1516)	1850	0 to 7200

Kolmogorov-Smirnov used to determine normal distribution

Table 4a. Weight Loss from Birth Correlated to Maternal Fluid Amounts (N = 109)

Timing of Weight Loss	Weight Loss in Grams		Weight Loss as a Percentage from Birth Weight	
	<i>IV fluids admit to birth</i>	<i>Oral and IV fluids admit to birth</i>	<i>IV fluids admit to birth</i>	<i>Oral and IV fluids admit to birth</i>
Birth to 60 hrs	.199, p = .035* n = 83	.249, p = .016* n = 74	.175, p = .057 n = 83	.215, p = .033* n = 74
Birth to 72 hrs	.189, p = .041* n = 86	.248, p = .016* n = 75	.181, p = .048* n = 86	.218, p = .030* n = 75

* Pearson Correlation, 1-tailed, $p < .05$

Note: no statistical significance on or before 48 hours

Table 4b. Percentage Weight Loss Correlated to All Types of Fluid Amounts (N = 109)

Timing of Weight Loss	Category of Maternal Fluid			
	<i>IV fluids* in last 2 hrs before birth</i>	<i>IV fluids* admit to birth</i>	<i>Oral fluids** admit to birth</i>	<i>All fluids* admit to birth</i>
Birth to 60 hrs	.243, p = .192 n = 15	.175, p = .057 n = 83	.263, p = .074 n = 75	.215, p = .033 n = 74
Birth to 72 hrs	.125, p = .322 n = 16	.181, p = .048 n = 86	.168, p = .074 n = 76	.218, p = .030 n = 75

* Pearson Correlation, 1-tailed; ** Spearman's rho, 1-tailed

Table 5. Average Neonatal Output (N = 109)

<i>Timing</i>	<i>n</i>	<i>Mean (SD)</i>	<i>Median</i>	<i>Range</i>
0 - 24 hrs	107	83.04 ±47.8	76	0 to 314
24 - 48 hrs	107	-	69	14 to 230
48 - 72 hrs	106	-	97	22 to 440

Kolmogorov-Smirnov used to determine normal distribution

Table 6. Maternal Fluid Amounts Correlated to Neonatal Output (N = 109)

<i>Timing of Diaper Weight</i>	<i>Category of Maternal Fluid</i>			
	<i>IV fluids in last 2 hrs before birth</i>	<i>IV fluids admit to birth</i>	<i>Oral fluids admit to birth</i>	<i>All fluids admit to birth</i>
0 to 24 hrs	.426, p = .044 [†] n = 17	.132, p = .105** n = 92	-.081, p = .236* n = 82	.115, p = .154** n = 81
24 to 48 hrs	.170, p = .257* n = 17	.171, p = .051* n = 92	-.166, p = .068* n = 82	.043, p = .351* n = 81
48 to 72 hrs	.311, p = .121* n = 16	.021, p = .423* n = 91	-.150, p = .091* n = 81	-.054, p = .316* n = 80

* Spearman's rho Correlation coefficient, 1-tailed

** Pearson Correlation, 1-tailed

[†] Pearson Correlation, 1-tailed, p < .05

Table 7. Percentage of Weight Loss Correlated to Neonatal Output (N = 109)

Time of Weight Loss	Timing of Neonatal Output		
	<i>0-24 hours</i> (<i>n</i> = 96)	<i>24-48 hours</i> (<i>n</i> = 95)	<i>48-72 hours</i> (<i>n</i> = 98)
Birth to 24 hours	.341* p < .0001	--	--
24 to 48 hours	--	-.107** p = .151	--
48 to 72 hours	--	--	-.351** p < .0001

* Pearson's correlation, 1-tail significance

** Spearman's rho Correlation coefficient, 1-tailed

Table 8. Hierarchical Regression of Predictor Variables for Percentage of Neonatal Weight Loss at 72 hours Postpartum (n = 68)

Step	Variable	B	β	Sr^2 (incremental)	p
1	Constant	7.060			
	All maternal fluids (mls)	.001	.244	.062	.031
	Output for 72 hours (mls)	-.007	-.363	.176	.002
	$R^2 = 0.193$ ($F_{2,66} = 7.890$, $p = .001$) (Adjusted $R^2 = .168$) Unique variability = .190, Shared variability .003				
2	Constant	33.542			
	All maternal fluids (mls)	.001	.294	.046	.038
	Output for 72 hours (mls)	-.007	-.394	.065	.001
	Parity (1 = primip, 2 = multip)	-.887	-.166	--	.177
	Gestational age (weeks)	-.693	-.299	.068	.011
	Oxytocin (1 = Y, 2 = N)	-.036	-.007	--	.956
	Epidural (1 = Y, 2 = N)	.657	.118	--	.394
	Birth type (1 = vaginal, 2 = section)	1.354	.214	--	.082
	$R^2 \Delta = 0.138$ ($F_{5,61} = 2.506$, $p = .040$) $R^2 = 0.330$ (Adjusted $R^2 = .254$)				
3	Constant	36.443			
	All maternal fluids	.001	.231	--	.089
	Output for 72 hours	-.008	-.458	.119	<.001
	Parity (1 = primip, 2 = multip)	-.980	-.184	--	.118
	Gestational age (weeks)	-1.003	-.433	.105	<.001
	Oxytocin (1 = Y, 2 = N)	-.096	-.018	--	.875
	Epidural (1 = Y, 2 = N)	1.145	.205	--	.117
	Birth type (1 = vaginal, 2 = section)	1.445	.229	.033	.054
	Sex of infant (1 = F, 2 = M)	.265	.051	--	.637
	Birth weight (grams)	.002	.399	.090	.001
	Supplemented (1 = Y, 2 = N)	-.117	-.019	--	.870
	Day of onset of lactogenesis II	.296	.112	--	-.313
	$R^2 \Delta = 0.146$ ($F_{4,57} = 3.988$, $p = .006$) $R^2 = 0.477$ (Adjusted $R^2 = .376$)				
	Unique variability = .348 Shared variability = .129				

Table 9. Frequency of Percentage Weight Loss with Two Different Baselines (N = 109)

Timing	Weight Loss from Birth				Weight Loss from 24 hours			
	<i>Sample Size</i> [†]	< 7%	7 to 10 %	> 10%	<i>Sample Size</i> [†]	< 7%	7 to 10 %	> 10%
12 hrs	95	100%	Ø	Ø	--	--	--	--
24 hrs	97	94.8%	5.2%	Ø	--	--	--	--
36 hrs	98	75.5%	24.5%	Ø	89	100%	Ø	Ø
48 hrs	105	59.0%	40.0%	1.0%	96	100%	Ø	Ø
60 hrs	96	59.4%	33.3%	7.3%	87	97.7%	2.3%	Ø
72 hrs	100	67.0%	29.0%	4.0%	91	98.9%	1.1%	Ø
Day 4	103	80.6%	15.5%	3.9%	92	100%	Ø	Ø
Day 5	96	87.5%	11.5%	1.0%	87	100%	Ø	Ø
Day 6	96	92.7%	6.3%	1.0%	86	100%	Ø	Ø
Day 7	101	93.1%	5.9%	1.0%	91	100%	Ø	Ø

Relationship Between Intravenous Fluids Given to Women During Parturition and Their Newborns' Weight Loss

CHAPTER 7 - Conclusion

In this thesis, I explored newborn weight loss in the first two weeks postpartum. When assessing breastfed newborns, nurses and other clinicians must interpret weight changes appropriately to ensure infants are safe and receiving optimum amounts of breast milk (i.e. not receiving unnecessary supplementation). Regarding assessment of neonatal weight change, there is a lack of evidence to support clinical practice. To produce useful evidence, researchers should focus on knowledge gaps identified in practice.

This research study was guided by clinical practice. In my work with breastfeeding women, newborn weight loss patterns puzzled me. How is it that all breastfed babies get small amounts of colostrum in the beginning, yet they lose weight at very different rates? Some babies lose copious amounts of weight while others do not lose any weight.

Observations of the IV fluids women receive in labour or before a cesarean section influenced the hypotheses in this research study. From the first bolus I observed in labour and delivery, I questioned both where the fluids shifted to and the consequences for neonatal weight change.

In my clinical experience, I also noted how neonatal weight change affects mothers. Measurement is important in our culture. Mothers know that their newborns should grow, and they trust a measurable gain in their newborns' weight as a positive sign. Understandably, newborn weight loss in the first days seems to negatively affect mothers' breastfeeding self-efficacy causing women to lose confidence in their ability to breastfeed.

Often the baby with the greatest loss was alert and nursing well. Interventions with supplementation based on the percentage of weight lost seemed counterintuitive. The nurses with whom I worked also sensed that babies born by cesarean lost more, but this opinion was based on intuition more than evidence.

Observations of newborn weight loss patterns, the use of IV fluids during parturition, the effect of weight loss for mothers, and conversations with colleagues contributed to this thesis. These observations and experiences from clinical practice guided the research study.

Overview of the Thesis

This thesis is manuscript-based with two classic monograph chapters and three stand-alone articles, bookended by an introduction and conclusion. The two monograph chapters are a literature review, which provides background and a rationale, and the methods chapter which presents the process for the research study.

The results of the thesis work are presented in the three manuscripts: (a) a systematic review; (b) a manuscript that presents a discussion about consent for neonates in breastfeeding and lactation studies; and (c) a final paper that details the study from background through to final discussion. Due the manuscript-based format for the thesis, there is some necessary overlap in information to afford coherence.

The original literature search for background information did not yield a reference weight loss for healthy newborns. The systematic review (Chapter 2) was completed in an effort to establish such a guide. Essentially, it was undertaken to determine whether 7% or 10% should be the reference weight loss. In the end, it contributed to an understanding of how weight loss is interpreted.

Primarily, this systematic review clarified how birth weight is used as baseline and how the percentage of loss, not morbidity or mortality, determines clinical decisions. It also established that there is insufficient evidence for either 7% or 10% as a reference weight loss. Two assumptions held by clinicians became clear as result of the systematic review: (a) weight loss is due to feeding; and (b) weight loss must be prevented or corrected to ensure no loss exceeds 7/10% and that there is a rapid return to birth weight.

The final manuscript (Chapter 6) was written for the Journal of Human Lactation using the journal's format: (a) abstract, (b) introduction, (c) methods, (d) results, and (e) discussion. Some elements of the thesis work are not provided in the final manuscript. Specifically, details about data collection and results of analyses were not reported; either to meet the journal's word limit or because such reports are not usually detailed in manuscripts. For example, to clarify and understand correlations, several graphs were generated. Scatterplots for neonatal output and weight loss in grams at 24, 48, and 72 hours show the positive relationship at 24 hours reverses to a negative relationship from 48-72 hours. The information is presented in a chart in Chapter 6, and the graphs are presented here in Figure 1.

An application for ethics approval submitted to the University of Ottawa Research Ethics Board (uOREB) led to the methods manuscript about consent (Chapter 5). The original uOREB application required consent from only the women in the study, but the uOREB stipulated the fathers (later referred to as second parents) had to also consent. The ensuing correspondence with the uOREB generated many philosophical and practical issues around consent for neonates in lactation and breastfeeding studies. In the end, both parents were asked to consent for the infant, and the discussion formed part of the results

for this thesis. The first manuscript was published in Open Medicine, an online open journal published in Canada, and the second manuscript was published in the Journal of Human Lactation.

Strengths

This thesis provides a comprehensive investigation of newborn weight change, and it contributes to lactation and breastfeeding knowledge and research methods. The principal investigator is an experienced clinician, and the work it is based on clinical practice. As a consequence, the results have practical application.

The designs for both research studies were rigorous. The first met the requirements for formal systematic reviews, and contributed to an understanding of patterns of weight loss. The final study, similar to weight change itself, was complex with data collection during and after admission to hospital. Continuing data collection after discharge was instrumental to understanding newborn weight loss, and it provided knowledge that had not been previously gathered for published research studies.

The conceptualization of possibly relevant variables was clarified during data collection. Initially 20 variables were considered relevant for a regression model to predict neonatal weight loss. With a better understanding of the conceptual framework, several were eliminated (e.g. maternal age and education level) because they were related to breastfeeding duration and exclusivity rather than neonatal weight loss. Others were removed (e.g. maternal confidence) because temporally they were unlikely to contribute to weight loss, and the opposite might be happening. For example, weight loss likely affected maternal confidence at 14 days rather than maternal confidence influencing weight loss.

Timing of data collection is also a strength of this study. Weight measures by 12-hour increments in the first 72 hours and daily weights to Day 14 yielded important data. The hypothesis and data collection were comprehensive because they included output and oral fluids, even though the relationship between maternal IV fluids and neonatal weight loss was the original concern.

Limitations and Challenges

One learns as one gains experience. Knowing what I know now, I would have designed this research as a case study. Such a case study would include three aspects: observations, interviews, and documentation. The data collection and hypothesis testing would not change, but the research study would benefit from onsite observations and interviews of staff and study participants. The phenomenon of neonatal weight is multifaceted and attitudes and systemic conditions seem to contribute to the complexities. Observations and data from the hospitals (e.g. the policy regarding IV use and the frequency of weight measurements and supplementation at the different sites) might have strengthened the findings.

This study did not have enough exclusively breastfed babies to run separate analyses in this group. Breastfeeding is the biological norm, and understanding weight changes of exclusively breastfed newborns would be useful to clinicians.

Recruitment and data collection were the greatest challenges. The study design is complex, requires recruitment before labour began, and involves data collection at different times and places (e.g. birth unit, mother/baby unit, and home). Recruitment and data collection took an inordinate amount of time. The original research ethics board

approvals, granted in 2008, were renewed in 2009 and 2010. Several amendments were sought to increase enrollment and ensure accurate data collection.

Recruitment was time consuming and labour intensive with uneven results. Many strategies were used to passively recruit (e.g. posters and pamphlets), but active recruitment with invitations and explanations to parents was required for successful enrollment. Participants rarely consented with first contact. Given the type, timing, and extent of data collection, women and their partners required time to consider their involvement. There were usually two or three contacts either in-person or by telephone before participants registered for the study.

During the first two months of recruitment, the study excluded multiparous women. The intention was to remove a confounding variable. Additionally, babies of first time mothers appear to lose more weight, and it seemed that differences in weight loss might be easier to detect. In the beginning, it was experienced mothers who expressed an interest, therefore inclusion criteria was changed to include multiparous women.

There were many opportunities to miss or lose track of data. Nursing staff were involved with recording fluid amounts and giving parents baby scales. There are many gaps in data regarding fluids in labour or before a cesarean section. Nurses might have missed the inservice or did not remember details for data collection; therefore they did not record information about fluids before birth. In some cases, the nurses were not able to record fluids that anesthetists administered during surgery. In cases where the study fluid sheet was not completed, the data could not be collected from patient charts because

pre and post-birth fluids were recorded together. Thirty-seven percent of parents who registered and wanted to participate did not receive a scale, and they did not collect data.

Recommendations

Implications for Clinical Practice

The results of this thesis require a shift in thinking for nurses and other clinicians who work with breastfeeding women and their families. The systematic review challenges both the 7% and 10% guidelines. With a mean of 7% used as a red flag, half of the newborns would be at risk. There is little evidence to connect morbidity and mortality to a certain percentage of weight loss.

The key finding of the main study, that birth weight is not a reliable baseline and the 24 hour weight measurement is a better baseline, has important implications. Iatrogenic weight loss, not recognized at this time, must be considered when determining a baseline and using percentages of weight loss to assess infant feeding.

Newborn weight loss is not a problem to prevent or cure. It is a measurement that must be used differently than it currently is used. Although weight needs to be measured and monitored, it should be only one of many factors and not the one factor for clinical decisions and recommendations to parents. These results provide evidence for practice and should be incorporated into current clinical practice. Dissemination of the results will include publishing the final paper and presentations at conferences. Key professions include lactation consultants, nurses, physicians, and midwives.

Implications for Education

This research study produced results that are applicable to clinical practice, and educators should focus on dissemination of results and knowledge uptake. For nurses

and clinicians who work with breastfeeding women and their families, the results of this research study should be added to inservices for clinical teaching and upgrading.

Nurses in many areas are often the point of first contact for lactating and breastfeeding women. Protecting, promoting, and supporting breastfeeding are within a nurse's scope of practice. Women identify breastfeeding as their greatest concern during the postpartum period. Undergraduate students require breastfeeding education to prepare as a generalist nurse. With increases in initiation and duration rates of breastfeeding, nurses will meet lactating and breastfeeding mothers in many areas including hospital emergency rooms and surgical suites, community settings, and public health programs.

Implications for Research

Clinicians need to know if the results are replicable in other birth units. It is possible that different birth practices will yield different results.

Clinicians need to understand weight loss at different time periods. It seems weight loss in the first three days may have iatrogenic causes, whereas, weight loss after three days may be a good indicator of feeding adequacy. Further research is needed to establish morbidity related to weight loss.

Timing of fluids and the relationship to newborn weight loss needs to be explored. In this study, the sample for IV fluids in the final two hours before birth is very small. Follow up with a larger sample is recommended.

Summary

This thesis is about factors related to newborn weight loss. Early weaning, despite the health benefits for women and their families, is identified as a clinical issue.

Supplementation with its associated health risks and interference with establishing lactation is often recommended based on newborn weight loss.

Throughout this study, there were many moments of illumination. Recognizing assumptions clinicians hold was one of those moments; in particular that birth weight is upheld as a baseline measurement and a goal newborns must recoup. Another of the moments occurred when the results demonstrated that timing of maternal fluids in parturition seems related to weight loss at different times postpartum.

In conclusion, the first paragraph bears repeating. Appropriate lactation (i.e. to make milk) and breastfeeding (i.e. to give milk) assessments in the early days and weeks are required to maintain infant health and to ensure optimal breastfeeding support. Because neonatal weight measurements are used as a key indicator of breastfeeding adequacy, nurses need to understand factors that affect neonatal weight loss: (a) to account for weight loss that requires no intervention; (b) to prevent unnecessary weight loss; and (c) to recommend appropriate interventions when required due to weight loss.

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Appendix A - Thesis Proposal Approval

ECOLE DES SCIENCES INFIRMIÈRES
Programmes
des études supérieures



SCHOOL OF NURSING
Graduate Programs

Approbation du projet de thèse – Thesis Proposal Approval

Nom de l'étudiante* / Student Name	Programme / Program	# Étudiant / Student #
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Directrice de thèse / Thesis Supervisor	<u>A. Kristen Wendland</u>	<u>[Signature]</u>
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Co-directrice de thèse / Thesis Co-supervisor / (s'il y a lieu / if applicable)	<u>[Signature]</u>	<u>[Signature]</u>
	Nom / Name	Signature
Autres membres du comité de direction de thèse / Other Thesis Committee Members		
<u>Dr. J. Cobb</u>	<u>[Signature]</u>	
Nom / Name		
<u>Dr. D. Grell</u>	<u>[Signature]</u>	
Nom / Name		
<u>Dr. W. Peterson</u>	<u>[Signature]</u>	
Nom / Name		
<u>Dr. J. Tranner</u>	<u>[Signature]</u>	
Nom / Name		

Rapport d'évaluation / Evaluation Report

- ☒ La proposition est acceptée / Proposal accepted
- ☐ La proposition devra être soumise à nouveau aux membres du comité, avec révisions avant d'obtenir l'approbation finale / Proposal must be resubmitted to Committee members, with revisions to obtain final approval
- ☐ La proposition est rejetée. L'étudiante doit refaire le processus d'approbation à nouveau. Proposal is rejected. The student must complete the thesis proposal approval process again.

	Signature de l'étudiante / Student signature	Date
Approuvé par / Approved by	<u>[Signature]</u>	<u>2012-12-07</u>
	Directrice des programmes de soins infirmiers et de santé / Assistant Director, Graduate Programs	Date

* le féminin englobe le masculin

Appendix B - Research Ethics Board Approvals



Université d'Ottawa University of Ottawa

HEALTH SCIENCES AND SCIENCE RESEARCH ETHICS BOARD

CERTIFICATE OF ETHICAL APPROVAL

This is to certify that the University of Ottawa Health Sciences and Science Research Ethics Board has examined the application for ethical approval of the research project entitled **Demographic, Physiological, and Latrogenic Factors Affecting Neonatal Weight Loss (H 01-08-02)** submitted by Dr. Kirsten Woodend of the School of Nursing at the University of Ottawa and her doctoral student Ms. Joy Noel-Weiss.

The Board found that this research project met appropriate ethical standards as outlined in the Tri-Council Policy Statement and in the Procedures of the University of Ottawa Research Ethics Boards, and accordingly gave it a Category 1a (approval). This certification is valid one year from the date indicated below.

Germain Zongo
Protocol Officer for Ethics in Research
For Dr. Daniel Lagarec, Chair of the
Health Sciences and Science REB

April 8, 2008
Date

Appendix B - Research Ethics Board Approvals

File Number: H01-08-02

Date (mm/dd/yyyy): 03/27/2009



Université d'Ottawa University of Ottawa
Service de subventions de recherche et d'éthologie Research Grants and Ethics Services

Ethics Approval Notice Health Sciences and Science REB

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

First Name	Last Name	Affiliation	Role
Kirsten	Woodend	Health Sciences - Nursing	Supervisor
Joy	Noel-Weiss	Health Sciences - Nursing	Student Researcher

File Number: H01-08-02

Type of Project: PhD Thesis

Title: Demographic, Physiological, and Intergenic Factors Affecting Neonatal Weight Loss

Renewal Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
04/08/2009	04/07/2010	Ia
(Ia - Approval, Ib - Approval for initial stage only)		

Special Conditions / Comments:

N/A

File Number: H01-08-02

Date (mm/dd/yyyy): 03/27/2009



Université d'Ottawa University of Ottawa
Service de subventions de recherche et d'éthologie Research Grants and Ethics Services

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

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

Please submit an annual status report to the Protocol Officer 4 weeks before the above referenced expiry date to either close the file or request a renewal of ethics approval. This document can be found at http://www.iges.uottawa.ca/ethics/application_dwn.asp.

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5841 or by e-mail at ethics@uottawa.ca.

Signature:

Carmen /ongo,
Protocol Officer for Ethics in Research
For Barbara Graves, Chair of the Sciences and Health Sciences REB

Appendix B - Research Ethics Board Approvals

File Number: H01-08-02

Date (mm/dd/yyyy): 02/17/2010



Université d'Ottawa
Service de subventions de recherche et d'éthique

University of Ottawa
Research Grants and Ethics Services

Ethics Approval Notice
Health Sciences and Science REB

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

<u>First Name</u>	<u>Last Name</u>	<u>Affiliation</u>	<u>Role</u>
Kursten	Woodend	Health Sciences - Nursing	Supervisor
Joy	Noel-Weiss	Health Sciences - Nursing	Student Researcher

File Number: H01-08-02

Type of Project: PhD Thesis

Title: Demographic, Physiologic, and Intragenic Factors Affecting Neonatal Weight Loss

<u>Renewal Date (mm/dd/yyyy)</u>	<u>Expiry Date (mm/dd/yyyy)</u>	<u>Approval Type</u>
04/08/2010	04/07/2011	Ia

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

Special Conditions / Comments:
N/A

File Number: H01-08-02

Date (mm/dd/yyyy): 02/17/2010



Université d'Ottawa
Service de subventions de recherche et d'éthique

University of Ottawa
Research Grants and Ethics Services

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

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

Please submit an annual status report to the Protocol Officer 4 weeks before the above-referenced expiry date to either close the file or request a renewal of ethics approval. This document can be found at: http://www.rges.uottawa.ca/ethics/application_dwn.asp

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5841 or by e-mail at ethics@uOttawa.ca.

Signature:

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

Appendix B - Research Ethics Board Approvals



Queensway Carleton
Hospital

May 6, 2008

Joel Noel-Weiss

RE: Study 08-05 - Demographic, Physiological and Iatrogenic Factors Affecting Neonatal Weight Loss

Dear Ms. Weiss,

Thank you for the submission of the protocol for the above named study. I am pleased to inform you that at its meeting of April 24th, 2008, the Consents & Research Committee granted full approval for the conduct of your study at Queensway Carleton Hospital. This approval, however, is contingent on the clarification of the consent form regarding weighing times for the infant as the number of weightings does not appear to be consistent with the study protocol. Dr. Dattani and Sue Macfarlane will determine resolution of this question on behalf of the Committee.

The approval will extend for a period of one year and will expire May 15th, 2009. We request that two months prior to that date you submit a Continuing Review Form (attached) at which time you may request an extension of approval.

Should you have any further questions please do not hesitate to contact me.

Best wishes for a successful study.

Sincerely,

^ ^

D. Crowe Ph.D., C. Psych.
Chair, Consents & Research Committee

cc- Dr. Andrew Falconer, Chief of Staff
- Kathleen Nunn, Director, Childbirth Program
- Marilyn Sgarbossa, Manager, Health Records.

Appendix B - Research Ethics Board Approvals



Queensway Carleton
Hospital

3 June 2009

**RE: Study 08-05 - Demographic, Physiological, and Iatrogenic Factors
Affecting Neonatal Weight Loss**

Dear Ms. Noel-Weiss,

At its meeting held May 28, 2009 the Consents & Research Committee reviewed your request for extension of approval for the above named project and I am pleased to inform you that formal approval has been granted for this extension. Approval will expire on 1st July, 2010. We request that two months prior to that expiration date you submit a summary of progress with the Protocol Continuing Review Form (enclosed) and you may request extension of approval at that time if so indicated.

Please note that you are required to request approval from the Consents & Research Committee for any modifications by which you plan to amend your protocol. As well, we require that you inform the Consents & Research Committee of any complaints made by participants in the study, or agents of those participants, within 7 days of having received the complaint.

Thank you for the submission of this application and should you have any further questions, please contact me.

Best wishes for a successful study.

Sincerely,

D. Crowe, Ph.D. C. Psych.
Chair, Consents & Research Committee

Cc, Dr. Andrew Falconer, Chief of Staff
Marilyn Sgarbossa, Manager Health Records

Appendix B - Research Ethics Board Approvals



Queensway Carleton
Hospital

29 April 2010

Dear Ms. ~~Noel~~ Weiss:

RE: Study 08-05 - Demographic, Physiological, and Iatrogenic Factors Affecting Neonatal Weight Loss

At its meeting held April 29, 2010 the QCH REB reviewed your request for extension of approval for the above named project and I am pleased to inform you that formal approval has been granted for this extension. Approval will expire on 15th May, 2011. We request that 2 months prior to that expiration date you submit a summary of progress with the Protocol Continuing Review Form (enclosed) and you may request extension of approval at that time if so indicated.

Please note that you are required to request approval from the QCH REB regarding any modifications by which you plan to amend your protocol. As well, we require that you inform the QCH REB of any complaints made by participants in the study, or agents of those participants, within 7 days of having received the complaint.

Thank you for the submission of this application and should you have any further questions, please contact me.

Best wishes for a successful study.

Sincerely,

D. Crowe, Ph.D. C. Psych.
Chair, Consents & Research Committee

cc- Dr. Andrew Falconer, Chief of Staff
Marilyn Sgarbossa, Manager Health Records

Appendix B - Research Ethics Board Approvals



Université d'Ottawa
Faculté des sciences
de la santé

École des sciences
Infirmières

University of Ottawa
Faculty of Health
Sciences
School of Nursing



Demographic, Physiological, and Iatrogenic Factors Affecting Neonatal Weight Loss

Letter of Agreement to Participate in Research Study

This is a letter of agreement that provides approval for research and data collection at the Queensway Carleton Hospital

Joy Noel-Weiss RN IBCLC PhD(c) has explained this research study to my satisfaction.

As a representative of the the Winchester District Memorial Hopspital, I agree to our participation in this study.

I understand that our hospital staff participation will involve:

- Notifying the reseacher that the mother and baby are in hospital
- Recording maternal fluids during labour and birth (including cesarean sections)
- Giving permission for chart audits
- Giving the scales provided by the researcher to the mothers when their babies are born

The researchers are expected to complete the research ethics requirements of our institution.

Data must be conserved for a minimum of 15 years and then disposed of in a proper manner (paper shredded and computer files deleted).

Lynn Hall, R.N., B.Sc.N., M.Sc.
Vice President Clinical Services
Chief Nursing Officer/Professional Practice Leader
Hospital Representative's Name and Position

☎ 613 562-5473
☎ 613 562-5443
451 Smyth
Ottawa ON K1H 8M5 Canada
www.uOttawa.ca

Hospital Representative's Signature

Date

Appendix B - Research Ethics Board Approvals



Almonte General Hospital
75 Spring Street
Almonte, Ontario K0A 1A0
Tel: 613-256-2500
Fax: 613-256-4889

Fairview Manor
Tel: 613-256-3113
Fax: 613-256-5780

August 28, 2008

Kristen Woodend
School of Nursing
Faculty of Health Sciences
University of Ottawa
451 Smyth Road, Room 3052
OTTAWA, Ontario
K1H 8M5

Joy Noel-Weiss RN IBCLC PhD(c)
Newborn Weight Loss Study
School of Nursing
University of Ottawa
451 Smyth Road
OTTAWA, Ontario
K1H 8M5

Re: Almonte General Hospital Ethical Approval

Dear Ms. Noel-Weiss:

Your proposal has been accepted for the period September 1, 2008 until April 8, 2009.

One question was generated by our review of your documents. We would appreciate further clarification of why information is being kept for 15 years before being destroyed.

Within the Research Approval Checklist the researcher indicated she was "unsure what is being asked" in relation to linking the personal health information. You have addressed this in the Participant Invitation and Information Sheet "Give permission for the researcher to be informed when you are admitted to the hospital and to obtain information from your patient chart".

Yours truly,

Teresa M. Lee, BScN, RN, MN
AED Patient/Resident Services
Chair of Research Ethics Subcommittee
Almonte General Hospital

CC: Almonte General Hospital Ethics Committee

Appendix B - Research Ethics Board Approvals

**Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches**

761 Parkdale Avenue Suite 106, Ottawa, Ontario K1Y 1J7 613-798-5555 ext. 14902 Fax: 613-761-4311
<http://www.ohrl.ca/ohreb>

Monday, May 25, 2009

Ms. Joy Noel-Weiss
 University of Ottawa
 School of Nursing
 Master of Science Nursing Program
 451 Smyth Road
 Ottawa, ON K1H 8M5

Dear Ms. Noel-Weiss:

Re: Protocol # 2009191-01H Demographic, Physiological, and Iatrogenic Factors Affecting Neonatal Weight Loss

Protocol approval valid until - Monday, March 15, 2010

Thank you for the French documents received May 21, 2009. This protocol was reviewed by the full Board of the Ottawa Hospital Research Ethics Board (OHREB) at the meeting held on March 16, 2009. You have met the requirements of the OHREB and your protocol has been granted approval by the OHREB to recruit English-speaking patients. No changes, amendments or addenda may be made to the protocol or the consent form without the OHREB's review and approval.

Approval is for the following:

- Research Proposal dated February 28, 2009
- English Prenatal Questionnaire
- English Instructions to Use Baby Scale
- English Maternal Fluid Chart
- English Output Chart (Diaper Weights)
- English Infant Weight Chart
- English Postpartum (2 weeks) Questionnaire
- English Telephone Questionnaire to Determine Feeding Category at Two Weeks
- English Participant Request and Information Sheet received May 6, 2009
- English Participant Consent Form received May 6, 2009
- English Consent form for Chart Audit received May 6, 2009
- English Recruitment Poster received May 6, 2009
- English Study Brochure received May 6, 2009
- French Participant Request and Information Sheet received May 21, 2009
- French Participant Consent Form received May 21, 2009
- French Consent form for Chart Audit received May 21, 2009
- French Recruitment Poster received May 21, 2009
- French Study Brochure received May 21, 2009

The validation date should be indicated on the bottom of all consent forms and information sheets (see copy attached). If the study is to continue beyond the expiry date noted above, a Renewal Form should be submitted to the OHREB approximately six weeks prior to the current expiry date. If the study has been completed by this date, a Termination Report should be submitted.

The Ottawa Hospital Research Ethics Board is constituted in accordance with, and operates in compliance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; Health Canada Good Clinical Practice: Consolidated Guideline; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Health Information Protection Act 2004 and its applicable Regulations.

Yours sincerely,

FRANÇOISE F-A SARRAZIN, Ph.D., C.F.Syng.
 Vice-Chairman
 Ottawa Hospital Research Ethics Board

Encl.

/s/

Appendix B - Research Ethics Board Approvals

**Ottawa Hospital Research Ethics Boards / Conseils d'éthique en recherches**

751 Parkdale Avenue Suite 108, Ottawa, Ontario K1Y 1J7 613-798-5555 ext. 14902 Fax: 613-781-4311
<http://www.ohri.ca/ohreb>

Tuesday, March 09, 2010

Ms. Joy Noel-Weiss
University of Ottawa
School of Nursing
Master of Science Nursing Program
451 Smyth Road
Ottawa, ON K1H 8M5

Dear Ms. Noel-Weiss:

RE: Protocol# - 2009191-01H Demographic, Physiological, and Iatrogenic Factors Affecting Neonatal Weight Loss

Renewal Expiry Date - Tuesday, March 15, 2011

I am pleased to inform you that your Annual Renewal Request (listed above) was reviewed by the Ottawa Hospital Research Ethics Board (OHREB) and is approved. No changes, amendments or addenda may be made in the protocol or the consent form without the OHREB's review and approval.

Renewal is valid for a period of one year. The validation date should be indicated on the bottom of all consent forms and information sheets (see attached copy). Approximately one month prior to that time, a single renewal form should be sent to the OHREB office.

The Tri-Council Policy Statement requires a greater involvement of the OHREB in studies over the course of their execution. As well, you must inform the Board of adverse events encountered during the study, here or elsewhere, or of significant new information which becomes available after the Board review, either of which may impinge on the ethics of continuing the study. The OHREB will review the new information to determine if the protocol should be modified, discontinued, or should continue as originally approved.

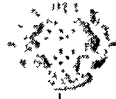
Yours sincerely,

Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

encl.

/km

Appendix C - Research Ethics Board Amendments



Université d'Ottawa | University of Ottawa

May 23, 2008

Kirsten Woodend
School of Nursing
Faculty of Health Sciences
University of Ottawa
451 Smyth Road, Room 3052
Ottawa, ON K1H 8M5

Joy Noel-Weiss

RE. Demographic, Physiological, and Latrogenic Factors Affecting Neonatal Weight Loss (H 01-08-02)

Dear Dr. Woodend and Ms. Noel-Weiss,

The Health Sciences and Science Research Ethics Board has examined your request received on May 5, 2008 for ethics approval of the following modifications to the above-mentioned project:

- The Winchester District Memorial Hospital does not have preregistration so the researcher cannot do the recruitment at that moment. Information about the research will therefore be given to women by physicians and midwives who will give them pamphlets on the research project. Those who are willing to be contacted by the researcher will provide their contacts and sign a consent to be contacted.

Your request has been accepted. The certificate of ethical approval granted on April 8, 2008 and valid until April 8, 2009 covers these modifications.

During the course of the study, any further modifications to the protocol or forms may not be initiated without prior written approval from the REB. You must also promptly notify the REB of any adverse events that may occur.

If you have any questions, please do not hesitate to contact me at

Sincerely yours,

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

Appendix C - Research Ethics Board Amendments



Université d'Ottawa | University of Ottawa

June 17, 2008

Kirsten Woodend
School of Nursing
Faculty of Health Sciences
University of Ottawa
451 Smyth Road, Room 3052
Ottawa, ON K1H 8M5

Joy Noël-Weiss

RE: Demographic, Physiological, and Latrogenic Factors Affecting Neonatal Weight Loss (H 01-08-02)

Dear Dr. Woodend and Ms. Noel-Weiss,

The Health Sciences and Science Research Ethics Board has examined your request received on June 12, 2008 for ethics approval of the following modifications to the above-mentioned project:

- ❑ At the Queensway Carleton Hospital and the Almonte General Hospital researchers will use the pamphlet and consent to contact approved by the Winchester District Memorial Hospital.
- ❑ Researchers have modified the poster by adding a picture and replacing the word "infant" with "newborn".
- ❑ At the Queensway Carleton Hospital and the Almonte General Hospital physicians and midwives will give pamphlets on the research project to women. Those who are willing to be contacted by the researcher will provide their contacts and sign a consent to be contacted.
- ❑ The questionnaires have been revised based on recommendations of expert clinicians.

Your request has been accepted. The certificate of ethical approval granted on April 8, 2008 and valid until April 8, 2009 covers these modifications.

During the course of the study, any further modifications to the protocol or forms may not be initiated without prior written approval from the REB. You must also promptly notify the REB of any adverse events that may occur.

If you have any questions, please do not hesitate to contact me at

Sincerely yours,

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

780-020-0000 / 1-800-561-5800 / 1-800-561-5800
1-800-561-5800 / 1-800-561-5800 / 1-800-561-5800
1-800-561-5800 / 1-800-561-5800 / 1-800-561-5800

Appendix C - Research Ethics Board Amendments



September 22, 2008

Kirsten Woodend
School of Nursing
Faculty of Health Sciences
University of Ottawa
451 Smyth Road, Room 3052
Ottawa, ON K1H 8M5

Joy Noel-Weiss

RE: Demographic, Physiological, and Latrogenic Factors Affecting Neonatal Weight Loss (H 01-08-02)

Dear Dr. Woodend and Ms. Noel-Weiss,

The Health Sciences and Science Research Ethics Board has examined your request received on September 17, 2008 for ethics approval of the following modifications to the above-mentioned project:

- ❑ Researchers are widening their inclusion criteria in order to also recruit women who have had children. Originally their rationale was that they would be avoiding a potential confounding variable by limiting participants to first-time mothers. Their rationale for changing the inclusion criteria is that enrollment would be more successful and generalizability would be better. The potential confounding variable will be accounted for with their statistical model.
- ❑ The abovementioned modification has led to modifications in the prenatal questionnaire (they will ask about parity) and in the pamphlet and the poster for recruitment (i.e. "your first baby" is changed to "a baby").

Your request has been accepted. The certificate of ethical approval granted on April 8, 2008 and valid until April 8, 2009 covers these modifications.

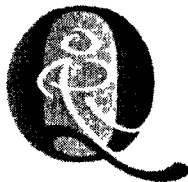
During the course of the study, any further modifications to the protocol or forms may not be initiated without prior written approval from the REB. You must also promptly notify the REB of any adverse events that may occur.

If you have any questions, please do not hesitate to contact me at

Sincerely yours,

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

Appendix C - Research Ethics Board Amendments



Queensway Carleton
Hospital

30 October 2008

Joy Noel-Weiss

**RE: Demographic, Physiological, and Iatrogenic Factors
Affecting Neonatal Weight Loss**

Dear Ms. Noel-Weiss,

At its meeting held October 30, 2008 the Consents & Research Committee reviewed the proposed amendment (the modification of inclusion criteria to include multiparous women) for the above named project and I am pleased to inform you that formal approval has been granted for this amendment. Approval will expire, as per the original approval on 15th May, 2009. We request that 2 months prior to that expiration date you submit a summary of progress with the Continuing Review Form (enclosed) and you may request extension of approval at that time if so indicated.

Please note that you are required to request approval from the Consents & Research Committee for any modifications by which you plan to amend your protocol. As well, we require that you inform the Consents & Research Committee of any complaints made by participants in the study, or agents of those participants, within 7 days of having received the complaint.

Thank you for the submission of this application and should you have any further questions, please contact me.

Best wishes for a successful study.

Sincerely,

D. Crowe, Ph.D. C. Psych.
Chair, Consents & Research Committee

Cc, Dr. Andrew Falconer, Chief of Staff
Marilyn Sgarbossa, Manager Health Records

Appendix C - Research Ethics Board Amendments



Université d'Ottawa | University of Ottawa

November 25, 2008

Kirsten Woodend
School of Nursing
Faculty of Health Sciences
University of Ottawa
451 Smyth Road, Room 3052
Ottawa, ON K1H 8M5

Joy Noel-Weiss

**RE: Demographic, Physiological, and Latrogenic Factors Affecting Neonatal Weight Loss
(H 01-08-02)**

Dear Dr. Woodend and Ms. Noel-Weiss,

The Health Sciences and Science Research Ethics Board has examined your request received on November 17, 2008 for ethics approval of the following modifications to the above-mentioned project:

- The researchers would like to modify their recruitment process that is not working. They will now use the following recruitment process:
 - The researcher or research assistant will attend parenting events in the community and handout pamphlets, answer questions, demonstrate the baby scale, and collect registration forms;
 - The researcher or research assistant will attend a prenatal class and, at the end of class, she would describe the study and ask parents who are interested to stay behind to have questions answered, see the baby scales, and/or to complete registration form;
 - The researcher or research assistant will attend a physician's office (with physician approval) to answer questions and collect completed registration forms.
- The researchers would like to change the data collection forms by dropping the infant feeding sheet. The reason for dropping the infant feeding sheet is that it is an onerous task for the participants and it is unnecessary because the two week questionnaire provides sufficient information about infant feeding patterns to detect a confounding factor.

Your request has been accepted. The certificate of ethical approval granted on April 8, 2008 and valid until April 8, 2009 covers these modifications.

During the course of the study, any further modifications to the protocol or forms may not be initiated without prior written approval from the REB. You must also promptly notify the REB of any adverse events that may occur

If you have any questions, please do not hesitate to contact me

Sincerely yours,

Germain Zougo
Assistant Director, Ethics (Interim)
For Daniel Lagarec, Chair of the Health Sciences and Sciences REB

Appendix C - Research Ethics Board Amendments



Queensway Carleton
Hospital

January 19, 2009

Joy Noel-Weiss

RE: Study 08-05 - Demographic, Physiological, and Iatrogenic Factors Affecting Neonatal Weight Loss

Dear Ms. Noel-Weiss,

At its meeting held January 15, 2009 the Consents & Research Committee reviewed the proposed amendment (the elimination of the Infant Feeding Form and consequent changes to study forms and reading materials for subjects) for the above named project and I am pleased to inform you that formal approval has been granted for this amendment. Approval will expire, as per the original approval on 15th May, 2009. We request that 2 months prior to that expiration date you submit a summary of progress with the Protocol Continuing Review Form (enclosed) and you may request extension of approval at that time if so indicated.

Please note that you are required to request approval from the Consents & Research Committee for any modifications by which you plan to amend your protocol. As well, we require that you inform the Consents & Research Committee of any complaints made by participants in the study, or agents of those participants, within 7 days of having received the complaint.

Thank you for the submission of this application and should you have any further questions, please contact me.

Best wishes for a successful study.

Sincerely,

D. Crowe, Ph.D. C. Psych.
Chair, Consents & Research Committee

Cc, Dr. Andrew Falconer, Chief of Staff
Marilyn Sgarbossa, Manager Health Records

3045 Baseline Road Ottawa, Ontario K2H 8P4 (613) 721-2000 · www.qch.on.ca

Appendix C - Research Ethics Board Amendments



Université d'Ottawa | University of Ottawa

March 30, 2009

Kristen Woodend
School of Nursing
Faculty of Health Sciences
University of Ottawa

Joy Noel-Weiss
School of Nursing
Faculty of Health Sciences
University of Ottawa

RE: Demographic, Physiological, and Iatrogenic Factors Affecting Neonatal Weight Loss (# H01-08-02)

Dear Doctor Woodend and Ms. Noel-Weiss,

The Health Sciences and Science Research Ethics Board has examined your request received on March 23, 2009 for ethics approval of the following modification to the above-mentioned project:

- The "Instructions Attached to Baby Scale" have changed. A copy of the instructions with the registration forms for parents to keep has been submitted. A copy of the original and a copy of a new version are provided. The rationales are:
 - In the interest of safety and clarity for operation, addition information is provided and there is emphasis to not leave baby unattended on the scale.
 - Also in the interest of safety and proper operation, I am providing a copy with registration to ensure parents have a copy of the operating and safety instructions

Your request has been accepted. These modifications are covered by the certificate of ethics approval granted on April 8, 2008 renewed on April 8, 2009 and valid until April 7, 2010.

During the course of the study, any further modifications to the protocol or forms may not be initiated without prior written approval from the REB. You must also promptly notify the REB of any adverse events that may occur.

If you have any questions, please do not hesitate to contact me at extension

Sincerely yours,

^

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

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1040 1

Joy Noel-Weiss

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

Appendix D - Pamphlet Announcing the Study

About the Study

What are the factors that affect weight loss in the breastfed baby in the first few days following birth?

Many mothers stop breastfeeding before they want to because of problems. This research is trying to find ways to help mothers succeed with breastfeeding. Understanding weight loss might help.

Information will be collected about factors that might affect a baby's weight loss in the first weeks after birth. Mothers in the study will be loaned a baby scale so that they can weigh their babies and their babies' diapers.

All study participants will complete a telephone questionnaire when their babies are 2 weeks old.

About the Researcher

Joy Noel-Weiss is a Registered Nurse and a Registered Lactation Consultant.

Joy is doing this research study as part of her thesis for a PhD in Nursing Science at the University of Ottawa.

The Request

You are being asked to participate in a research study.

What will I be asked to do?

Register for the study before your baby is born. This will include the 1st questionnaire, two consent forms, and a contact information sheet.
(about 15 minutes)

Weigh all of your baby's diapers and record the weights for the first 3 days
(about 30 minutes)

Weigh your baby for two weeks. A chart and a baby scale will be provided so you can record your baby's weight every 12 hours for 3 days and then once each day until your baby is fourteen days old.
(about 30 minutes over two weeks)

Complete a telephone questionnaire when your baby is two weeks old.
(about 20 minutes)

Give permission for the researcher to be told when you are admitted to the hospital and for the researcher to obtain some information from your patient chart.



If You Would Like to Participate in this Study

Please Contact
Joy Noel-Weiss at

This research study has been approved by the
Ottawa Hospital Research Ethics Board
Version 2 February 17, 2010

Are there any risks from participating?

Answering questions and volunteering personal information may cause you to feel uncomfortable or inconvenienced. You are free not to answer any question. As well, every effort will be made to minimize inconvenience by being considerate of your time and the timing of telephone calls to you. You will receive all standard care and you can get any help with breastfeeding that you think is needed before or after your baby is born.

Is there any benefit from participating?

Your participation in this study may help nurses to understand how to best support breastfeeding mothers and infants.

What if I change my mind about being in the study after I register?

You may withdraw from the study at any time. You may also choose not to answer any questions, at any point, without consequence. Your doctor or midwife will not know whether you completed the study.

Are there any costs or expenses if I participate?

There is the cost of your time which is not reimbursed.



Are You Expecting A Baby...

... in 2010?

... at The Ottawa Hospital?
Planning to Breastfeed?

We are Researching
Newborn Weight Loss



The Ottawa Hospital
L'Hôpital d'Ottawa

Are my answers confidential and anonymous?

The information you share will remain confidential unless release is required by law. The researchers will be the only ones with access to your information unless an audit is required by a research ethics board. No identifying information will be published.

What if I have questions after I register?

If you have any questions about the study, you may contact Joy or her supervisor at these numbers:

Researcher - Joy Noel-Weiss
613-228-9529

noelweiss@rogers.com

Supervisor - Dr. A. Kirsten Woodend

613-562-5426

kwoodend@uottawa.ca

If you have any concerns regarding your rights as a research participant, you may contact the Protocol Officer for Ethics in Research, at the University of Ottawa, 613-562-5841 or ethics@uottawa.ca

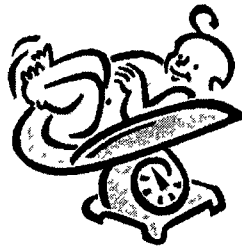
Summary and Consent

By agreeing to participate in this study, you are agreeing to complete a consent form, a contact sheet, two questionnaires, and to record information about your baby's weight patterns.

Appendix E - Poster Announcing the Study



What are the Factors that Affect Weight Loss in the Newborn Breastfed Baby?



**Are You Expecting
A Baby...
... in 2010?
Planning to Breastfeed?**

**We are Researching Factors that Affect
Newborn Weight Loss**

**If you would like more information
Please contact Joy Noel-Weiss :**

Appendix F - Patient Information Sheet



University of Ottawa
 Faculté des sciences
 de la santé
 Faculté des sciences
 de la santé
 University of Ottawa
 Faculté de santé
 Sciences
 School of Nursing



Participant Request and Information Sheet

Title of the Study: Factors Affecting Newborn Weight Loss

Invitation to participate:

Dear Participant:

You are being asked to participate in a research study which will be conducted in English.

Joy Noel-Weiss is a nurse and certified lactation consultant and she is doing a study about newborn weight loss as part of her thesis for a PhD in Nursing Science at the University of Ottawa. If you have questions, you may call Joy at the study line 613-737-8111 or contact Joy's thesis supervisor, Dr. Kirsten Woodend,

Many mothers stop breastfeeding before they want to because of problems. This research is trying to find ways to help mothers succeed with breastfeeding. About 250 women and their babies will be involved in this study. Information will be collected about your birth experience, the weight of all diapers for the first 72 hours, and about your baby's weight in the first two weeks.

Questions you might have:

What will I be asked to do?

- ❖ Register for the study when you pre-register for the hospital (about 15 minutes)

Registration includes two consent forms (one for the study and one for the chart audit), a contact sheet, and a prenatal questionnaire. After you register, the researcher will call you to confirm receipt of your consent.

- ❖ Weigh all your baby's diapers for the first 3 days (about 30 minutes)

An unused diaper needs to be weighed and the weight written down. Each diaper is then weighed and the difference in weight between the dry diaper and the soiled diaper will tell the researchers how much your baby voided and stoolled.

- ❖ Weigh your baby for 2 weeks (about 30 minutes over two weeks)

A scale and chart will be provided by the researcher so you can weigh your baby and record your baby's weight every 12 hours for 3 days then once each day until two weeks.

- ❖ Answer a telephone questionnaire two weeks after your baby is born (about 15 minutes)

This is a questionnaire about your birth experience and how you are feeding your baby

- ❖ Give permission for the researcher to be informed when you are admitted to the hospital and to obtain information from your patient chart

This will be information about medications, fluids, and treatments you received during your labour and birth or during your planned Cesarean birth.

Are there any risks from participating?

Answering questions and volunteering personal information may cause you to feel uncomfortable or inconvenienced. You are free to not answer any question.

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Université d'Ottawa
Faculté des sciences
de la santé

École des sciences
infantiles

University of Ottawa
Faculty of Health
Sciences

School of Nursing

(2)

Are there any benefits to participating?

Your participation in this study may help nurses and lactation consultants understand patterns of weight gain and loss in the early weeks. This may help us provide better support for breastfeeding mothers.

What if I change my mind about being in the study after I register?

You may withdraw from the study at any time. You may also choose not to answer any questions without consequence. Your doctor or midwife will not know whether or not you participated.

Are there any costs or expenses if I participate?

There is no cost to participating in the study. There will be an investment of your time with no compensation.

Are my answers confidential and anonymous?

Joy Noel-Weiss, the researcher, and the research assistants, identify participants by a number. The list matching the names and code numbers will be kept separately in a locked cabinet. No identifying information will be revealed in the study results nor will leave the Ottawa Hospital unless carried by you. Only anonymous statistical information will be published.

Representatives of the Ottawa Hospital Research Ethics Board, University of Ottawa Research Ethics Board, and the Ottawa Health Research Institute may review your original medical records under the supervision of Mrs. Noel-Weiss' staff for audit purposes.

The information you share will remain confidential unless release is required by law. The researcher, her supervisor and research assistants will have access to your information which will be kept in a locked file in Joy's office and will be destroyed after 15 years. The information you share will only be used to determine the factors that affect newborn weight loss.

What if I have questions about the study after I register?

If you have any questions about the study, you may contact Joy or her supervisor at these numbers:

Researcher - Joy Noel-Weiss

Supervisor - Kirsten Woodend

If you have any questions with regards to the ethical conduct of this study, you may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550, Cumberland Street, Room 159, Ottawa, ON K1N 6N5, tel.: 613-562-5841, email: ethics@uottawa.ca. You may also consult the chair of the Ottawa Hospital Research Ethics Board at 613-798-5555, extension: 1111.

Summary and Consent

By agreeing to participate, you agree to complete a consent form and register, collect your baby's diapers, weigh your baby, and complete a telephone questionnaire after your baby is born.

If you are willing to participate in this study please complete the study information when you pre-register for the hospital.

This research study has been approved by the Ottawa Hospital Research Ethics Board valid until March 15, 2011

☎ 613-562-5425

✉ ethics@uottawa.ca

☎ 613-562-5425

☎ 613-562-5425

☎ 613-562-5425

☎ 613-562-5425

Appendix G - Consent Forms



The Ottawa Hospital
L'Hôpital d'Ottawa

Participant's ID # _____

Participant Consent Form

Title of the Study: Factors Affecting Newborn Weight Loss

I, _____ agree to participate in this study led by Joy Noel-Weiss RN IBCLC PhD(c). The data from the study might help nurses understand factors that affect newborn weight loss.

My participation will involve:

- Registering for the study before my baby is born
- Weighing my baby's diapers for the first 3 days
- Weighing my baby every 12 hours for the first 3 days
- Weighing my baby daily after four days until my baby is 2 weeks old
- Completing a telephone questionnaire when my baby is 2 weeks old about my birth experience and how my baby is fed
- Giving my permission for researchers to be informed when I am admitted to the hospital and to obtain information from my patient chart

Only the researchers will know my answers and the information will be kept confidential at all times.

Hospital staff will be aware that I am participating in the study and they will provide the baby scales from the researcher. My doctor/midwife and nurses will not be aware of my responses and therefore this information will not influence the care received by me or my baby.

I can withdraw from the study at any time, and neither my care nor my baby's care will be affected by my decision to participate or not participate in the study. My records will not be used if I withdraw from the study.

If I have questions, I may call Joy at the _____ y's
thesis supervisor, Dr. Kirsten Woodend, at _____

I have read the Participant Request and Information Sheet and I understand the information in this Consent Form. I will receive a copy of the information sheet and this consent form.

I voluntarily consent to participate in the study.

Mother's Name (Please Print) Mother's Phone Number

Mother's Signature Date

I consent to my child's involvement.

Second Parent's Name (Please Print) Second Parent's Phone Number

Second Parent's Signature Date

If there is no Second Parent's consent, please state a reason _____

Investigator/Delegate's Signature Print Name Date

This research study has been approved by the Ottawa Hospital Research Ethics Board
valid until March 15, 2011

1 of 1

Appendix G - Consent Forms



Participant's ID # _____

Consent Form for Chart Audit**Title of the Study: Factors Affecting Newborn Weight Loss**

I, _____, agree to allow the researcher, Joy Noel-Weiss, to access my chart hospital chart to determine the following:

- Amounts and rates of fluids I received during labour or before my c-section
- My baby's sex
- Gestation in weeks and days
- My baby's weight at birth
- The type of birth
- Medications I received during labour/surgery
- Length of my 1st and 2nd stages of labour
- Interventions during my labour/birth (e.g. forceps, vacuum, epidural, induction)
- Complications during my labour/birth (e.g. fever, prolonged 1st/2nd stage, meconium, baby needed suctioning)
- Details about feeding my baby that are in my chart (e.g. breastfed for the first time, how many bottles of formula were used in the hospital)
- My baby's age and weight at discharge

This is the only information that will be retrieved.

The information will leave the hospital with only my study code number on it.

I voluntarily consent to the above chart audit.

Participant's Name (Please Print)

Participant's Phone Number

Participant's Signature

Date

Investigator/Delegate's Signature

Print Name

Date

This research study has been approved by the Ottawa Hospital Research Ethics Board
valid until March 15, 2011

1 of 1

Appendix H - Prenatal Questionnaire

Factors Affecting Newborn Weight Loss Research Study
Prenatal Questionnaire

Participant's ID # _____

These 18 questions will help the researcher learn about the participants in the study.

Please answer by FILLING IN THE BLANK or CIRCLING the number beside your choice:

1. Is this your first baby?
Yes - please go to question 3
No - if you have other children, please go to question 2
2. How many children do you have and if they were breastfed, how long were they breastfed?

3. What will your age be when your baby is born? _____
4. What is your marital status?
married/common law..... 1
single/never married/
separated/divorced..... 2
5. What level of education have you completed?
high school or less..... 1
some college or university..... 2
completed university or
post graduate degree..... 3
6. What is your family income before taxes?
less than \$17,000..... 1
17,000 - 31,999..... 2
32,000 - 69,999..... 3
over 70,000..... 4
7. Have you attended any prenatal classes?
Yes No If yes, How many classes? _____
8. What preparation have you done for breastfeeding (e.g. read, class, watch videos)

Appendix H (con)

Participant's ID # _____

9. What is your smoking status?

- never smoked..... 1
 recently quit..... 2
 1 - 2 per day..... 3
 25 per week..... 4
 more than 25 per week..... 5

10. Have you had any breast surgery?

Yes No

11. If yes to #10, what type of surgery?

12. What is your main reason for breastfeeding?

13. Did your mother breastfeed any of her children? (please circle one)

Yes No

14. How many of your friends or other family members have breastfed?

15. When did you make your decision to breastfeed?

- before getting pregnant
 after getting pregnant

16. Describe your partner's opinion of your decision to breastfeed? (circle one)

not supportive	somewhat supportive	no opinion	supportive	very supportive
1	2	3	4	5

17. How long are you planning to breastfeed your baby without supplements or other foods?

18. How long are you planning to breastfeed your baby overall? (any amount before weaning)

Finally

We will be calling you to complete questionnaires. Would you prefer calls in the
 (please circle one) 1) morning 2) afternoon 3) evening

Thank you

uOttawa



Participant's ID # _____

University of Ottawa
Faculty of Health
Sciences
Department of Health
Sciences
University of Ottawa
Faculty of Health
Sciences
Department of Health
Sciences

Name (on health card) _____

Mother's Date of Birth _____

[Home](#)

Work

Cell _____

Relative/Friend (where you might stay after the baby's birth)

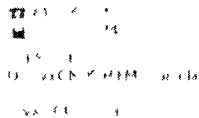
Email Address _____

Expected Due Date _____

Campus (circle one)	Civic	General
---------------------	-------	---------

Physician name _____

The study telephone number



Appendix J - Instructions for Use of Baby Scale

Newborn Weight Loss Study**Instructions to Use Baby Scale****NEVER LEAVE BABY UNATTENDED ON SCALE****Please use all safety precautions**

Baby scales **MUST ALWAYS** be on a **flat, secure surface**.

Electronic equipment such as computers, cell phones, or cordless phones can interfere with scales.

Baby needs to be weighed **without** clothes (**no diaper, please**)

BEFORE picking up your baby:

1. Place a small, clean blanket on the baby scale
2. Turn on the scale
3. Push the "zero" button (blanket will not be part of baby's weight)

Place your baby on the scale and wait until the baby's weight is registered.

PUSH "HOLD" for weight to stay displayed for 2 minutes.

REMOVE your baby from the scale as soon as weight has been taken.

NEVER leave your baby alone on the scale.

PLEASE carry the scale by its base and do not store objects on the scale.

The scale is only meant to weigh babies.
Weighing larger children may break the scale.

If the baby scale does not seem to be working properly:

Please contact the researcher Joy Noel-Weiss at
call Joy at _____ or the study line at 1-

1 or

Scales vary, please keep this in mind if your baby's weight is different on a different scale (for example at the pediatrician's or with the public health nurse). There may be no cause for concern.

Appendix K - Data Collection Sheet for Maternal Fluids

Newborn Weight Loss Study

Maternal Fluid Chart

Please complete sheet **prior to birth** to track maternal fluids from admission through labour or before c-section.

Date _____

Time	IV	Oral
0700 - 1900 or start time	Hourly rate	
	Type (Ringer's, NS)	
	Total mls for 12 hours	
1900 - 0700 or start time	Hourly rate	
	Type (Ringer's, NS)	
	Total mls for 12 hours	
Comments		

Date _____

Time	IV	Oral
0700 - 1900	Hourly rate	
	Type (Ringer's, NS)	
	Total mls for 12 hours	
1900 - 0700	Hourly rate	
	Type (Ringer's, NS)	
	Total mls for 12 hours	
IV Fluids in last 2 hours _____ mls (please give the approx. amount) Joy 613-228-1413		Sm. glass - 120 ml Lg. glass - 150 ml Mug - 150 ml Soup bowl - 120 ml Dessert bowl - 90 ml Creamer - 30 ml Ice cream - 60 ml Juice - 125 ml
Comments		

TOTAL INTAKE

Oral - intake to time of birth _____

Patient name _____

IV - initiation to time of birth _____

PLEASE RETURN TO Joy Noel-Weiss 613-228-1413

Appendix L - Data Collection - Newborn Weights

Factors Affecting Newborn Weight Loss Research Study

Infant Weight Chart **(includes first 72 hours if home)**

Baby's Age	Weight in GRAMS (NO CLOTHES AND NO DIAPER, please around same time each day, if possible)	Any Comments??	Security Bracelet included in weight? (check Yes or No)	
			YES	NO
birth or first weight	(pls specify baby's age for first weight on	study scale - e.g at 1hr or 3hrs)		
12 hours				
24 hours				
36 hours				
48 hours				
60 hours				
72 hrs/3 days				
4 days				
5 days				
6 days				
7 days				
8 days				
9 days				
10 days				
11 days				
12 days				
13 days				
14 days				

Thank you for helping with this part of the study

Date Started _____

Patient name _____

Appendix M - Data Collection - Neonatal Output

Participant's ID # _____

Factors Affecting Newborn Weight Loss Research Study

OUTPUT CHART (Diaper Weights)

Please write down the type and weight of one new dry diaper

1) Please weigh EACH USED diaper (be sure to ZERO the scale first)

2) Please keep diaper in plastic bag if you cannot weigh it right away

3) Please write down full weight [DO NOT subtract weight of dry diaper]

Brand of diaper _____ Weight of 1 dry diaper _____ gms

	Day 1 (1st 24 hrs)	Day 2 (2nd 24 hrs - 24-48 hrs)	Day 3 (3rd 24 hrs - 48-72 hrs)
may not need all spaces			
1st diaper (in grams)			
2nd diaper (in grams)			
3rd diaper (in grams)			
4th diaper (in grams)			
5th diaper (in grams)			
6th diaper (in grams)			
7th diaper (in grams)			
8th diaper (in grams)			
9th diaper (in grams)			
10th diaper (in grams)			
Were all diapers weighed on this day?			
If no How many diapers were not weighed?			
space for more diapers			
space for more diapers			
space for more diapers			
space for more diapers			

Patient name _____

Thank you for helping with this part of the study

Appendix N - Chart Audit Form

Participant's ID # _____

Factors Affecting Newborn Weight Loss Research Study**Maternal Chart Audit** (to be completed by Joy)

1. Infant's sex _____
2. Gestation in weeks and days?
_____ (number of weeks./days)
3. Neonate's weight at birth? _____ Age baby first weighed? (hours minutes)
_____ (grams) _____ (timing of first weight?)
4. What was the type of birth?
Planned caesarean..... 1
Unplanned caesarean..... 2
Vaginal.....3
5. Amount of time spent skin to skin with baby without
interruption? _____ (hours minutes)
6. Medications given during labour/surgery (epidural, oxytocin, narcotics)

7. Length of 1st stage _____ (hours) 2nd stage _____ (hours)
8. Interventions in the labour/birth (e.g. forceps, vacuum, epidural, induction)

9. Complications during the labour/birth?
(e.g. fever, prolonged 1st/2nd stage, meconium, baby needed suctioning)

10. Breastfed for the first time? _____ (number of hours after birth)
11. How many bottles of formula were used in the hospital? _____
12. Infant's age and weight at discharge _____

Appendix O - Postpartum Questionnaire

Postpartum (2 weeks) Questionnaire

Participant's ID # _____

These 20 questions will help the researcher learn about the participants in the study.

Please answer by FILLING IN THE BLANK or CIRCLING the number:

1. What type of care did you receive for the birth of your baby? **home or hospital?**
 Family Doctor..... 1
 Midwife.....2
 Obstetrician..... 3
2. How far along was your pregnancy when your baby was born?
 _____ (number of weeks)
3. What is your baby's sex? Female _____ Male _____
4. What was your baby's weight at birth?
 _____ (grams or lbs.) Time baby born?
5. What was the type of birth?
 Planned caesarean..... 1
 Unplanned caesarean..... 2
 Vaginal.....3
6. Describe any interventions in the labour/birth (e.g. forceps, vacuum, epidural, induction)

7. Describe any complications for you or your baby during the labour/birth
 (e.g. fever, prolonged 1st/2nd stage, meconium, baby needed suctioning)

8. When did you breastfeed your baby for the first time? first days - well medium poorly?
 _____ (number of hours after birth)
9. How much time did you spend skin-to-skin with your baby in the delivery/birthing room?
 _____ (total minutes or hours after birth)
10. How many bottles of formula did your baby receive in the hospital? _____ time of first _____
 reason _____
11. When did your milk come in? (day you felt fullness) _____ (birth is day 1)

...2

Appendix O (con)

-2-

Participant's ID # _____

12. How confident do you feel about breastfeeding? (circle one)

not at all									very much
1	2	3	4	5	6	7	8	9	10

13. Since leaving the hospital, which professional services have you used for breastfeeding help? _____
 (e.g. hospital clinic, public health nurse visits or phone calls, private lactation consultant)

Helpful? Yes _____ Not really _____

14. Among friends and family, who provides ongoing breastfeeding support for you?

Helpful? Yes _____ Not really _____

15. Describe any breastfeeding aids you have used? (e.g. nipple cream, breast pump, nipple shields, breast shells, supplemental nursing systems)

16. How much does your baby cry? (circle one)

not at all				very much
1	2	3	4	5

17. How helpful have friends and family been since coming home with the baby? (circle one)

not at all				very much
1	2	3	4	5

18. Did you have swelling (edema) **before** or **after** your baby's birth?
 (e.g. your rings would not fit, your ankles were puffy, specify before or after)

19. Please describe any difficulties you have had with breastfeeding
 (e.g. engorgement, sore nipples, thrush, plugged duct/mastitis)

20. Describe any significant health problems you or your baby have had since the birth
 (e.g. you - infection, postpartum hemorrhage, hypertension / your baby jaundice or dehydration)

Did you weigh your baby without a diaper?

When can I pick up the baby scale and forms?

Thank you

Appendix P - Week Two Infant Feeding Category

Participant's ID # _____

Telephone Questionnaire to Determine Feeding Category at Two Weeks

(please circle the number on the right that matches the definition)

Definitions for Infant Feeding

To ensure consistency in reporting duration rates, definitions for breastfeeding will be:

- (1) **Exclusively breastfed**: Fed at mother's breast **from birth** with 0-2 feeds of EBM per day
No other food or liquid except breastmilk [vitamins and meds do not count]
- (2) **Exclusively breastmilk fed**: Many or all feeds are EBM (3 or more EBM feeds every day)
No other food or liquid except breastmilk **from birth** [vitamins and meds do not count]
- (3) **Totally breastfed**: Fed at mother's breast with 0-2 feeds of EBM per day
No other food or liquid except breastmilk in past 7 days.
- (4) **Total breastmilk fed**: Many or all feeds are EBM (3 or more EBM feeds every day)
No other food or liquid except breastmilk in past 7 days.
- (5) **Predominant breastmilk**: Breastmilk plus 1 or 2 non-breastmilk (formula) feeds in past 7 days.
- (6) **Partial breastmilk**: Breastmilk plus 3 or more non-breastmilk (formula) feeds in past 7 days.
- (7) **No breastmilk**: No breastmilk given to infant/weaned

1. Is your baby being breastfed any amount as of today?

Yes.....[Go to question 2]

No.....[Go to question 4]

2. Has your baby had any food other than breastmilk (water, formula, tea, juice) **since birth**?

Yes, baby had supplements besides breastmilk.....[Go to question 3]

No, baby had only breastmilk since birth.....[specify how much EBM below]

How much pumped/expressed breastmilk (EBM) do you use?

Usually 0-2 feeds of EBM per day → **Exclusively Breastfed**.....(1)Usually 3 or more/all EBM per day → **Exclusively Breastmilk Fed**.....(2)

3. How much has your baby been **supplemented in the past 7 days**? (see definitions above for category)

Totally breastfed fed at mother's breast [0-2 feeds of EBM per day].....(3)**Total breastmilk fed** past 7 days [3 or more feeds of EBM per day].....(4)**Predominant breastmilk** [1 or 2 non-breastmilk feeds].....(5)**Partial breastmilk** [3 or more non-breastmilk feeds].....(6)

What was the supplement? _____

4. Weaned

No breastmilk.....(7)

If not breastfeeding, how old was your baby (in days) when you stopped breastfeeding? _____

Please describe your reason/s for stopping _____

Does your baby use a pacifier/soother? No___ Yes___ if yes, then how often _____ (per day)

(Breastfeeding Committee of Canada, 2006; Labbok & Krasovec, 1990)

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Appendix Q - Steps for Managing Data

Based on the collection periods, these are the steps that the researcher completed:

A. When a registration package was received, the researcher

1. added the name to a confidential list and assigned a participant number;
2. wrote the participant number on all registration package sheets;
3. emailed or phoned the participant to acknowledge registration;
4. informed the hospital of participant's enrollment - faxed TOH and brought a copy of fluid sheet with participant's name and EDC to other hospitals;
5. placed a coloured sticker on calendar to note due date; and
6. filed contact info sheet and consents.

B. Once informed of the baby's birth, the researcher

1. prepared 2 week follow up questionnaire with DOB and date for two week follow up;
2. brought a scale to the hospital to replace the one being used;
3. completed a chart audit and picked up maternal fluid sheet; and
4. filed the data sheets.

C. When a participant's baby was two weeks old, the researcher

1. called to make an appointment for the postpartum questionnaire;
2. phoned and completed the questionnaire and feeding category sheets;
3. arranged to pick up the baby scale;
4. picked up the scale and measurement sheets;
5. numbered and filed all data collection sheets; and
6. calibrated, sanitized, and wrapped the scale.

Appendix R - Posters for Nurses

**Newborn Weight Loss Study
Please Remember****Before Birth**

Both IV and oral fluids are recorded on Maternal Fluid Chart which mother takes home with her.

At Birth

Hospital weight is used for first weight in study

Following Birth

- Mothers weigh diapers and baby - instructions for scale use & safety included
- Mothers chart baby weights on a pink sheet
- Study weights are not to be documented in patient chart

About Diapers

- Mothers weigh diapers for 3 days
- **PLEASE DO NOT THROW AWAY DIAPERS** without weighing
- Diaper may put in a plastic bag if it cannot be weighed right away (e.g. nighttime)
- Mothers chart diaper weights on a yellow sheet

About Discharge

- **SAME** baby scale is taken home (important for consistent weight measurement)
- Mother takes data collection sheets home with her
- Mother maintains data collection until baby is 2 weeks old (weight of diapers & q 12 hour baby weights x 3 days; then daily baby weight x Days 4-14)
- Joy follows up at 2 weeks

Thank you for your help with data collection

Joy Noel-Weiss

Appendix S - Gentle Reminders

**Newborn Weight Loss Study
Gentle Reminder
Birth Nurses**

When a women tells you that
she is in the study:

1. Please complete a fluid sheet
(available in the study binder)
2. Please inform the postpartum
nurses

Newborn Weight Loss Study

Birth Nurse

Completed ☐ Not Completed ☐ Date _____

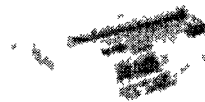
Postpartum Nurse

Completed ☐ Not Completed ☐ Date _____

**Newborn Weight Loss Study
Gentle Reminder
Postpartum Nurses**

When a women tells you that
she is in the study:

1. Please give her a study scale
(available in Room 40)
2. Please do not throw out diapers
until they have been weighed
(may save in plastic bag - for
example overnight or in SCN)



Appendix T - Steps for Hospital Unit Binders



Factors Affecting Newborn Weight Loss

Steps in the Research Study at TOH

Prenatally:

- Inclusion criteria are women expecting a single baby and planning to breastfeed, able to read and write in English, recruitment is through physician offices and prenatal classes
- First questionnaire completed

During labour or prior to C-section (emergency or pre-booked):

- Nurses collect data about fluids (see one-page chart)
- N.B.: data collection at this point is key to determining if there is a relationship between fluids received prior to birth and the amount of newborn weight loss

When her baby is born (see data collection envelope with scales):

- After mother gives birth, she receives a study baby scale to weigh diapers and baby - it can be labelled with mother's name and should only be used by her
- Mother begins data collection (two forms - pink baby weights & yellow diaper weights)
- First weight on study scales is called birth weight regardless of time
- 1-2 study baby scales are stored at TOH and the Joy Noel-Weiss has back up scales

When mother and baby go home:

- **SAME** baby scale is taken home (important for consistent weight measurement)
- Mother maintains data collection until baby is two weeks old (weight of diapers, and q 12 hour baby weight x first 72 hours; then daily baby weight x Days 4-14)
- Day 14 - last questionnaire is completed by telephone and study baby scale is picked up from mom by Joy or research assistant
- Joy completes a chart audit for each participant

Any questions or concerns can be addressed to the researcher:

Joy Noel-Weiss

1

m

Thank you for your help with data collection.

Appendix U - Weight Conversion Chart

Pounds and ounces to grams

	0	1	2	3	4	5	6
0	0	454	907	1361	1814	2268	2722
1	28	482	936	1389	1843	2296	2750
2	57	510	964	1417	1871	2325	2778
3	85	539	992	1446	1899	2353	2807
4	113	567	1021	1474	1928	2381	2835
5	142	595	1049	1503	1956	2410	2863
6	170	624	1077	1531	1984	2438	2892
7	198	652	1106	1559	2013	2466	2920
8	227	680	1134	1588	2041	2495	2949
9	255	709	1162	1616	2070	2523	2977
10	284	737	1191	1644	2098	2551	3005
11	312	765	1219	1673	2126	2580	3033
12	340	794	1247	1701	2155	2608	3062
13	369	822	1276	1729	2183	2637	3090
14	397	850	1304	1758	2211	2665	3119
15	425	879	1332	1786	2240	2693	3147

	7	8	9	10	11	12	13
0	3175	3629	4082	4536	4990	5443	5897
1	3204	3657	4111	4564	5018	5472	5925
2	3232	3685	4139	4593	5046	5500	5953
3	3260	3714	4167	4621	5075	5528	5982
4	3289	3742	4196	4649	5103	5557	6010
5	3317	3771	4224	4678	5131	5585	6039
6	3345	3799	4252	4706	5160	5613	6067
7	3374	3827	4281	4734	5188	5642	6095
8	3402	3856	4309	4763	5216	5670	6124
9	3430	3884	4338	4791	5245	5698	6152
10	3459	3912	4366	4819	5273	5727	6180
11	3487	3941	4394	4848	5301	5755	6209
12	3515	3969	4423	4876	5330	5783	6237
13	3544	3997	4451	4905	5358	5812	6265
14	3572	4026	4479	4933	5386	5840	6294
15	3600	4054	4508	4961	5415	5868	6322

Appendix V - Copyright Permission for Article 2

From: Joy Noel-Weiss [mailto:
Sent: Tuesday, May 25, 2010 5:46 PM
To: ,
Subject: FW: Permission for Manuscript ID JHL-10-01-001

-----Original Message-----

From: Hutchinson, Adele on behalf of permissions (US)
Sent: Mon 5/24/2010 4:43 PM
To: Joy Noel-Weiss
Cc: Journal of Human Lactation; Ballinger, Jim
Subject: RE: Permission for Manuscript ID JHL-10-01-001

Dear Joy,

Thank you for your request. Please consider this written permission to reuse your article detailed below in your dissertation. Please include proper attribution to the original source. Please note that this permission does not include any 3rd party material found within the work. I have provided the link to our author reuse page: http://www.sagepub.com/repository/binaries/journals/permissions/author_use.doc

"Lactation and Breastfeeding Research Studies: who Should Provide Consent for the Neonate?" by Joy Noel-Weiss, A. Kirsten Woodend, & Sonya Kujawa-Myles (J Hum Lact. 26(2):180-182).

Best,
Adele

From: Joy Noel-Weiss [mailto:
Sent: Friday, May 21, 2010 5:38 AM
To:
Subject: Permission for Manuscript ID JHL-10-01-001

Dear Dr Heinig

I hope this email finds you well. I am not sure how to go about asking for permission to use the recently published article I coauthored.

The topic is the result of issues I encountered when seeking ethics review approval for my doctoral thesis (dissertation), and I want to add the article to my thesis.

How do I seek permission to use it now that Sage owns the copyright?

Your help or the help of someone you work with would be much appreciated.

Joy

Joy Noel-Weiss RN IBCLC PhD(c)
Lecturer/Chargée de cours
École des sciences infirmières/School of Nursing
University of Ottawa/Université d'Ottawa
451 Smyth RGN3249C

Appendix W - Statements of Contribution



uOttawa

STATEMENT OF CONTRIBUTIONS FORM

September 2, 2010
(Date)

To Whom It May Concern:

The present is to confirm that

Joy Noel-Weiss
(Student Name)

contributed as a whole to the manuscript entitled:

Physiological Weight Loss in the Neonate: A Systematic Review

(Name of Supervisor)

in his/her role as supervisor,

and Genevieve Courant

(Names of co-authors, if appropriate)

Guided the work and made editorial suggestions for the manuscript

[Signature]
Student Signature

[Signature]
Supervisor Signature



uOttawa

STATEMENT OF CONTRIBUTIONS FORM

September 8, 2016
(Date)

To Whom It May Concern:

The present is to confirm that

Joy Noel-Weiss
(Student Name)

contributed as a whole to the manuscript entitled: _____

Lactation and Breastfeeding Studies: Who Should
Provide Consent for the Neonate?

Dr. A.K. Woodend
(Name of Supervisor)

in his/her role as supervisor.

and Sonya Kijawa-Myles

(Names of co-authors, if appropriate)

Guided the work and made editorial suggestions for the manuscript

[Signature]
Student Signature

Supervisor Signature



uOttawa

STATEMENT OF CONTRIBUTIONS FORM

September 2011
(Date)

To Whom It May Concern:

The present is to confirm that

Joy Noel Weiss
(Student Name)

contributed as a whole to the manuscript entitled: Maternal Fluids
During Parturition, Neonatal Output, & Newborn
Weight Loss An Observational Study to Determine Relationships

Dr. A.K. Woodend in his/her role as supervisor,
(Name of Supervisor)

and Wendy Peterson
Bill Gibb
Dianne Grell
(Names of co-authors, if appropriate)

Guided the work and made editorial suggestions for the manuscript

Student Signature

(

Supervisor Signature