

**IN HEALTHY FULL AND LATE PRE-TERM BABIES, DOES DELAYING THE
FIRST BATH UNTIL AT LEAST 24 HOURS OF LIFE EFFECT IN-HOSPITAL
BREASTFEEDING RATES, THERMOREGULATION AND GLYCEMIC
CONTROL?**

By

© Susan Warren

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ABSTRACT

Objective: To determine if delaying a newborn's first bath until at least 24 hours of life, as recommended by the World Health Organization, effects in-hospital breastfeeding rates, infant hypothermia rates and/or infant hypoglycemia rates.

Methods: Retrospective cohort study comparing 680 infants bathed before 24 hours to 545 infants bathed after 24 hours. The primary outcome was comparison of the rates of in-hospital breastfeeding initiation and exclusive breastfeeding at discharge. Secondary outcomes were a comparison of rates of infant hypothermia and hypoglycemia.

Results: Exclusive breastfeeding rates were 33% higher in the delayed bathing cohort compared to the early bathing cohort (AOR 1.334, 95% CI 1.049-1.698, $p=0.019$). No significant difference in breastfeeding initiation rates were observed in the total population or high-risk subgroup but in the average risk subgroup there was a significant 43% increase in breastfeeding initiation rates when bathing was delayed (AOR 1.433, 95% CI 1.008-2.039, $p=0.045$). Infants bathed after 24 hours were 2.5 times more likely to experience a hypothermic event than those bathed before 24 hours (AOR 2.524, 95% CI 1.239-5.142, $p=0.011$). No significant differences in rates of hypoglycemia were observed (AOR 0.916, 95% CI 0.421-1.994, $p=0.826$).

Conclusions: Delaying newborn bathing was associated with increased likelihood of exclusive breastfeeding at discharge and increased rates of hypothermia.

Keywords: Delayed newborn bathing, infant bathing, breastfeeding, hypothermia, hypoglycemia.

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* High risk babies are those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of diabetic mothers.

** Average risk babies are those > 36 weeks gestation, average size for gestational age and born of non-diabetic mothers

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LIST OF ABBREVIATIONS

| | |
|--------------|---|
| AF | Amniotic Fluid |
| AOR | Adjusted odds ratio |
| BFI | Breast feeding initiation |
| CI | Confidence interval |
| EBFD | Exclusive breastfeeding at discharge |
| GDG | Guideline development group |
| HEP B | Hepatitis B |
| HEP C | Hepatitis C |
| HIV | Human Immunodeficiency Virus |
| MM/L | Millimoles per litre |
| MRSA | Methicillin-resistant staphylococcus aureus |
| RCT | Randomized control trial |
| SD | Standard deviation |
| SPSS | Statistical package for the social sciences |
| SSC | Skin-to-skin contact |
| WHO | World Health Organization |

Chapter 1: Introduction

1.1 Background and Rational

It has been suggested that delivery room and postpartum hospital routines and practices may significantly disrupt a newborn's adjustment to the extra-uterine environment as well as early maternal-infant interactions including breastfeeding (Anderson, Chiu, Dombrowski, & Swinth, 2003; Winberg, 1995; Winberg, 2005; Anderson, Chiu, Morrison, Burkhammer, & Ludington-Hoe, 2004). Infant birthing and care practices have, and continue to evolve based on emerging evidence in an attempt to achieve the healthiest birthing and neonatal care possible. One such practice is that of newborn bathing.

At birth newborns experience a dramatic change from an intra-uterine aquatic environment to an extra-uterine atmospheric environment. This change requires adjustment of all organ systems of their body and is impacted by the actions and procedures of health care staff. Newborn bathing and the timing of it, has the potential to affect and possibly disrupt the newborns adjustment to the extra-uterine environment. These effects include: disruption of breastfeeding, increased maternal-infant separation, negative impacts on infant thermoregulation and glycemic control as well as the removal of potentially protective biological substances. These factors independently affect newborn wellbeing and are interconnected in their role in newborn adjustment.

The most commonly referenced guideline for newborn bathing practices is the World Health Organization's (WHO) "Recommendations on Postnatal Care of the Mother and Newborn" (World Health Organization, 2013). These guidelines state that

“Bathing should be delayed until 24 hours after birth”. The WHO has also included this delayed bathing recommendation as part of their Baby-friendly Hospital Initiative (BFHI), a global effort to implement practices that protect, promote and support breastfeeding.

Although an increasing number of hospitals are adopting delayed bathing policies and numerous public health organizations like the WHO are recommending they do so, there is limited published clinical evidence on the subject. To date, there is only one known published study on the impact of delayed bathing on breastfeeding (Preer, Pisegna, Cook, Henri, & Philipp, 2013). Similarly, there has been only one study conducted examining the impact of delayed bathing on hypoglycemia rates (McInerney & Gupta, 2015). In both of these studies delayed bathing was at 12 hours, not the 24-hour delay recommended by the WHO. The effect of timing of newborn bathing on thermoregulation has been examined in two studies but again both compared very early bathing times not the 24-hour delay recommended by the WHO. Penny-MacGillivray (1996) compared the impact on thermoregulation of bathing newborns at 1 hour of life versus 4 hours and Varda and Behnke (2000) examined the thermoregulation impact of bathing newborns at 1 hour of life versus 2 hours of life. There are no studies assessing the clinical effects of the specific recommendation by the WHO to delay newborn bathing by 24 hours.

Historically babies born in western hospital settings were bathed within the first 4 hours of life. This typically occurred during transfer from the delivery room to maternity ward and was performed by a nurse. This practice was based the premise that bathing is essential to prevent cross-contamination from newborns to health care providers. The

timing of bathing was based on thermoregulation theory and dictated that admission bathing of newborns be delayed until normal body temperature is achieved and maintained (Public Health Agency of Canada, 2000; Health and Welfare Canada, 1987). No evidence has been reported that indicates when thermoregulation of the newborn is complete, nor has any evidence been reported that supports delaying the bathing of newborns until normal body temperature is sustained. The reasons cited for health care professionals bathing newborns are to conduct a physical assessment, to reduce the effect of hypothermia, and to allow the mother to rest. Frequently cited as a reference for these practices is the research of Fredrick Leboyer who advocated bathing immediately following birth as part of what is commonly referred to as the Leboyer method (Leboyer, 1975).

Published literature on newborn bathing frequently suggests that early bathing may negatively impact infant hypothermia, hypoglycemia and breastfeeding despite a lack of published research to validate this practice (Penny-MacGillivray, 1996; Varda & Behnke, 2000; Medves & O'Brien, 2004; Bramson, et al., 2010; Moore, Anderson, Bergman, & Dowswell, 2012; Preer, Pisegna, Cook, Henri, & Philipp, 2013). These data also suggest that the impacts of early newborn bathing are not mutually exclusive. Instead, these outcomes are related. Bathing reduces infant temperature which may subsequently affect glycemic control. Infant hypothermia and hypoglycemia can impair breastfeeding which can in turn further perpetuate hypothermia and hypoglycemia (World Health Organization, 1993). Newborn bathing may negatively impact thermoregulation and glycemic control but also requires physical separation of mother and infant and decreased skin-to-skin time which may further hinder infant thermoregulation and

glycemic control as well as impair breastfeeding. The removal of biologic fluids which are believed to be involved in mother-infant signaling may further compounds these negative effects.

In response to the WHO's recommendation and BFHI there has been increasing adoption globally, of hospital policies to delay newborn bathing despite very limited clinical evidence in support of this practice. In March 2015, the Janeway Children's Health and Rehabilitation Center in St. John's Newfoundland adopted a new policy to delay newborn bathing. The policy states that "the healthy newborn's bath should be delayed until the infant is at least 24 hours of age in order to decrease cold stress and energy expenditure and improve parental bonding". It further specifies that "Babies born < 36 weeks gestation (near term protocol), SGA, LGA are at risk for hypoglycemia and should not be washed until 24 hours of age. If parents request an earlier bath, staff should counsel/explain the risks of delaying the bath and the associated benefits for the near term newborn". The implementation of this new policy presented an opportunity to examine the clinical impacts of delayed newborn bathing on newborn breastfeeding rates, hypoglycemia and hypothermia.

Although breastfeeding is known to provide the best possible nutrition to babies with extensive and well documented health benefits, Newfoundland and Labrador consistently has the lowest rates of breastfeeding in Canada. Recent research indicates that prior to delivery, approximately 65% of pregnant women in NL report intention to exclusively breastfeed their infants for 6 months, yet national statistics show that only 16% of women in the province do so (Statistics Canada., 2014). Provincial breastfeeding initiation rates average 72.0%, but are as low as 53.5% in some rural regions (Eastern

Health, 2015), compared to an average of 90.4% in Canada as a whole (Statistics Canada., 2014). Over the past several years, considerable effort has been put forth to improve breastfeeding supports and improve breastfeeding rates within the province. The collaborative work of the Baby-friendly Council of Newfoundland, the Perinatal Program of Newfoundland and Labrador (PPNL) and the Breastfeeding Research Working Group of Memorial University has made significant strides in identifying and addressing barriers to breastfeeding. A number of initiatives, educational programs and policy changes aimed at fostering breastfeeding in the province have been instituted. As a result, the rate of breastfeeding at neonatal screening has increased over the past 30 years from 35.3% in 1986 to 74.2% in 2016 (Perinatal Program Newfoundland and Labrador, 2016). Despite successful efforts to improve breastfeeding rates in the province they continue to lag behind the national average. 2016 breastfeeding initiation rates in NL were 77.2% compared to 89.9% in Canada (Statistics Canada, 2018). Continued efforts and practice changes are being instituted to support breastfeeding within the province. The ‘delay the bath policy’ is an example of one such change.

1.2 Purpose

The purpose of this research is to examine the effects of delaying newborn bathing until at least 24 hours of life on breastfeeding rates, glycemic control and thermoregulation. This will be accomplished by comparing the rates of breastfeeding, hypoglycemia and hypothermia, before and after implementation of the hospital’s policy to delay newborn bathing until at least 24 hours of life.

1.3 Research Questions

The current study was designed to answer the following questions; In healthy, full (≥ 37 weeks gestation) and late pre-term babies (≥ 34 weeks gestation), does delaying newborn bathing by 24 hours effect;

1. In-hospital breastfeeding initiation and/or exclusive breastfeeding at discharge.
2. Infant blood glucose levels
3. Infant thermoregulation

1.4 Summary

The care and treatment of newborns immediately following birth and for the first few days of life significantly impacts their adjustment to the extra-uterine world. The general health and well being of newborns and subsequent breastfeeding success are affected by the actions of not only their mother but of health care providers as well as hospital policy and procedure. Emerging research has guided change in practice to allow mother and baby the best opportunities for health and breastfeeding success. Delayed newborn bathing is an example of evolving practice that has the potential to decrease infant health risks and support breastfeeding. This research aims to provide evidence for the effects of delayed newborn bathing.

Chapter 2: Literature Review

The purpose of this literature review is to appraise, summarize and discuss the knowledge gaps in the published studies on newborn bath timing and its effects on breastfeeding rates, hypoglycemia and hypothermia. This review will outline the evidence supporting the influence of skin-to-skin contact and bio-fluids on breastfeeding rates, hypoglycemia and hypothermia. In addition to the removal of potentially beneficial naturally occurring bio-fluids, bathing requires a physical separation of mother and child, disrupting skin-to-skin and bonding time. Evidence suggests that these natural processes are inextricably related to the outcomes of interest in this research and will thus be examined in this review.

The first section of this review begins with a summary of the current clinical practice guideline recommendations for new born bath timing and concludes that there is limited clinical evidence to support or refute these guidelines. The second section outlines the evidence on the removal of bio-fluids and the disruption of skin-to-skin as they relate to breastfeeding rates, hypoglycemia and hypothermia. In sections, three, four and five, the clinical literature on the effects of newborn bath timing on 1) breastfeeding rates, 2) hypothermia and 3) hypoglycemia is reviewed and appraised. Finally, section six will summarize the presented literature and identify the current knowledge gaps.

2.1 Recommendations for Infant Bathing

The most commonly referenced clinical practice guidelines for newborn bathing practices is the World Health Organization (WHO)'s "Recommendations on Postnatal

Care of the Mother and Newborn” (World Health Organization, 2013). These guidelines state that “Bathing should be delayed until 24 hours after birth. If this is not possible due to cultural reasons, bathing should be delayed for at least six hours”. No specific recommendations are made for pre-term or late pre-term infants and this recommendation is assumed to apply to all newborns. Recommendations made in this report are graded as “strong” or “weak” based on the quality of evidence reviewed by the Guideline Development Group (GDG). In the recommendation to “delay infant bathing” no evidence grading was cited. Instead the WHO states that this recommendation is based on existing WHO guidelines. An exhaustive search of all existing WHO guidelines and reports produced no cited reference evidence for this recommendation. Earliest reference to delaying newborn bathing appears in a report entitled “Thermal Control of the Newborn: a practical guide” (World Health Organization, 1993) but again no evidence is cited. This reinforces what was discovered in the current literature search in that there is little if no evidence to support an improvement in clinical outcomes when delaying the timing of newborn bathing despite recommendations to delay it.

Save the Children, USAID/CORE group and The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), all recommend delaying infant bathing for at least 8 (AWOHNN) to 24 hours post delivery (USAID/CORE Group, 2004; Save the Children, 2010; AWHONN, 2007). All of these guidelines cite the WHO as their primary reference for the recommendation.

The Public Health Agency of Canada’s most recent guidelines were published in 2000 and entitled: Family-Centered Maternity and Newborn Care: National Guidelines (FCMNC). With respect to newborn bathing these guidelines state “Newborn babies are

bathed primarily for esthetic reasons. Such bathing should thus be postponed until thermal and cardiorespiratory stability is ensured.” (Public Health Agency of Canada, 2000). As these Canadian guidelines do not specify a timeline for bathing, most Canadian hospitals reference the WHO’s guidelines in their delayed bathing policies.

Research for this review revealed that the most frequently cited reference for delayed bathing policies is the WHO or their Baby-friendly Hospital Initiative (BFHI), a global effort to implement practices that protect, promote and support breastfeeding (World Health Organization, UNICEF, 2009). Despite being the basis for most hospital bathing policies as well as many neonatal practice guidelines, review of published literature and WHO references reveals little to no published evidence for this recommendation. There is thus an urgent need for research on the clinical implications of newborn bath timing and to specifically evaluate the WHO’s recommendation to delay newborn bathing by at least 24 hours post-delivery.

2.2 Interrelated Effects of Early Newborn Bathing

Published literature suggests that newborn bathing has the potential to impact breastfeeding success, infant hypothermia and hypoglycemia. These outcomes are not mutually exclusive and are further impacted by mother/infant skin-to-skin contact (SSC) and the presence of biofluids and olfactory cues which are also impacted by bathing. Understanding the evidence surrounding the potential clinical impact of early newborn bathing requires discussion of the complex relationship between infant hypothermia, hypoglycemia, breastfeeding, SSC, biofluids and olfactory cues.

Early newborn bathing defined as bathing within 24 hours of life may: i) impede breastfeeding success (Preer, Pisegna, Cook, Henri, & Philipp, 2013), ii) increase infant hypothermia (Smales & Kime, 1978; Bergström, Byaruhanga, & Okong, 2005; Takayama, Wang, Uyemoto, Newman, & Pantell, 2000) and iii) increase infant hypoglycemia rates (McInerney & Gupta, 2015). Early bathing also imposes a physical separation of mother and baby which interferes with SSC and removes biofluids and olfactory cues required for adaptation to extra-uterine life. These effects are inter-related in that:

- a) Infant hypothermia and hypoglycemia can impair breastfeeding which can in turn further perpetuate hypothermia and hypoglycemia (World Health Organization, 1993),
- b) Bathing reduces infant temperature which may subsequently affect glycemic control (Cohen, Kenner, & Hollingsworth, 1991; Greer, 1988; Sinclair, 1992),
- c) Decreased skin-to-skin contact can negatively impact breastfeeding success as well as thermoregulation and glycemic control (Moore, Bergman, Anderson, & Medley, 2016; Durand, et al., 1997; Mazurek, et al., 1999) and,
- d) Bathing potentially removes biofluids (like vernix) that can act to regulate temperature as well as chemical cues (like amniotic fluid) that can aid in breastfeeding (Hoath, Pickens, & Visscher, 2006; Saunders, 1948; Shaulak, 1963; Schaal, Marlier, & Soussignan, 1995; Varendi, Christensson, Porter, & Winberg, 1998; Porter, Varendi, & Winberg, 1996).

There is thus a complex relationship between skin-to-skin contact, biofluids and olfactory cues, breastfeeding and infant thermoregulation and glycemic control. Newborn bathing

has the potential to impact any and all of these processes, functions and outcomes which may, in turn, impact each other. Examination of the effects of newborn bathing requires consideration of these interrelations.

2.2.1 Biofluids and Olfactory Cues.

The gestation and birthing of newborns results in the deposit of a number of biological fluids and substances on a newborns skin. Although there is much research to be done in this area, current available science suggests that these biological substances play a crucial role in newborns adaptation to the extra-uterine environment, their protection, growth and development, as well as breastfeeding success (Shaulak, 1963; Hoath, Pickens, & Visscher, 2006; Varendi, Porter, & Winberg, 1994). Accumulation evidence supports the hypothesis that newborns respond to familiar chemical cues present in their intrauterine environment and these cues play an important role in early food seeking behaviour in infants (Varendi, Porter, & Winberg , Attractiveness of amniotic fluid odor: evidence of prenatal learning?, 1996). Evidence also suggests that biological substances like vernix caseosa may provide protection from cold stress. The removal of biofluids through bathing may thus result in increased incidents of hypothermia as well as impede the chemical signaling during skin-to-skin bonding and the neurobehavioural reflex pattern that results in successful breastfeeding.

2.2.1a Vernix Caseosa.

Vernix caseosa is a white, creamy, naturally occurring biofilm covering the skin of the fetus during the last trimester of pregnancy. If not washed away after birth, vernix

presence on newborn skin acts as a barrier to moisture and heat loss, has antimicrobial and antioxidant properties and can act as a skin cleanser. For the purpose of this research evidence for the role of vernix caseosa in thermoregulation and breastfeeding will be presented.

Despite frequent reference in published literature to the potential impact of vernix caseosa on infant thermoregulation (Shaulak, 1963; Hoath, Pickens, & Visscher, 2006), very few studies have been published on the subject and results are conflicting.

Saunders (1948) published a retrospective cohort study comparing the incidents of subnormal temperatures ($>97^{\circ}\text{F}$) in premature infants weighing less than 5 pounds, born before a policy change to retain vernix caseosa immediately post-delivery, to those born after the policy change at the National Maternity Hospital in Dublin. Saunders reported a 28.2% incidence of subnormal temperatures in those infants for whom vernix caseosa was removed versus a 19.1% incidence of subnormal temperatures in infants whose vernix caseosa was not washed off but allowed to separate naturally. Saunders conclusions that “It would appear that vernix caseosa may influence heat control” are the earliest reported reference to the potential function of vernix caseosa in temperature regulation. Being published in 1948 this study lacks much of the detail required of modern publications. Results obtained in this study are reported in a table containing the actual number of subnormal temperatures observed and the percentage per year that this represents. The statistical significance (p values) of these results are not reported. Authors merely state that “considerable reduction in the number of cases of subnormal temperature” occurred but do not mention whether or not these results were statistically significant. The author does not provide a description of the pre-policy change procedure for removal of vernix

caseosa nor the average time at which it was removed. There is no mention of how or when infant temperatures were measured, only that they were recorded for the first seven days of life. Subject selection procedure is also not discussed and thus the potential for selection bias cannot be assessed. Although reported results of this study support the hypothesis that the retention of vernix caseosa may decrease incidents of infant hypothermia, this publication is lacking in much of the detail required for critical appraisal.

In 2005 Visscher et al. conducted a randomized control trial of 130 infants born at 32 to 41 weeks gestation excluding those with major congenital abnormalities or a need for resuscitation (Visscher, Narendran, Pickens, LaRuffa, & et al, 2005). Infants were randomly assigned to one of two treatment groups. For Group A, amniotic fluid and blood were blotted with an absorbent towel, but vernix was retained on the skin surface (n=66). In Group B, vernix, amniotic fluid and blood were removed by firm wiping (n=64). Axillary temperatures were measured at 30 and 60-minutes after fluid removal. During the 60-minute period, the infants were bundled and placed with the parents. Results found that axillary temperatures during the first hour for the vernix retained group were 98.1 ± 0.9 (mean \pm SE) and $98.1 \pm 1.0^{\circ}\text{F}$ at 30 and 60 minutes, respectively. For the vernix removed group, temperatures were 98.3 ± 1.1 and $98.1 \pm 0.9^{\circ}\text{F}$ at 30 and 60 minutes, respectively. Authors concluded that “vernix retention had no significant effect on thermal regulation in our population”.

The differences in results observed in these two trials may be attributed to the weight differences between infants enrolled in these studies. Saunders’ study only included infants weighing less than 5lbs where as the mean weight of infants in

Visscher's study was 7.7 pounds. Lower birth weight babies are at greater risk of heat loss due to their disproportionate body mass-to-surface ratio, less thermal-insulating subcutaneous tissue and undeveloped vasomotor response to cold stress (Polin , Abman, Rowitch, & Benitz, 2016; Lyon , Pikaar, Badger, & McIntosh , 1997). It is thus possible that the lower weight infants in Saunders study were more vulnerable to heat loss when vernix was removed.

Despite a lack of definitive evidence that vernix prevents heat loss in newborns the fact is that post bath, we are exposing damp skin, without it's natural protective vernix barrier at a time when temperature regulation is vital.

There is ongoing investigation into the possibility that vernix caseosa contains pheromones which may contribute to olfactory cues between newborns and caregivers aiding in bonding and breastfeeding (Hoath, Pickens, & Visscher, 2006). Whether vernix caseosa is a source of olfactory pheromones similar to amniotic fluid and breastmilk is unknown, but is consistent with the fact that many pheromones are derived from glandular skin secretions.

Traditional nursing practices have been to wipe vernix caseosa from newborns immediately after birth and to bathe newborns during transition from case room to mothers' room removing any remaining vernix. Evidence has shifted practice away from the removal of vernix. The National Association of Neonatal Nursing (NANN) and the Association of Women's Health Obstetrical and Neonatal Nursing (AWHONN) joint consensus statement directs that "removal of all vernix is not necessary for hygienic reasons" and "vernix may provide antibacterial promotion and wound healing" (Association of Women's Health Obstetrical and Neonatal Nurses (AWHONN) and

National Association of Neonatal Nursing (NANN) , 2001). The WHO also recommends leaving vernix caseosa intact after birth (World Health Organization, 1993). The removal of vernix through bathing potentially hinders the chemical and olfactory cues involved in mother-child bonding and breastfeeding as well as disrupts natural antimicrobial, thermoregulatory and moisture protection.

2.2.1b Amniotic Fluid

Newborns have been shown to respond positively to the odor of their own amniotic fluid (AF) (Schaal , Marlier, & Soussignan, 1995; Varendi, Porter, & Winberg , 1996). Although further research is required on the biological and clinical relevance of this, it has been suggested that prenatal familiarisation with odors that are likely to continue to be encountered immediately after birth may help newborns adapt to the extra-uterine environment and aid in breastfeeding success.

Varendi et. al (1998) demonstrated that babies exposed to a cloth treated with AF during the 60-min period beginning 30 min after birth, spent less time crying than did unexposed control babies or neonates exposed to a pad previously worn over their mother's breast/axillae. The effect was considered an olfactory response since none of the subject infants had direct physical contact with the stimulus. Authors concluded that “exposure to the odor of AF had a calming effect on newborn infants, at least as measured by their crying behavior”. They proposed that “in the natural setting the baby was held by the mother immediately after delivery without cleaning, as seen in the great apes, and was thus continuously exposed to the familiar odor of AF. This might have made the transition from intrauterine to extrauterine life appear less abrupt”.

There has been some epidemiological work published suggesting that the presence of amniotic fluid aids in breastfeeding and consequently the removal of it through bathing may hinder breastfeeding. Porter et al (1996) assessed newborns response to the odor of amniotic fluid when attempting to locate the nipple and latch for the first time. Using a sterile gauze pad, they transferred amniotic fluid to the nipple and areola of one breast and placed the naked newborn on mothers' chest with nose to the midline of mothers' sternum and eyes at the level of the nipple allowing baby to sample olfactory signals from both sides of mothers' chest. They observed that 23 of the 30 newborns chose the AF treated breast while only 7 chose the naturally scented breast. They propose that this attraction, based on olfactory cues, played an important role in earlier human birthing and feeding experiences. Throughout most of our evolutionary history it was common for mothers to handle their babies during and following delivery. The mothers' hands would have thus been covered with birth fluids which would have likely been transferred to their breast during the initial attempt to feed. In this context, newborns recognition of AF odor would have played a role in nipple location. In current context, AF transferred from an unwashed newborn to mothers' breast during skin-to-skin contact could guide the newborn to the nipple for initial feeding.

Vernix and amniotic fluids have been shown to contain antimicrobial peptides believed to aid in the bacterial colonization of both infant skin and gut (Walker, et al., 2008; Akinbi H. T., Narendran, Pass, Markart , & Hoath , 2004; Visscher, Narendran , Pickens , LaRuffa, & et al, 2005). The removal of these substances through bathing may interfere with development of necessary skin and gastrointestinal microbiome.

Newborns emerge from the womb blanketed in amniotic fluid, vernix caseosa, a flora of bacterium as well as chemical and biological substances which emerging evidence suggests play a role in the newborns adjustment to the extra-uterine environment. Removal of these substances, during bathing, has been suggested to have a negative effect on the newborn as well as infant-maternal interactions. Of most notable concern is the impact on breastfeeding and infant thermoregulation. Removal of these substances through early newborn bathing may unnecessarily place infants at risk for hypothermia as well as impede breastfeeding.

2.2.2 Skin-to-Skin Contact and Mother-Infant Bonding Disruption.

The role of biofluids and olfactory cues are underscored by the role of mother-infant physical contact or skin-to-skin contact (SSC). A number of studies have been published on the important role of SSC in mother-infant bonding and newborns adaptation to the postnatal environment. It has been shown that a healthy newborn infant has an inborn sequential behavioral pattern during the first hours of life if placed skin-to-skin on the mother's chest. Gradually, the newborn displays sucking and rooting reflexes, fists the hand, brings the hand to its mouth and usually between 30 mins and one hour after birth, finds the mother's breast and begins suckling (Widström, et al., 1987; Nissen, et al., 1995; Widström, et al., 2011; Righard & Alade, 1990; Varendi, Christensson , Porter, & Winberg, 1998). These reflexes are postulated to be aided by biological olfactory cues and require uninterrupted SSC between mother and infant immediately following delivery and lasting for a minimum of one hour. In addition to being necessary to facilitate a newborns innate behavior leading to breastfeeding, SSC has been shown to

regulate infant temperature and glucose levels. Early newborn bathing not only removes biological fluids that aid in the chemical messaging required to facilitate this natural sequence of events it imposes physical separation of mother and infant further disrupting this critical stage of newborns adaptation.

A 2016 systematic review entitled “Early skin-to-skin contact for mothers and their healthy newborn infants” (Moore, Bergman, Anderson, & Medley, 2016) assessed the effects of immediate or early SSC for healthy newborn infants compared to standard on establishment and maintenance of breastfeeding and infant physiology.

This review included 38 randomized controlled trials. Quasi-randomized trials (e.g. where assignment to groups was alternate or by day of the week, or by other non-random methods), observational studies and cross-over trials were not included.

Immediate SSC was defined as SSC occurring within 10 minutes after birth and early SSC defined as occurring anytime between 10 minutes and 24 hours post birth. Standard contact included: swaddled or dressed infants held in their mothers arms or with other family; infants placed in open cribs or under radiant warmers; or infants placed in a cot in the mother’s room or elsewhere without holding.

Study subject inclusion criteria were mothers and their healthy infants born at \geq 34 weeks gestation, who had immediate or early SSC starting less than 24 hours after birth, and controls undergoing standard patterns of care. Also included were women randomized to SSC after cesarean birth (eight trials). Eligible infants weighed more than 2500 g, although some healthy late preterm infants weighed less and were not excluded. Infants weighing \leq 1500g were excluded as were any infant admitted to the neonatal intensive care unit.

Outcomes in this systematic review were divided into three categories: 1) breastfeeding outcomes 2) infant outcomes and 3) maternal outcomes. Of interest to this literature review are the breastfeeding and infant outcomes. The primary breastfeeding outcomes were: i) number of mothers breastfeeding (any breastfeeding) one month to four months post birth and ii) duration of any breastfeeding in days. Primary infant outcomes were i) infant stabilization during the transition to extra-uterine life (the first six hours post birth). Measured by the SCRIP score (a composite score of heart rate, respiratory status and arterial hemoglobin oxygen saturation (SaO₂), range of scores = 0-6 (Bergman, Linley, & Fawcus, 2004)). ii) blood glucose levels during/after SSC compared to standard care in mg/dL 75 to 180 minutes post birth. iii) infant thermoregulation: temperature changes during/after SSC compared to standard care (measured by axillary temperature in degree Celsius (°C) 90 minutes to 2.5 hours post birth. The secondary outcome of interest for this literature review is breastfeeding rates/exclusivity at hospital discharge up to one month post birth.

A total of 38 studies including 3472 mother-infant dyads met the inclusion criteria and contributed data to the analyses. The studies represented very diverse populations in Canada, Chile, Germany, Guatemala, India, Iran, Israel, Italy, Japan, Nepal, Pakistan, Poland, Russia, South Africa, Spain, Sweden, Taiwan, Thailand, the UK, USA and Vietnam.

Bias in included studies was independently assessed by two assessors using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (The Cochrane Collaboration, 2011). Any disagreement was resolved by discussion or by involving a third assessor. Overall, no trial met all criteria for low risk of bias, due to lack

of blinding in all trials. Many studies had high risk of bias for incomplete reporting of outcome data, attrition or other sources of bias, including multiple co-interventions or baseline differences in important potential or known covariates such as socio-economic status. All analyses were imprecise due to small sample size (just 12 trials randomized more than 100 women). Many analyses had statistical heterogeneity due to considerable differences between SSC and standard care control groups. The quality of the body of evidence was assessed using a GRADE approach outlined by Cochrane (Cochrane, 2017). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome and classifies quality as low, moderate or high.

This review provides evidence to support the positive effects of SSC not only on breastfeeding success but on increased longevity of breastfeeding. Results reported that breastfeeding SSC infants were more likely to breast feed successfully during their first feed (average RR 1.32, 95% CI 1.04 to 1.67; participants = 575; studies = five). Women in the SCC group had higher mean scores for breastfeeding effectiveness (IBFAT (Infant Breastfeeding Assessment Tool) score MD 2.28, 95% CI 1.41 to 3.15; participants = 384; studies = four). Analysis of trials in this review also concluded that SSC results in longer duration of breastfeeding. Women experiencing SSC with their infants were 24% more likely to continue breastfeeding between one and four months post birth (14 trials; 887 mother-infant pairs). Women who experienced SSC with their newborns also breastfed their infants on average 64 days longer, though data were limited (95% CI 37.96 to 89.50; participants = 264; studies = six; GRADE: *low quality*). Authors reported that women who experienced SSC with their newborns were probably more likely to exclusively

breast feed from hospital discharge to one month post birth and from six weeks to six months' post birth, though both analyses had substantial heterogeneity (from discharge average RR 1.30, 95% CI 1.12 to 1.49; participants = 711; studies = six; $I^2 = 44\%$; GRADE: *moderate quality*; from six weeks average RR 1.50, 95% CI 1.18 to 1.90; participants = 640; studies = seven; GRADE: *moderate quality*). Overall, analysis of the 38 RCT's in this review supports the fact that SSC promotes breastfeeding.

With respect to SSC effects on infant glycemic control, the 2016 systematic review by Moore et. al found that babies held in SSC had higher blood glucose levels. Three studies including 144 infants measured blood glucose 75 to 90 minutes following the birth and found blood glucose was higher in SSC infants (MD 10.49 mg/dL, 95% CI 8.39 to 12.59; participants =144; studies = three; GRADE *low-quality evidence*). Authors reported that “a difference of 10 mg/dL in blood glucose levels is clinically significant because symptomatic or high-risk infants may be given supplemental bottles of infant formula, a practice that can interfere with the establishment of successful breastfeeding”. This statement reiterates the interrelation between breastfeeding and hypoglycemia.

Moore et.al did not find any significant differences in infant temperatures among babies held in SSC compared to those in standard care. Although five of the six studies included in this review found that axillary temperatures were significantly higher in SSC infants (MD 0.30, 95% CI 0.13 to 0.47; participants = 558; studies = six; GRADE *low-quality evidence*), authors concluded that a mean difference of 0.30 °C does not represent a clinically meaningful difference in temperature. All infants in the analysis had a temperature between 36.4 and 37.1 °C. Interpretation of these results must keep in mind the small sample sizes of the studies included and the heterogeneity of the studies.

Based on the results of this systematic review Authors concluded that; 1) evidence supports using immediate or early SSC to promote breastfeeding, 2) babies held in SSC had higher blood glucose levels, and 3) there was no significant difference in infant temperatures among babies held in SSC compared to those in standard care. Of relevance to this review authors noted that they “found no clear benefit to immediate SSC rather than SSC after the baby had been washed and examined”.

Published studies have also reported a dose dependant relationship between SSC and breastfeeding. A descriptive study by Gomez (1998) examined 651 normal full term newborn infants delivered over an 8 month period. Immediately after birth, the newborn infants were dried and placed in skin-to-skin contact between their mother's breasts. They remained in SSC in the delivery room, during transportation to the post-partum area and in their room (up to two hours). The SSC duration, the infant's post SSC axillary temperature, the mother's and infant's attitudes and the type of newborn feeding were recorded. Results found that newborns who spontaneously did the first breastfeeding during the skin-to-skin contact were the ones who had spent more time in SSC (60 +/- 22 vs 36 +/- 17 minutes; $p < 0.0001$) and infants were eight times more likely to breast feed spontaneously if they spent more than 50 minutes in SSC with their mothers immediately after birth (odds ratio = 7.73; IC 95%: OR = 4.02-15.1). Authors concluded that the dose of SSC might be an essential component regarding breastfeeding success.

The dose-response relationship between SSC and breastfeeding was supported by the findings of Bramson's (2010) study. This large hospital-based prospective cohort study analyzed data collected on 21,842 mother/infant pairs born between July 2005 through June 2006 in one of 19 hospitals in California. Inclusion criteria were mothers

who gave birth to healthy singleton infants (gestational age 37-40 weeks) who were not separated from their infant for more than 1 hour during the mother's maternity hospital stay. A 1-page data collection measurement form was developed the Perinatal Services Network (PSN) of Loma Linda University Medical Center/Children's Hospital and data was collected by peripartum staff who admitted mothers the labor and delivery unit. Independent variables examined and reported were (1) maternal infant-feeding method intention; (2) maternal sociodemographic characteristics, which included mother's primary language, race and ethnicity, age, smoking status, educational level, and the maternal intrapartum variables of analgesia and anesthesia usage and mode of infant delivery (vaginal or cesarean); (3) and the duration spent in early skin-to-skin contact during the first 3 hours after delivery. The primary outcome of this study was the type and method of feeding the infant received during the maternity hospital stay, recorded as exclusive breastfeeding or other.

Of interest to this literature review were results examining the impact of SSC duration on breastfeeding. Researchers found that the odds ratios of the likelihood of exclusive breastfeeding continued to increase as the period of early skin-to-skin contact increased. Compared with mothers with no early SSC, exclusive breastfeeding was higher in mothers who experienced SSC for 1 to 15 minutes (odds ratio [OR] 1.376; 95% confidence interval [CI], 1.189-1.593), 16 to 30 minutes (OR 1.665; 95% CI, 1.468-1.888), 31 to 59 minutes (OR 2.357; 95% CI, 2.061-2.695), and more than 1 hour (OR 3.145; 95% CI, 2.905-3.405). Authors concluded that "the longer a mother experiences early skin-to-skin contact during the first 3 hours following birth, the more likely that she will breastfeed exclusively during her maternity hospitalization" (Bramson, et al., 2010).

Although this was not a randomized control trial the large size of the cohort analyzed strengthens the results. A limitation of this study is the lack of information collected and provided on infants. Descriptive, sociodemographic and intrapartum information on mothers was collected and analyzed but little to no information is examined for infants. Inclusion criteria for infants is stated as being any healthy singleton baby born at 37-40 weeks gestation. There is no definition of the term “healthy” and no mention of any infant characteristics which may have confounded results.

In light of the mounting evidence supporting the positive impact of SSC on breastfeeding success, the practice of SSC has become a widely-accepted method to promote breastfeeding. The proven relationship between SSC and breastfeeding has the potential to confound results obtained in studies examining the impact of newborn bath timing on breastfeeding. Results of such trials must thus be interpreted in light of this proven correlation.

Moore et al’s (2016) conclusion that SSC positively impacts infant temperature but does not result in any clinically meaningful difference, is supported by additional studies not included in their analysis. The following review of such literature outlines the evidence supporting SSC in the temperature regulation of newborns and the clinical relevance of this.

One of the effects of SSC is the release of maternal oxytocin (Winberg, 2005; Uvnas-Moberg & Eriksson, 1996). Oxytocin causes the skin temperature of the mother’s breast to rise, providing warmth to the infant (Uvnas-Moberg & Eriksson, 1996). Christidis (2003) found that SSC was as effective as radiant warmers in preventing heat loss in healthy full-term infants by using infrared thermography.

Thermoregulation of the healthy full term newborn immediately after birth has traditionally been obtained through the use of radiant warmers and swaddling in warm blankets but research suggests that the mother is the preferred heat source. Newborns in close contact with the skin of their mothers are more likely to maintain temperatures in the neutral thermal range (American Academy of Pediatrics., 2005; Anderson, Chiu, Dombrowski, & Swinth, 2003). According to Bystrova et al (2003), newborns placed skin-to-skin with mothers remained considerably warmer during the first three hours of life than did newborns swaddled in mother's arms or receiving nursery care. A randomized control trial by Bergman et al. (2004) found better thermoregulation and cardiorespiratory stability in preterm infants with SSC compared with those cared for in an incubator. Gabriel (2010) reported that "SSC may imply better thermal regulation in term and nearly term infants. Infants in the SSC group of this study presented a temperature increase in the first few minutes of life with almost no changes in the first 2 hours of life, whereas those with standard care showed a progressive reduction in temperature during the same period". Similar to Moore et al (2016), authors of this study also cautioned that these results may not have clinical significance. Similarly, Mori et. al. (2010) conducted a meta-analysis including 23 studies (13 case-series, five RCT's, one cross-over RCT and four cohort studies), evaluating the physiological effects of SSC in newborns. Results reported an increase in body temperature during skin-to-skin care by 0.22°C (22 studies, weighted mean difference [WMD] 0.22°C; 95% confidence interval [CI]: 0.18–0.27, $P < 0.001$), and after skin-to-skin care by 0.14°C (12 studies, WMD 0.14; 95%CI:0.09–0.18, $P < 0.001$). As with previously discussed trials, this small temperature change may have no clinical significance.

Evidence suggests that although SSC positively impacts newborn thermoregulation and the use of direct contact with mother's skin may be as effective as radiant warmers and swaddling in warm blankets, the impact of SSC on newborn temperature may not be clinically relevant.

The proven benefits of SSC for both mother and newborn have led to recommendations by both the American Academy of Pediatrics (AAP) and the WHO that healthy term infants should be placed in skin-to-skin contact with their mothers immediately after birth (American Academy of Pediatrics., 2005; World Health Organization, 2013).

Examination of the impact of newborn bath timing on breastfeeding rates, infant thermoregulation and glycemic control requires consideration of the role of mother-infant skin-to-skin contact (SSC). There is an established relationship between SSC and breastfeeding success (Moore, Bergman, Anderson, & Medley, 2016; Bramson, et al., 2010; Gomez , et al., 1998). SSC also appears to impact glycemic control (Moore, Bergman, Anderson, & Medley, 2016) and thermoregulation (Bergman, Linley, & Fawcus, 2004; Gabriel, et al., 2010; Mori , Khanna, Pledge, & Nakayama, 2010). In light of these relationships, consideration of the role of SSC and the impact of bathing on SSC must be considered when evaluating the impact of newborn bath timing on these outcomes.

Successful newborn adaptation to the extra-uterine environment and breastfeeding relies on a sequence of natural processes directed by olfactory cues and requires direct SSC between mother and baby. Disruption of any of these elements has the potential to hinder breastfeeding success and/or newborn thermoregulation and glycemic control.

Newborn bathing potentially disrupts the ideal post birth conditions because it requires a physical separation of mother and baby thus disrupting time spent skin-to-skin and potentially removes biofluids and olfactory cues involved in successful newborn adaptation processes.

2.3 Impact of Delaying Newborn Bathing on Breastfeeding Rates

Studies have demonstrated that SSC and biofluids effect breastfeeding rates (Preer, Pisegna, Cook, Henri, & Philipp, 2013; Moore, Anderson, Bergman, & Dowswell, 2012; Bramson, et al., 2010; Schaal , Marlier, & Soussignan, 1995; Varendi, Christensson , Porter, & Winberg, 1998; Porter, 2004). It thus stands to reason that early newborn bathing which removes biofluids and disrupts SSC has the potential to negatively impact breastfeeding rates. To date, there is only one trial published that examines the impact of delayed newborn bathing on breastfeeding rates.

In 2013 Preer et al. published a trial entitled “Delaying the bath and In-Hospital Breastfeeding Rates” (Preer, Pisegna, Cook, Henri, & Philipp, 2013). This study was conducted at the Boston Medical Centre where the protocol had recently (2010) been changed to delay newborn bathing till at least 12 hours after birth. Prior to the protocol change, infants were bathed at an average of 2.4 hours after birth. Afterward, infants were bathed at an average of 13.5 hours after birth and were placed skin-to-skin immediately after the bath.

Investigators conducted a retrospective chart review of infants born from November 1, 2009, through October 31, 2010, 6 months before and 6 months after the bathing protocol changed. The primary endpoints of this study were breastfeeding

initiation and in-hospital exclusive breastfeeding or near exclusive breastfeeding.

Breastfeeding initiation was defined as having been breastfed at least once. In-hospital exclusive breastfeeding was defined as having received no formula, water, or glucose water during the birth hospitalization. Infants who received at least one formula feed, even for a medical indication, were defined as not being exclusively breastfed. In-hospital near-exclusive breastfeeding was defined as having between 90% to <100% breastmilk feeds.

Primary inclusion criteria were admission to the well infant nursery and eligibility to breastfeed. Infants were excluded because of the following maternal factors: human immunodeficiency virus infection, illicit drug use, or any other contraindication to breastfeeding as identified by the American Academy of Pediatrics. Also excluded were infants whose mothers were admitted to the intensive care unit after delivery and infants who were initially admitted to the nursery but then transferred to the neonatal intensive care unit.

A total of 702 mother/child charts were included in the study (348 pre-protocol change and 354 post). Results reported that in-hospital exclusive breastfeeding rates increased from 32.7% in the six months prior to the policy change to 40.2% in the six months subsequent to the policy change ($p < 0.05$). After adjusting for mother's race/ethnicity, mother's age, mode of delivery, low birth weight, high birth weight, and insurance type, multivariate logistic regression analysis showed that infants born after implementation of the delayed bathing policy had an odds of exclusively breastfeeding that were 39% greater than infants born prior to the intervention (adjusted odds ratio [AOR] = 1.39; 95% confidence interval [CI] 1.02, 1.91) and 59% greater odds of near-

exclusive breastfeeding (AOR = 1.59; 95% CI 1.18, 2.15). The odds of breastfeeding initiation were 166% greater for infants born after the intervention than for infants born before the intervention (AOR = 2.66; 95% CI 1.29, 5.46). Investigators concluded that “a delayed newborn bath was associated with increased likelihood of breastfeeding initiation and with increased in-hospital breastfeeding rates” (Preer, Pisegna, Cook, Henri, & Philipp, 2013).

In their discussion, the investigators stated they believed that the observed relationship between delayed infant bathing and improved breastfeeding rates was due to two primary factors: (1) delayed infant bathing may reduce the risk of hypothermia and hypoglycemia requiring mother/infant separation and/or supplementation with formula or glucose. (2) Delaying the bath decreased maternal–infant separation and increased time spent skin-to-skin. Authors also acknowledge that “It is also possible that the timing of the bath is only a proxy for decreased separation and increased time spent skin-to-skin, which may independently have been responsible for the measured improvement in breastfeeding rates”. Due to the retrospective nature of the study and inadequate charting information, investigators were unable to quantify skin-to-skin time or mother/infant separation time. Although this study was not designed to examine hypothermia rates investigators did report that after initiation of delayed bathing “no adverse effects—such as a post-bathing temperature low enough to require a pediatrician to evaluate the infant or to necessitate the use of the radiant warmer—were reported” (Preer, Pisegna, Cook, Henri, & Philipp, 2013). No mention is made of hypothermia rates prior to the policy change.

A potential limitation of this study, acknowledged by investigators, was the potential for confounding interventions that resulted in, or contributed to, the observed increase in breastfeeding rates. Authors report the impetus for this policy change was the 2009 Maternity Practices in Infant Nutrition and Care (mPINC) survey conducted by the Centers for Disease Control and Prevention. This survey allows U.S. maternity facilities to score themselves based on adoption of maternity practices that promote breastfeeding. The protocol change to delay the bath at Boston Medical Center was an attempt to improve their mPINC score. Although investigators reported they did not identify any other changes to maternity protocols or procedures during the study period that may have affected breastfeeding rates, this facility was actively striving to improve maternity practices and promote breastfeeding and it is thus likely that confounding interventions existed.

This study compared charts from the 6-month period immediately before the policy change to those from the 6-month period immediately after the policy change. By not allowing a window of adaptation time before and after the policy change, it is possible that overlap in procedure existed. When new policy is enacted it is common to see an adaptation period before and after as staff and patients adjust to the new process. In this case staff and mothers may have been aware of the pending policy change prior to its official launch and may have been delaying baths in the period leading up to the change. This could have led to higher breastfeeding rates in the pre-policy change group. Conversely, there may have been a period of adjustment post policy change when staff were bathing newborns earlier than 12 hours as they became comfortable with the new procedure. This could have led to lower breastfeeding rates in the post-policy change

group. If these overlaps occurred the differences in reported breastfeeding rates would be lower than if there had been no overlap in procedure. Had investigators left an adjustment period before and after the policy change date and examined a 6-month period ending 1-3 months prior to the change and beginning 1-3 months after the change they could have avoided this potential overlap in procedure.

To the best of our knowledge, the published literature that examines the impact of delaying the bath on breastfeeding rates is limited to the one study by Preer et al. The authors reported a significant increase in the rates of initiation and exclusive breastfeeding after the delay the bath policy was implemented, but as discussed above, there are a number of limitations and potential confounding factors associated with this study. More research is needed to help elucidate the relationship between delaying the bath and breastfeeding. In addition, despite investigators statements that the positive findings of the study may be attributed in part to decreases in infant hypothermia and hypoglycemia, the study did not include data on these measures. Therefore there is an additional gap in the published literature on the effects of bathing practices on hypothermia and hypoglycemia. A better understanding of how these factors are related is also needed.

2.4 Impact of Delaying Newborn Bathing on Infant Hypothermia

Despite numerous studies examining the effects of newborn bathing on infant temperature regulation, evidence remains inconclusive and often contradictory. Although evidence has established that immersion bathing in a tub is superior to washing in that it reduces heat loss and infant stress (Henningsson, Nystrom, & Tunnell, 1981; Blume-

Peytavi, et al., 2009; Hylén, Karlsson, Svanberg, & Walder, 1983), the question of when to bathe newborns has not been adequately answered.

One of the earliest sources of guidance on this subject was Frederick Leboyer's 1975 book entitled "Birth Without Violence". Leboyer (1975) advocated bathing immediately following birth. Commonly referred to as the Leboyer method, these techniques were employed for many years and shown to be safe. Early studies indicated that hypothermia (defined as temperature below 35°C [95°F]) did not develop in newborns even after prolonged immersion in water (Crystle, Kegel, France, Brady, & Olds, 1980; Nelson, et al., 1980; Oliver & Oliver, 1978). These early findings have been refuted by subsequent research and recommendations.

The effects of bather and location on newborn thermo-stability has been examined by Anderson et al. (1995) and Medves and O'Brien (2004). These two studies tested the assumption that only nurses are able to bathe newborns without causing significant heat loss. These studies confirmed that there was no significant difference in newborn temperature between those newborns bathed by nurses under a radiant warmer, as is the standard of care in many institutions, compared with having parents administer the bath. Medves and O'Brien (2004) also confirmed findings of previous studies that infant temperature decreased significantly during bathing in both the control and the intervention groups. Infants bathed by parents lost an average of 1.2 °C, whereas infants bathed by nurses lost an average of 1.5 °C, a statistically significant difference ($p = 0.013$).

Although evidence has established that immersion bathing in a tub is the best method of maintaining thermal stability and that bather and location are irrelevant, the

question of bath timing remains. There is a paucity of research that evaluates the relationship between timing of the initial newborn bath and temperature stability. The WHO's practical guide entitled *Thermal Protection of the Newborn* states that "bathing the newborn soon after birth causes a drop in the baby's body temperature and is not necessary" (World Health Organization, 1997). This sentiment has been echoed in a number of studies demonstrating significant temperature drop in newborns immediately following bathing (Smales & Kime, 1978; Penny-MacGillivray, 1996; Varda & Behnke, 2000; Bergström, Byaruhanga, & Okong, 2005; Takayama, Wang, Uyemoto, Newman, & Pantell, 2000). This evidence will be further outlined below. All of these studies examined the effects of very early bathing- between 1-4 hours post-delivery. To date, there have been no studies comparing the effect on newborn thermal stability of delaying newborn bathing by 24 hours (as recommended by the WHO) to traditional early bathing (between 1-4 hours). Thus, despite research consensus that newborn bathing negatively impacts thermal stability, no evidence has been reported that indicates when thermoregulation of the newborn is complete, nor has any evidence been reported that supports delaying the bathing of newborns until 24 hours of life as recommended by the WHO.

2.4.1 Prevalence of Thermal Instability in Infants After Early Bathing

The WHO defines normal body temperature between 36.5° and 37.5°C and hypothermia at < 36.5°C. Early newborn bathing has been shown to significantly decrease infant temperature and often induce hypothermia but contradictory evidence has also been published.

One of the earliest studies demonstrating the effect of bathing on infant thermal stability was published by Smales and Kime in 1978 and entitled “Thermoregulation in Babies Immediately After Birth” (Smales & Kime, 1978). This study examined the effects of washing and the use of radiant heaters on infant temperatures. The 40 subjects were divided into four groups; group 1 were washed and not kept under a radiant heater; group 2 were not washed and not kept under a radiant heater; group 3 were washed and kept under a heater; group 4 were not washed and kept under a heater. Washing was done with warm swabs approximately 50 minutes after birth. Results reported that whether or not a radiant heater was used, infant temperatures were lower in the bathed groups versus those not bathed. Authors concluded that “Washing a baby soon after birth clearly contributes to a fall in body temperature and for this reason it is difficult to justify this practice”. These conclusions should be interpreted with caution in light of the evidence published subsequent to this study which has shown that tub bathing is superior to the sponge type washing employed by this study.

In 2000 bathing induced temperature drops in infants was demonstrated by Takayama et al (Takayama, Wang, Uyemoto, Newman, & Pantell, 2000). This chart review of 203 healthy full term infants identified factors that affect temperatures for newborns. The impact of bathing was determined only for those infants who had temperatures recorded within 1 hour before and 1 hour after bathing (n=114). Investigators found that the mean axillary temperature in newborns significantly declined by 0.2°C after bathing (p=0.0001). Authors only reported mean temperatures which would not be considered hypothermic (before bath = 36.85°C, after bath = 36.65°C).

Although they reported the methods employed to manage hypothermic events they did not report the number or percentage of infants who became hypothermic post bath.

Bergstrom et. al published an RCT in 2005 examining the impact of newborn bathing on the prevalence of neonatal hypothermia among newborn babies exposed to the SSC technique before and after bathing (Bergström , Byaruhanga , & Okong, 2005). In this trial, 249 newborns were randomized either to bathing at 60 min postpartum (n=126) or no bathing (n=123). All mothers practised SSC with their newborns. Four rectal and tympanic recordings of newborn temperatures were carried out in both groups directly after drying at birth, and at 60, 70 and 90 min postpartum. Investigators reported that bathing newborns within the first hour post delivery significantly increased the prevalence of hypothermia, defined as temperature $<36.5^{\circ}\text{C}$, at 70 and at 90 min postpartum despite the use of warmed water and the application of the STS method. Aside from the bathing procedure, no background factor potentially predisposing the newborns to hypothermia was identified. Interestingly, there were significantly more infants in the bathed group than the unbathed group that initiated early breastfeeding (65 versus 46, $p=0.03$). Investigators concluded that this randomized, controlled study “demonstrated that bathing the newborn in warmed water induces significant hypothermia even if appropriate thermal protection, including immediate drying at birth and STS contact with the mother, is maintained. There is no evidence to justify the practice of bathing newborns soon after delivery”.

In contrast to this evidence suggesting that early newborn bathing results in decreased newborn temperatures and an increased incidence of hypothermia, a Japanese study published in 2000 reported that early bathing resulted in higher infant temperatures

(Nako, et al., 2000). In Japan, early bathing is a common traditional practice referred to as 'mokuyoku'. In a study by Nako et al., the authors examined the effects of this cultural practice on hypothermia in a prospective comparative study that randomized 187 healthy term and near-term newborns into two groups. Ninety-five cases were bathed 2–5 min after birth, compared to 92 controls who received dry care instead. Investigators reported the mean rectal temperature at 30 min after birth (i.e. approximately within 20 min after intervention) was significantly higher in the bathed group than in the control (dry care) group (37.30 ± 0.06 vs $37.00 \pm 0.05^\circ\text{C}$, respectively; $P=0.000022$).

There remains debate as to whether or not bathing newborns soon after birth causes thermal instability. Although studies have shown that bathing as early as 2 minutes post delivery is safe, other studies have reported that early bathing results in a significant temperature drop and sometimes hypothermia. There is also debate over the clinical relevance of these reported temperature drops and whether or not a post bath temperature decrease poses any health risk to the newborn. These inconsistent findings warrant further investigation on the effects of early newborn bathing on thermal stability.

2.4.2 The Effect of Bath Timing on Thermal Stability of Infants

The effect on infant temperature of historical and cultural early bathing practices compared to the 24-hour delayed bathing recommendation by the WHO has not been studied. To date a number of studies have been published examining the effect of newborn bath timing on infant thermal stability but all three studies compared very early bath times (1-6 hours post birth), not the 24-hour delay recommended by the WHO. These studies (detailed below) reported that infant body temperatures were significantly

lower post bath which confirms results observed in prevalence studies but none of these studies found any significant temperature differences in infants bathed between 1-6 hours of life.

In 1996, Penny-MacGillivray published a study examining the effect on newborn thermoregulation of bathing at one hour of life versus four hours of life (Penny-MacGillivray, 1996). This aim of this study was to determine the effects of early admission bathing on thermoregulation in newborns.

In this RCT, 97 full-term healthy newborns were randomized to a control group (n=49) who were bathed at 4 hours of age, or the experimental group who were bathed at 1 hour of age (n=48). All newborns were bathed using warm tap water deemed appropriate by immersion of nurse's hand in water. After bathing, newborns were dressed, double-bundled in warmed flannelette blankets and placed in an open crib with bedding. Physiologic data (e.g., rectal temperatures, apical heart rate, and respiratory rate) and air temperature were recorded on admission, before and after bathing, and at 1 and 2 hours after bathing.

Results showed no significant difference in mean rectal temperatures between the two groups at either 1 hour after bathing or 2 hours after bathing. This study did however find a significant difference between the two groups in mean temperature change from before to after the bath. (i.e., .27° C for the experimental group and .08° C for the control group. $p = .02$). Infants bathed at 1 hour of life had a significantly greater decrease in temperature from before to after the bath than those bathed at 4 hours of life. It is notable that all infants, regardless of whether bathed at 1 or 4 hours of life, experienced a decrease in temperature.

The short time frame used for comparison (1 vs. 4 hours) in this study limits the applicability of the reported results. As current WHO guidelines recommend delaying newborn bathing by at least 24 hours this study does not contribute evidence for against the adoption of this recommendation.

A major potential measurement bias existed due to the determination of appropriate bath temperature by the attending nurses' hand, a very subjective measure. This process most likely produced differing bathing temperatures and may have impacted resultant post bath temperatures of newborns.

This study was designed to assess the feasibility of bathing infants earlier (1 hour) than what was the standard procedure at the time (4 hours), in an attempt to reduce health care providers' exposure to bloodborne pathogens. Although no significant differences were observed between the two groups there was a statistically significant difference in post bath temperatures between the experimental group (1 hour) and the control (4 hours). Despite this finding that delaying infant bathing by 4 hours significantly reduced the immediate evaporative heat loss that occurs during bathing authors conclude that delaying newborn bathing until 4 hours of life places health care professional at risk for exposure to bloodborne pathogens and thus "may do more harm than good" (Penny-MacGillivray, 1996). This conclusion should be interpreted in light of this studies goal to insure caregivers' safety.

A similar finding of infant bathing timing on temperature was found by Varda and Behnke (2000). This RCT compared the axillary temperature of healthy, full term newborns bathed at 1 hour of life (n=40) versus 2 hours of life (n=40) and found no

significant differences between the two groups, but did demonstrate significant body temperature decreases in all newborns after bathing.

Newborns were bathed in 36.7°C water and had to have a temperature of 36.8°C in order to be included. Participants were bathed in the newborn nursery under an infant warmer and then placed under a radiant warmer for a minimum of 10 minutes after the bath and until his or her temperature returned to at least 36.7°C. Axillary temperatures of each study participant were recorded before the bath and at 10, 20, and 60 minutes after the bath.

The four outcome variables in this study were: 1) temperatures at 10, 20, and 60 minutes after the bath, 2) magnitude of change at each of the time intervals, 3) maximum change in temperature for each newborn during the 60 minutes after the bath and 4) designation of the newborn as recovered or not recovered, based on whether the temperature 60 minutes after the bath had returned to or exceeded the baseline temperature or was at least 36.7°C.

Results found no significant differences in any of the four outcome variables between newborns bathed at 1 hour of life versus those bathed at 2 hours of life. Although between-group differences at all data points were not significant, within-group changes in temperature from baseline to 10 minutes post-bath were significant for both groups at $p = .001$. This significant drop in body temperature as a result of evaporative and convective heat loss during the bathing is similar to that seen in previously discussed studies and further confirms that bathing produces a significant temperature drop in newborns.

Authors note that “although family members were informed of the importance of keeping their newborn swaddled until their temperature stabilized, the urge to unwrap the

infant may have been overwhelming” (Varda & Behnke, 2000). This potentially introduced cold exposure to some subjects. The publication also outlines that although nursery temperatures were monitored, temperatures of the mothers’ room were not, which may explain the drop in temperatures noted at 60 minutes compared to 20 minutes. It may also have impacted comparative data as no mention is made of rooming-in procedure in this facility. In this study infants were bathed under an infant warmer and then placed under a radiant warmer for a minimum of 10 minutes. This practice may have mitigated any risk of significant temperature decreases in either group and resulted in very little chance of observing temperature differences between the groups.

Similar to Penny-MacGillivray (1996), the short window of time comparison (1 vs. 2 hours of life) may not be sufficient to observe a difference in groups and does not provide any evidence for the basis of the WHO’s recommendation to delay bathing by 24 hours.

Additional studies have confirmed the results observed by Penny-MacGillivray (1996) and Varda and Behnke (2000). In 2003, Behring & colleagues evaluated the effects of bathing on thermoregulation of healthy newborns within the first hour of life compared to bathing 4-6 h of life. This study found that axillary temperatures did not differ significantly between infants bathed within 1 h birth and those bathed 4-6 h after birth (Behring , Vezeau, & Fink, 2003). Similarly, Alizadeh et. al (2007) found that rectal temperatures as measured at four different times (before bathing and immediately as well as 30 and 60 min after bathing) did not differ significantly between infants bathed within 1-2 h of birth and those bathed 4-6 h after birth (Alizadeh Taheri, Fakhraee , & Sotoudeh, 2007).

In addition to the debate as to whether or not early newborn bathing results in a clinically significant temperature drop, the question of the appropriate timing of newborn bathing remains unanswered. A number of studies have compared the thermal impact of very early bath times, between 1-6 hours post delivery and have found no significant difference in infant temperatures when bathing is delayed by 4-6 hours. Much of the motivation for these studies was to permit healthcare professionals to dispense with using gloves, or to justify traditional cultural practices. To date there have been no studies comparing the impact on infant thermoregulation of delaying bathing by 24 hours as recommended by the WHO versus the early bathing (1-4 hours) which has been the predominant clinical practice.

2.5 Impact of Delaying Newborn Bathing on Infant Hypoglycemia

Despite reference to hypoglycemia as a potential negative outcome of early newborn bathing (Preer, Pisegna, Cook, Henri, & Philipp, 2013; Medoff-Cooper, et al., 2012; Lund, 2016), there is limited published clinical evidence to suggest this is the case.

In 2015 the Journal of Obstetric, Gynecologic, & Neonatal Nursing (JOGNN) published a supplement outlining proceedings of the 2015 AWHONN Convention. It contained a summary of a poster presentation entitled: Delaying the First Bath Decreases the Incidence of Neonatal Hypoglycemia (McInerney & Gupta, 2015). To date, this study has not been published and to our knowledge is the only known research examining the effects of newborn bath timing on infant hypoglycemia. This poster presentation outlined a retrospective chart review of 1135 newborns examining rates of neonatal hypoglycemia

before and after implementation of a hospital policy to delay the bath until at least 12 hours of life.

This study compared blood glucose measurements of 578 infants born pre-policy change to those of 557 infants born post-policy change. The reason for the blood glucose measurement was cross referenced against the risk factors for neonatal hypoglycemia. A blood glucose level of 49 mg/dl (2.7mmol/L) or less was considered hypoglycemic.

Researchers found that newborns whose bath was delayed by at least 12 hours of life had a 3.5% incidence of hypoglycemia versus an 8.5% incidence of hypoglycemia in those infants bathed within 2 hours of life. Investigators further examined newborns at high risk for hypoglycemia; those large for gestational age, small for gestational age, and born of mothers with gestational diabetes. Sample A (no delayed bath) had 176 high-risk infants and Sample B (delayed bath) had 142 high-risk infants. The high-risk infants bathed within 2 hours of life had a 27.8% rate of hypoglycemia versus 14% in those infants bathed after 12 hours of life. Investigators concluded that “delaying the initial bath for the newborn may decrease rates of hypoglycemia by 50% in high-risk infants and can result in a similar reduction in hypoglycemia for low-risk infants”.

As the only currently available publication of this study is a poster presentation much of the detail required to critically appraise this study are not available. There is no mention of inclusion and exclusion criteria, gestational age of newborns, skin-to skin policy and practice at study hospital or of other initiatives that may have impacted breastfeeding rates thus confounding results. This publication merely reports incidence rates with no mention of statistical significance or reporting of p-values. This lack of study information impairs interpretation of results.

The reported results suggest that delayed newborn bathing decreases hypoglycemia rates, particularly in newborns at increased risk for hypoglycemia. This being the only study found that examines the impact of bath timing on hypoglycemia rates and, combined with the lack of a full publication suggests that, additional clinical evidence is needed to better understand the relationship between delaying newborn bathing and the risk of hypoglycemia.

2.6 Summary of Gaps in the Clinical Literature

The current trend of implementation of hospital policies to delay newborn bathing is based primarily on the WHO's guidelines entitled: "Recommendations on Postnatal Care of the Mother and Newborn" (World Health Organization, 2013). The evidence base for the recommendation to delay newborn bathing for at least 24 hours is not clearly referenced in this publication and reflects the knowledge gap surrounding the effects and ideal timing of newborn bathing. An extensive literature review confirmed the dearth of published studies on the relationship between delaying the bath policy and its impact on breastfeeding, hypothermia and hypoglycemia. Several gaps in knowledge exist regarding the WHO recommendation.

In summary, the most commonly proposed potential complications associated with early bathing are newborn hypothermia, hypoglycemia and reduced exclusive breastfeeding and breastfeeding initiation. These outcomes are inter-related and influenced by the presence of biofluids and the practice of skin-to-skin contact which are also impacted by bathing. This complex relationship is not fully understood and the impact of bathing on any or all of these outcomes and processes is not determined.

Although an increasing number of hospitals are adopting delayed bathing policies and numerous public health organizations like the WHO are recommending they do so, there is a very small body of published clinical evidence on the subject. To date, there is only one known clinical trial published on the impact of delayed bathing on breastfeeding (Preer, Pisegna, Cook, Henri, & Philipp, 2013). Similarly, there has been only one trial conducted examining the impact of delayed bathing on hypoglycemia rates (McInerney & Gupta, 2015). In both of these studies, delayed bathing was at 12 hours, and not the 24-hour delay recommended by the WHO. The effect of timing of newborn bathing on thermoregulation has been examined in two studies, but both compared very early bathing times (1 hour versus 2 or 4 hours) not the 24-hour delay recommended by the WHO. Penny-MacGillivray (1996) compared the impact on thermoregulation of bathing newborns at 1 hour of life versus 4 hours and Varda and Behnke (2000) examined the thermoregulation impact of bathing newborns at 1 hour of life versus 2 hours of life and both studies reported no differences in infant thermal stability.

To date there are no studies assessing the clinical effects of the specific recommendation by the WHO to delay newborn bathing by 24 hours on hypothermia, hypoglycemia or breastfeeding rates.

Chapter 3: Methods

This chapter outlines the study design, population and sample, procedure, definitions of interventions and outcomes, data analysis, and ethical considerations.

3.1: Study design

This research was conducted using a retrospective cohort study design comparing two cohorts, one before and one after, the Eastern Health bathing policy change (March 2015). The primary outcomes of this study were in-hospital breastfeeding initiation and exclusive breastfeeding at discharge. Secondary outcomes were infant hypoglycemia rates and infant hypothermia rates. A total of 1409 charts of healthy full and late pre-term newborn/mother pairs were reviewed. A total of 30 charts were excluded based on inclusion criteria leaving 1379 charts included in the analysis. Data was abstracted from 721 randomly selected charts from the 6-month period of June through November 2014 (prior to the policy change) and 658 randomly selected charts from the 6-month period of July through December 2015 (subsequent to the change of policy).

3.2: Population and Sample

The sample for this study was drawn from the Janeway Children's Health and Rehabilitation Center in St. John's Newfoundland and Labrador (NL). This hospital provides obstetrical services, newborn and pediatric health care to the approximately

200,000 people living in the surrounding area through the combined 42 bed (8 birthing and 34 antepartum and postpartum) Obstetrics & Gynaecology Unit.

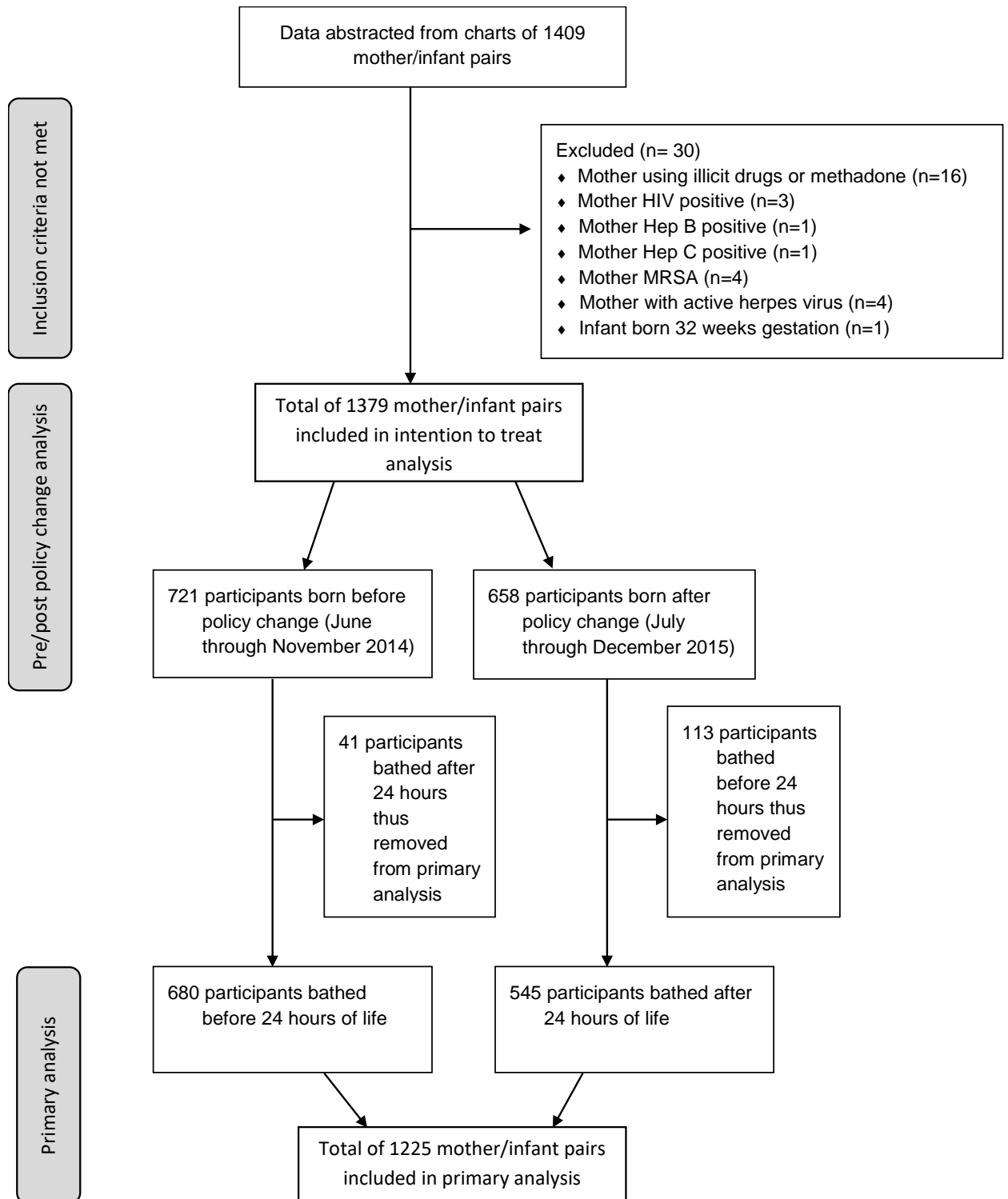
3.2.1: Inclusion Criteria

Included were those mother/child pairs born during the specified time periods who were 34 weeks gestation and greater and subsequently admitted to the Maternity Ward (5 North B).

3.2.2: Exclusion Criteria

Excluded infants were any infants for whom delaying the bath or breastfeeding is contraindicated, or infants at higher risk for the outcomes of interest: babies of mothers using illicit drugs or on methadone treatment, infants born to mothers with HIV, hepatitis B, hepatitis C, active herpes simplex virus infection, and methicillin-resistant staphylococcus aureus. Mothers who were admitted to ICU post-delivery were excluded as were infants who were admitted to NICU directly from the case room. Cases where infants were not bathed in the time frame directed by the policy at the time of their birth were excluded from the primary intention to treat analysis (comparing those infants bathed before 24 hours to those bathed after 24 hours) but included in analysis comparing those born pre policy change to those born post policy change. That is, infants born pre-policy change but bathed after 24 hours and infants born post-policy change but bathed before 24 hours. Figure 3.1 shows the study participant flow diagram.

Figure 3.1 Study Participant Flow Chart



3.3: Statistical Methods and Sample Size Calculations

Using a power of 80% and a significance level of 0.5 the required sample size for this study was determined to be 700 participants in total, 350 pre-policy change and 350 post-policy change. Sample size was inflated to 1300 to allow for examination of the secondary outcome of hypoglycemia. Sample size was inflated to 1300 to allow for examination of the secondary outcome of hypoglycemia. Sample size inflation calculations used a power of 80% and a significance level of 0.5 and an effect size of 20% based on results observed in McInerney and Gupta (2015).

To insure accurate reflection of late pre-term infants (34-36 weeks gestation) in the study population, the average percentage of late pre-term's born at the study hospital was determined to be 7.9%. Computer generated random sampling was conducted such that our sample reflected the general population with 7.5% late pre-terms (103/1379). This was done to prevent random sampling from over selecting late pre-term infants who have been shown to have greater risk of hypothermia and hypoglycemia.

Subgroup analysis was conducted on two groups defined a priori. The first group being those infants at high risk for hypoglycemia; those born ≤ 36 weeks gestation, those small or large for gestational age and/or those born of diabetic mothers. The second subgroup consisted of participants not at high risk for hypoglycemia i.e. excluding those at high risk.

3.4: Procedure and Variable Definitions

A standardized data abstraction form was created after review of relevant literature (Banks, 1998; Pan , Fergusson , Schweitzer, & Hebert, 2005; Jansen, et al.,

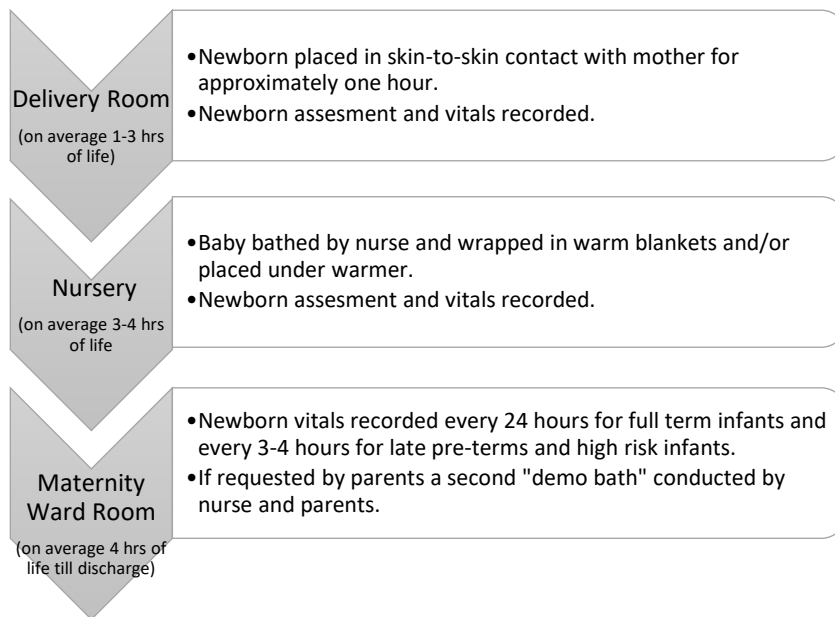
2005). Pertinent information on mother, child, labour, delivery and the immediate postpartum period was collected by a research nurse trained and experienced in such data collection and management. This data abstraction form was review by the Health Research Ethics Authority (HREA), the hospital Research Proposals Approval Committee (RPAC), co-authors and theses supervisory committee and piloted by the research nurse using 20 charts. A copy of this form can be found in Appendix B.

3.4.1: Exposure Variable

Control Group – Received Early Bath

Prior to the policy change in March 2015 to delay the newborns bath, newborns were taken, by a nurse, from the delivery room to the nursery where they were bathed and assessed before being returned to mothers' room. On average, this bathing occurred at 3.5 hours of life and consisted of tub bathing with baby soap after which baby was wrapped in blankets and placed in a radiant warmer or cot. The post delivery hospital procedure for infants born prior to the policy change to delay newborn bathing by at least 24 hours is outlined in figure 3.2.

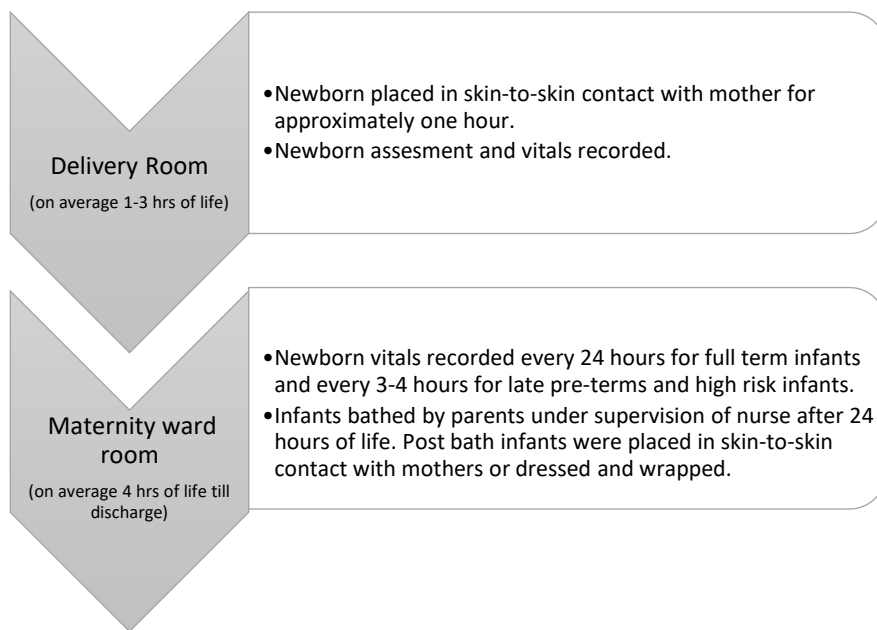
Figure 3.2 Post Delivery Hospital Procedure for Infants Born Prior to Policy Change.



Exposure Group – Bath Delayed at Least 24 Hours

Subsequent to the policy change, the average newborn bathing time was at 30 hours of life. This bathing was typically done by parents in mothers' room under the guidance of a nurse. After bathing moms were encouraged to place baby skin-to-skin or babies were wrapped and given to mother. The post delivery hospital procedure for infants born subsequent to the policy change to delay newborn bathing by at least 24 hours is outlined in figure 3.3.

Figure 3.3 Post Delivery Hospital Procedure for Infants Born Subsequent to Policy Change.



3.4.2: Outcome Variables

As per the electronic medical recording practices of the study hospital, breastfeeding initiation was defined as any action of baby to breast during the hospital stay. Exclusive breastfeeding was defined as having received no formula, water, glucose or any substance other than breast milk during the hospital stay. If infant feeding supplementation occurred or the infant was given any substance (formula, glucose, water) other than breastmilk and prescribed medications then feeding was recorded as “mixed”. If no breastfeeding occurred and baby was fed only formula this was recorded as exclusively formula fed.

In accordance with the Canadian Pediatric Society’s position statement, “Screening guidelines for newborns at risk for low blood glucose” (Aziz & Dancey, 2004), infant hypoglycemia was defined as a recorded glucose level $<2.6\text{mmol/L}$. As per

the WHO's guideline entitled "Thermal Protection of the Newborn: A practical guide" (World Health Organization, 1997), infant hypothermia was defined as a recorded temperature $<36.5^{\circ}\text{C}$.

3.5 Statistical Analysis

Data collected through the chart reviews were coded and entered into Statistical Package for the Social Sciences (SPSS) version 19.0 (IBM Corp., Armonk, NY) for analysis. The database computer was password protected. Each chart was assigned a unique patient ID. Unclear or incomplete chart reviews were flagged during data entry and followed up by the research nurse.

Descriptive statistics, in the form of frequency (proportion) and mean \pm standard deviation, were conducted on categorical and continuous variables, respectively. Bivariate tests of association between the predictor variable (intervention-delayed bath vs. control-early bath) and each outcome variable (breastfeeding initiation, exclusive breastfeeding at discharge, hypothermia and hypoglycemia) were performed using χ^2 tests. Multivariate logistic regression analyses was used to test for differences in odds of breastfeeding before and after the policy change while controlling for potential confounding factors as well as to test for differences in odds of infant hypothermia or hypoglycemia before and after the intervention while controlling for potential confounders. All tests of statistical significance used a < 0.05 . Confounding factors included gestational age, induction augmentation, large or small for gestational age. C-section and use of epidural as these factors have been shown to effect breastfeeding rates.

3.6 Ethical and Privacy Considerations

Ethical approval and subsequent renewals for this research have been obtained from Memorial University's Health Research Ethics Authority (Appendix A, file number 20160696) and Eastern Health's Research Proposal Approvals Committee (RPAC).

No directly identifiable patient information was collected for study analysis. Random selection of eligible charts was done by the Perinatal Program of Newfoundland and Labrador (PPNL)'s data analyst who then supplied those selected chart numbers to the research nurse who assigned each chart a unique non-identifying ID number and conducted the chart review.

Chapter 4: Results

The following chapter presents the results of the study into four sections, the first outlines the descriptive statistics, the second presents the results of the primary intention to treat (ITT) analysis comparing infants bathed before 24 hours to those bathed after 24 hours. This primary analysis is further divided into three sections presenting the results of the three a priori defined populations and subgroups; 1) the total population, 2) the high-risk population subgroup and 3) the average risk population subgroup. The third section presents results of secondary analysis comparing infants born pre-policy change to those born post-policy change. The final section summarizes the results.

4.1 Descriptive Statistics

The characteristics of the study population are presented in Table 4.1. Maternal, infant, and labour and delivery characteristics of the total population as well as that of the two comparative cohorts: those bathed before 24 hours (pre-policy change) and those bathed after 24 hours (post policy change) are provided. The majority (99.3%) of mothers in the study population received prenatal care and the majority of these (80.7%) indicated they intended to breastfeed. The rate of pre-existing diabetes among mothers was 0.9% while 4.8% developed gestational diabetes. The caesarean-section (c-section) rate in the total study population was 28% with just less than half of deliveries (43.7%) being induced or augmented and 75.4% of mothers receiving an epidural. The average gestational age of infants in the study population was 39 weeks with 18% of infants being small or large for gestational age. During the hospital stay 12.7% of the infants in this study received supplemental feeding of formula, glucose or water.

There were no significant differences among cohorts ($p<0.05$) in rates of c-section, epidural, maternal diabetes or infant characteristics. The proportion of deliveries induced or augmented in the early bathing group (<24 hours) was significantly higher ($p<0.05$) than the delayed bathing group (>24 hours). The proportion of mothers that reported an intention to breastfeed was significantly higher ($p<0.05$) in the delayed bathing group than the early bathing group.

Table 4.1

Characteristics of Study Population and a Comparison of Babies Bathed Before and After 24 Hours of Life)

| CHARACTERISTIC | TOTAL (N=1225) | | BATHED BEFORE 24HRS (N=680) | | BATHED AFTER 24HRS (N=545) | | P- VALUE |
|-----------------------------|-------------------|------|--------------------------------|------|----------------------------------|------|-------------|
| | n | % | n | % | n | % | |
| Maternal characteristics | | | | | | | |
| PRENATAL CARE | 1212 | 99.3 | 670 | 99.0 | 542 | 99.6 | 0.176 |
| PRE-EXISTING DIABETES | 11 | 0.9 | 5 | 0.7 | 6 | 1.1 | 0.500 |
| GESTATIONAL DIABETES | 59 | 4.8 | 35 | 5.1 | 24 | 4.4 | 0.546 |
| INTENTION TO BREASTFEED | 962 | 80.7 | 516 | 78.7 | 446 | 83.2 | 0.048 |
| Labour and Delivery | | | | | | | |
| C-SECTION | 342 | 28.0 | 177 | 26.1 | 165 | 30.5 | 0.087 |
| INDUCTION OR AUGMENTATION | 535 | 43.7 | 316 | 46.5 | 219 | 40.2 | 0.027 |
| EPIDURAL | 924 | 75.4 | 501 | 73.7 | 423 | 77.3 | 0.112 |
| Infant characteristics | | | | | | | |
| GESTATIONAL AGE (MEAN) | 39 wks | | 39 wks | | 39 wks | | |
| LATE PRE-TERMS (< 37 WEEKS) | 91 | 7.4 | 50 | 7.4 | 41 | 7.5 | |
| SMALL OR LARGE FOR GEST AGE | 221 | 18.0 | 122 | 17.9 | 99 | 18.2 | 0.919 |
| SUPPLEMENTED | 156 | 12.7 | 91 | 13.4 | 65 | 11.9 | 0.442 |

Note. Denominator of n varies between 1191-1225 for total population, between 656-680 for early bath group and between 536-545 for delayed bath group based on missing data.
Significant at the $p<0.05$ level

4.2 Primary Analysis Significance Testing

4.2.1 Total Population

A comparison of the cohorts bathed before 24 hours of life is compared to those bathed after 24 hours of life and is presented in Table 4.2. When bathing was delayed until at least 24 hours of life, breastfeeding initiation rates increased by 23% (79.1% in the early bathing cohort and 82.4% in the delayed bathing cohort) but this difference was not a statistically significant ($p=0.151$). Rates of exclusive breastfeeding at discharge were statistically significantly higher ($p=0.039$) in the delayed bath group (59.4%) compared to the early bath group (53.6%). There was a highly statistically significant ($p=0.009$) association between delayed bathing and hypothermia with those in the delayed bath group being 2.5 times more likely to experience a hypothermic event. Rates of hypoglycemia did not differ significantly ($p=0.744$) between the two groups.

Table 4.2

A Comparison of the Rates of Breastfeeding Initiation, Exclusive Breastfeeding at Discharge, Hypothermia and Hypoglycemia in Babies Bathed Before 24hrs of Life Versus Those Bathed After 24hrs of Life (n=1225).

| OUTCOMES | BATHED BEFORE 24HRS (N=680) | | BATHED AFTER 24HRS (N=545) | | UNIVARIATE ANALYSIS | | |
|--------------------------|--------------------------------|------|-------------------------------|------|---------------------|-------------|---------|
| | n | % | n | % | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 538 | 79.1 | 449 | 82.4 | 1.234 | 0.926-1.646 | 0.151 |
| EXCLUSIVE BREASTFEEDING | 361 | 53.6 | 324 | 59.4 | 1.271 | 1.012-1.597 | 0.039 |
| HYPOTHERMIA | 12 | 1.8 | 24 | 4.4 | 2.564 | 1.270-5.176 | 0.009 |
| HYPOGLYCEMIA | 17 | 2.5 | 12 | 2.2 | 0.878 | 0.416-1.855 | 0.733 |

Note. Denominator of n varies between 674-680 for early bath group based on missing data. Denominator is consistently 545 for delayed bath group.
Significant at the $p<0.05$ level

Multivariate analysis was conducted that controlled for gestational age, induction or augmentation, large or small for gestational age, c-section and epidural and found similar results. When bathing was delayed; breastfeeding initiation increased by 27% but was not statistically significant ($p=0.103$), and exclusive breastfeeding at discharge increased by 33% and was statistically significant ($p=0.019$). When bathing was delayed, hypothermia rates were 2.5 times higher than the early bathing cohort ($p=0.011$) and there was no difference in hypoglycemia rates ($p=0.826$) (Table 4.3).

Table 4.3

Multivariate Analysis of Total Population Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Cesarean Section and Epidural.

| OUTCOMES | TOTAL POPULATION | | |
|--------------------------|------------------|-------------|---------|
| | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 1.275 | 0.952-1.708 | 0.103 |
| EXCLUSIVE BREASTFEEDING | 1.334 | 1.049-1.698 | 0.019 |
| HYPOTHERMIA | 2.524 | 1.239-5.142 | 0.011 |
| HYPOGLYCEMIA | 0.916 | 0.421-1.994 | 0.826 |

Note. Significant at the $p<0.05$ level

4.2.2: High Risk Population

The comparison of early and delayed bath cohorts in the high risk population (those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes) subgroup analysis are presented in Table 4.4. Univariate analysis demonstrated no statistically significant ($p<0.05$) differences in rates of breastfeeding initiation, exclusive breastfeeding at discharge or hypoglycemia rates

between babies bathed before or after 24 hours of life. There was a statistically significant ($p=0.020$) increase in hypothermia rates; those infants in the delayed bath group were 3.9 times more likely to experience a hypothermic event compared to the early bathing group.

Table 4.4

A Comparison of Rates of Breastfeeding Initiation, Exclusive Breastfeeding at Discharge, Hypothermia and Hypoglycemia in High Risk Babies Bathed Before 24hrs of Life Versus Those Bathed After 24hrs of Life (n=337).*

| OUTCOMES | BATHED BEFORE 24HRS (N=186) | | BATHED AFTER 24HRS (N=151) | | UNIVARIATE ANALYSIS | | |
|---------------------------------|-----------------------------------|------|----------------------------------|------|---------------------|--------------|---------|
| | n | % | n | % | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 146 | 78.5 | 118 | 78.1 | 0.980 | 0.582-1.649 | 0.938 |
| EXCLUSIVE BREASTFEEDING | 69 | 37.7 | 61 | 40.4 | 1.120 | 0.720-1.742 | 0.616 |
| HYPOTHERMIA | 4 | 2.2 | 12 | 7.9 | 3.928 | 1.240-12.442 | 0.020 |
| HYPOLYCEMIA | 13 | 7.0 | 12 | 7.9 | 1.149 | 0.508-2.597 | 0.739 |

Note. Denominator of n varies between 183-186 for early bath group based on missing data.

Denominator is consistently 151 for delayed bath group.

Significant at the $p<0.05$ level

* High risk babies include those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes.

Multivariate analysis that controlled for gestational age, induction or augmentation, large or small for gestational age, c-section and epidural were similar to previously discussed results in the high-risk subgroup. There were no statistically significant differences in breastfeeding initiation, exclusive breastfeeding at discharge, or hypoglycemia rates between those infants bathed before or after 24 hours of life. However the delayed bathing cohort had a significantly ($p=0.028$) higher rate of hypothermia.

Table 4.5

Multivariate Analysis of High Risk Population Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Caesarean Section and Epidural.*

| OUTCOMES | HIGH RISK POPULATION | | |
|--------------------------|----------------------|--------------|---------|
| | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 0.948 | 0.554-1.620 | 0.844 |
| EXCLUSIVE BREASTFEEDING | 1.176 | 0.711-1.944 | 0.528 |
| HYPOTHERMIA | 3.860 | 1.161-12.836 | 0.028 |
| HYPOGLYCEMIA | 1.268 | 0.549-2.928 | 0.578 |

Note. Significant at the $p < 0.05$ level

* High risk babies include those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes.

4.2.3: Average Risk Population

The results of univariate analysis of the average risk subgroup (those > 36 weeks gestation, average size for gestational age and born of non-diabetic mothers) comparing the cohort of babies bathed before 24 hours of life to those bathed after 24 hours of life are presented in Table 4.6. In this subgroup there was a 36% increase in breastfeeding initiation rates when bathing was delayed by at least 24 hours but this difference was not statistically significant ($p = 0.077$). Exclusive breastfeeding at discharge was 36% higher in the delay bathing group and was statistically significant ($p = 0.026$). In this particular subgroup there was no significant difference ($p = 0.161$) in hypothermia rates between the two groups. Hypoglycemia rates decreased from 0.8% (4/494) in the early bathing group to 0% (0/394) in the delayed bath group. Due to the lack of incidents of hypoglycemia in

the delayed bathing group (n=0) chi squared tests of association are not able to be calculated for this outcome.

Table 4.6

*A Comparison of Rates of Breastfeeding Initiation, Exclusive Breastfeeding at Discharge, Hypothermia and Hypoglycemia in Average Risk** Babies Bathed Before 24hrs of Life Versus Those Bathed After 24hrs of Life (n=888).*

| OUTCOMES | BABIES BATHED BEFORE 24HRS (N=494) | | BABIES BATHED AFTER 24HRS (N=374) | | UNIVARIATE ANALYSIS | | |
|-------------------------------------|---------------------------------------|------|--------------------------------------|------|---------------------|-------------|---------|
| | n | % | n | % | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 392/494 | 79.4 | 331/394 | 84 | 1.367 | 0.967-1.933 | 0.077 |
| EXCLUSIVE BREASTFEEDING | 292/491 | 59.5 | 263/394 | 66.8 | 1.368 | 1.038-1.804 | 0.026 |
| HYPOTHERMIA | 8/494 | 1.6 | 12/394 | 3 | 1.908 | 0.772-4.715 | 0.161 |
| HYPOGLYCEMIA | 4/494 | 0.8 | 0/394 | 0 | 0 | 0 | 0 |

Note. Denominator of n varies between 491-494 for early bath group based on missing data.

Denominator is consistently 394 for delayed bath group.

Significant at the p<0.05 level

** Average risk babies are those >36 weeks gestation, average size for gestational age and born of non-diabetic mothers

Multivariate analysis controlled for gestational age, induction or augmentation, large or small for gestational age, c-section and epidural. Significant increases in both breastfeeding initiation and exclusive breastfeeding at discharge were seen in the delayed bathing group with breastfeeding initiation increasing by 43% (p=0.045) and exclusive breastfeeding at discharge increasing by 40% (p=0.019). Rates of hypothermia were not significantly different (p=0.147) and differences in the rates of hypoglycemia were unable to be calculated due to the lack of events in the delayed bath group.

Table 4.7

*Multivariate Analysis of Average Risk** Population Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Cesarean Section and Epidural.*

| OUTCOMES | AVERAGE RISK POPULATION | | |
|--------------------------|-------------------------|----------------|----------------|
| | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 1.433 | 1.008-2.039 | 0.045 |
| EXCLUSIVE BREASTFEEDING | 1.401 | 1.056-1.857 | 0.019 |
| HYPOTHERMIA | 1.958 | 0.790-4.849 | 0.147 |
| HYPOGLYCEMIA | Not calculable | Not calculable | Not calculable |

Note. Significant at the $p < 0.05$ level

** Average risk babies are those >36 weeks gestation, average size for gestational age and born of non-diabetic mothers

4.3: Secondary Analysis

Cases where infants were not bathed in the time frame directed by the policy at the time of their birth were excluded from the primary ITT analysis but included in the secondary analysis. Forty-one infants born pre-policy change and described as early bathing cohort were actually bathed after 24 hours and thus excluded from the primary analysis. Similarly, 113 infants born post-policy change and described as late bathing cohort were actually bathed before 24 hours and thus excluded from the primary analysis. Secondary analysis was conducted that analyzed all participants allocated to the cohort corresponding to the time of their birth (pre- or post-policy change). This analysis included all infants despite non-adherence to bathing policy at the time of birth. A total of

1379 infants were included in this analysis, 721 born pre-policy change and 658 born post policy change.

The univariate analysis of those infants born before the policy change compared to those born after the policy change are presented in Table 4.8. Infants born after the policy change had a 21% increase in breastfeeding rates, but this was not a significant difference ($p=0.158$). Similarly, exclusive breastfeeding rates were 20% higher in those infants born post-policy change, but this was also not significant ($p=0.088$). Hypothermia rates were significantly higher ($p=0.012$) in infants born post-policy change. There was no statistically significant difference in hypoglycemia rates ($p=0.807$).

Table 4.8

A Comparison of Rates of Breastfeeding Initiation, Exclusive Breastfeeding at Discharge, Hypothermia and Hypoglycemia in Babies Born Before Policy Change Versus Those Born After Policy Change (n=1380).

| OUTCOMES | BABIES BORN BEFORE POLICY CHANGE (N=721) | | BABIES BORN AFTER POLICY CHANGE (N=659) | | UNIVARIATE ANALYSIS | | |
|-----------------------------|--|------|---|------|---------------------|-------------|---------|
| | n | % | n | % | OR | 95% CI | P-value |
| BREASTFEEDING INITIATION | 569 | 78.9 | 540 | 81.9 | 1.212 | 0.928-1.584 | 0.158 |
| EXCLUSIVE BREASTFEEDING | 385 | 53.8 | 385 | 58.4 | 1.204 | 0.973-1.491 | 0.088 |
| HYPOTHERMIA | 12 | 1.7 | 26 | 3.9 | 2.427 | 1.214-4.850 | 0.012 |
| HYPOGLYCEMIA | 19 | 2.6 | 16 | 2.4 | 0.919 | 0.469-1.803 | 0.807 |

Note. Denominator of n varies between 615-721 for babies born before policy change based on missing data.

Denominator is consistently 659 for babies born after policy change.

Significant at the $p<0.05$ level

4.4: Summary

In the cohort of infants for whom bathing was delayed, no significant difference in breastfeeding initiation was seen in either the total population nor high-risk subgroup (those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes) (Table 4.9). A significant increase in breastfeeding initiation was seen in the average risk subgroup (those >36 weeks gestation, average size for gestational age and born of non-diabetic mothers). Exclusive breastfeeding rates at discharge were significantly higher when bathing was delayed in both the total population and average risk subgroup but not in the high-risk subgroup (Table 4.10). The rates of hypothermia were significantly higher in both the total population and the high-risk subgroup when bathing was delayed, but not in the average risk subgroup (Table 4.11). No significant differences were seen in the rates of hypoglycemia among any of the cohort comparisons (Table 4.12).

Table 4.9

Comparison of Changes in Breastfeeding Initiation Rates Observed in the Three Study Populations; Total Population, High Risk Population and Average Risk Population.

| OUTCOMES | BABIES BATHED BEFORE 24HRS | | BABIES BATHED AFTER 24HRS | | MULTIIVARIATE ANALYSIS | | |
|--------------------------------|----------------------------|------|---------------------------|------|------------------------|-------------|---------|
| | n | % | n | % | AOR | 95% CI | P-value |
| TOTAL POPULATION | 538/680 | 79.1 | 449/545 | 82.4 | 1.275 | 0.952-1.708 | 0.103 |
| AVERAGE RISK POPULATION | 392/494 | 79.4 | 331/394 | 84 | 1.433 | 1.008-2.039 | 0.045 |
| HIGH RISK POPULATION | 146/186 | 78.5 | 118/151 | 78.1 | 0.948 | 0.554-1.620 | 0.844 |

Note. Significant at the $p < 0.05$ level

AOR = Adjusted Odds Ratio. Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Cesarean Section and Epidural.

* High risk babies include those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes.

** Average risk babies are those >36 weeks gestation, average size for gestational age and born of non-diabetic mothers

Table 4.10

Comparison of Changes in Rates of Exclusive Breastfeeding at Discharge Observed in the Three Study Populations; Total Population, High Risk Population and Average Risk Population.

| OUTCOMES | BABIES BATHED BEFORE 24HRS | | BABIES BATHED AFTER 24HRS | | MULTIVARIATE ANALYSIS | | |
|--------------------------------|----------------------------|------|---------------------------|------|-----------------------|-------------|---------|
| | n | % | n | % | AOR | 95% CI | P-value |
| TOTAL POPULATION | 361/674 | 53.6 | 324/545 | 59.4 | 1.334 | 1.049-1.698 | 0.019 |
| AVERAGE RISK POPULATION | 292/491 | 59.5 | 263/394 | 66.8 | 1.401 | 1.056-1.857 | 0.019 |
| HIGH RISK POPULATION | 69/183 | 37.7 | 61/151 | 40.4 | 1.176 | 0.711-1.944 | 0.528 |

Note. Significant at the $p < 0.05$ level

AOR = Adjusted Odds Ratio. Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Cesarean Section and Epidural.

* High risk babies include those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes.

** Average risk babies are those > 36 weeks gestation, average size for gestational age and born of non-diabetic mothers

Table 4.11

Comparison of Changes in Hypothermia Rates Observed in the Three Study Populations; Total Population, High Risk Population and Average Risk Population.

| OUTCOMES | BABIES BATHED BEFORE 24HRS | | BABIES BATHED AFTER 24HRS | | MULTIVARIATE ANALYSIS | | |
|--------------------------------|----------------------------|-----|---------------------------|-----|-----------------------|--------------|---------|
| | n | % | n | % | AOR | 95% CI | P-value |
| TOTAL POPULATION | 12/680 | 1.8 | 24/545 | 4.4 | 2.524 | 1.239-5.142 | 0.011 |
| AVERAGE RISK POPULATION | 8/494 | 1.6 | 12/394 | 3 | 1.958 | 0.790-4.849 | 0.147 |
| HIGH RISK POPULATION | 4/186 | 2.2 | 12/151 | 7.9 | 3.860 | 1.161-12.836 | 0.028 |

Note. Significant at the $p < 0.05$ level

AOR = Adjusted Odds Ratio. Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Cesarean Section and Epidural.

* High risk babies include those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes.

** Average risk babies are those > 36 weeks gestation, average size for gestational age and born of non-diabetic mothers

Table 4.12

Comparison of Changes in Hypoglycemia Rates Observed in the Three Study Populations; Total Population, High Risk Population and Average Risk Population.

| OUTCOMES | BABIES BATHED BEFORE 24HRS | | BABIES BATHED AFTER 24HRS | | MULTIVARIATE ANALYSIS | | |
|------------------------------------|-------------------------------|-----|------------------------------|-----|-----------------------|-------------------|-------------------|
| | n | % | n | % | AOR | 95% CI | P-value |
| TOTAL POPULATION | 17/680 | 2.5 | 12/545 | 2.2 | 0.916 | 0.421-1.994 | 0.826 |
| AVERAGE RISK POPULATION | 4/494 | 0.8 | 0/394 | 0 | Not calculable | Not calculable | Not calculable |
| HIGH RISK POPULATION | 13/186 | 7.0 | 12/151 | 7.9 | 1.268 | 0.549-2.928 | 0.578 |

Note. Significant at the $p < 0.05$ level

AOR = Adjusted Odds Ratio. *Controlling for Gestational Age, Induction or Augmentation, Large or Small for Gestational Age, Cesarean Section and Epidural.*

* High risk babies include those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes.

** Average risk babies are those > 36 weeks gestation, average size for gestational age and born of non-diabetic mothers

Chapter 5: Discussion

The purpose of this study was to determine the effect of delaying newborn bathing until at least 24 hours of life as recommended by the World Health Organization, on rates of breastfeeding initiation, exclusive breastfeeding at discharge, infant hypothermia and/or infant hypoglycemia. This study is the first, and at the time of this writing, the only study evaluating the specific WHO recommendation to delay bathing by 24 hours.

Previous studies evaluated the effects on breastfeeding rates (Preer, Pisegna, Cook, Henri, & Philipp, 2013) and hypoglycemia (McInerney & Gupta, 2015) of delaying newborn bathing by 12 hours and others examined the effects on hypothermia of delaying bathing by 1-4 hours (Varda & Behnke, 2000; Penny-MacGillivray, 1996) but no studies to date have examined the effects of delaying bathing by 24 hours. With a sample size of 1225, the current study is also significantly larger than all other comparable published studies.

The discussion of findings is organized into seven sections. The first discusses the characteristics of the study population and potential impact of these characteristics on observed outcomes. The subsequent four sections discuss primary analysis results for the four outcomes of interest in this study; 1) breastfeeding initiation (BFI), 2) exclusive breastfeeding at discharge (EBFD), 3) infant hypothermia (HT) 4) infant hypoglycemia(HG). The sixth section presents discussion of the results of secondary analysis comparing infants born pre-policy change to those born post and the final section summarizes the discussion of results

5.1: Characteristics of Study Population

Characteristics of study population were comparable in both cohorts with respect to all but two variables: Intention to breastfeed and percentage of mothers induced or augmented.

Intention to breastfeed was statistically significantly higher ($p=0.048$) in the delayed bathing cohort (83.2%) than in the early bathing cohort (78.7%). This slight increase in breastfeeding intention could explain some of the increased breastfeeding rates observed in the delayed bathing group.

The rate of induction or augmentation in the early bathing cohort was significantly higher ($p=0.027$) in the early bathing cohort (46.5%) than in the delayed bathing cohort (40.2%). Studies have shown that induction and/or augmentation can lead to breastfeeding difficulties (Erickson & Emeis, 2017; Out, Vierhout, & Wallenburg, 1988). It is thus possible that the higher rate of induction and augmentation in the early bathing cohort led to the lower breastfeeding rates observed in this group.

5.2: Breastfeeding Initiation (BFI)

The current study suggests that delayed newborn bathing has the potential to improve breastfeeding initiation (BFI) in the average healthy newborn. After controlling for potential confounders (gestational age, induction or augmentation, large or small for gestational age, c-section and epidural) there was a significant ($p=0.045$) 43% increase in BFI when bathing was delayed until 24 hours of life in the average risk subgroup (excluding those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of diabetic mothers). Delayed bathing resulted in a non-significant

($p=0.844$) 6% decrease in BFI in the high-risk subgroup (those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes) and when both these subgroups are combined, results for the total population, showed a non-significant ($p=0.103$) 27% increase in BFI when bathing is delayed (AOR 1.275, 95% CI 0.952-1.708, $p=0.019$). Although non-significant this 27% increase in BFI observed in the total population could be considered of clinical relevance.

The non-significant result observed in the high-risk subgroup is not unexpected considering the complicating factors experienced by these newborns. Included in this subgroup are all late pre-terms infants (34-36 weeks gestation). A study by Cooper et al. (2012) reported that 41% of late pre-term infants have breastfeeding difficulties and that the younger the gestational age the greater the difficulties, with 61% of infants born at 34 weeks experiencing feeding difficulties. These late pre-terms have also been shown to have higher rates of hypothermia and hypoglycemia (Lubchenco & Bard, 1971; Ishiguro, Namai, & Ito, 2009; Dimitriou, et al., 2010; Engle, Tomashek, & Wallman, 2007) which can further contribute to difficulties in breast feeding. This high-risk subgroup also included those infants who were small or large for gestational age (66%) and these infants have been shown to have significantly higher rates of hypothermia and hypoglycemia (Lubchenco & Bard, 1971; Doctor, O'riordan, Kirchner, Shah, & Hack, 2001; Lawrence, 2007; Lawrence, 2006; Kramer, et al., 2001). In addition to these evidenced barriers to breastfeeding these high-risk newborns may simply have required greater separation from mother due to procedural and medical requirements and this physical separation alone may hinder breastfeeding.

Interpretation of these results requires consideration of the definition of breastfeeding initiation (BFI) employed by this hospital and thus this study. In this study any action of placing baby to the breast was recorded as breastfeeding initiation. This definition does not necessitate adequate latch, the presence of milk transfer or ultimate breastfeeding success. The policy of the study hospital is to allow uninterrupted skin-to-skin contact between mother and baby for the first hour of life and to assist any mother intending to breastfeed in attempting a first feed (baby to breast) during that time. Because this first attempt to breast feed is part of a larger hospital policy it is likely that most mothers intending to breastfeed will have record of a BFI attempt and unlikely that there would be significant differences observed between those babies bathed before or after 24 hours of life. Additionally, this outcome measure typically occurs before either early or late bathing and is thus unlikely to be affected by bathing practices.

The current study adds to the limited published data on the effects of delayed bathing on BFI rates. The only other published study on the effects of delayed bathing, Preer et.al (2013) reported the odds of breastfeeding initiation were 166% greater for infants born after the intervention than for those born before the intervention (AOR = 2.66, 95% CI 1.29, 5.46). These results are not comparable to the results of the current study as the definition of BFI in the Preer study was significantly different than the one used in this study. Preer et.al (2013) defined BFI as “infant receiving any breastmilk at all during his or her neonatal hospital stay”. Additional differences between the current study and the Preer study that preclude comparison of results are the fact that Preer et. al. evaluated the effects of delaying newborn bathing by 12 hours not the 24 hours evaluated in the current study. As well, Preer et. al. state in their publication that their study hospital

had been actively addressing areas for improving breastfeeding support by analyzing their results from the Centers for Disease Control and Prevention's Maternity Practices in Infant Nutrition and Care (mPINC) survey, which allows U.S. maternity facilities to score themselves based on adoption of maternity practices that promote breastfeeding. Shortly before the implementation of the delayed bath policy examined in Preer et.al (2013) the study hospital underwent a complete redesign of their maternity unit that created private rooms for all patients and installed specially designed sinks for bathing newborns. Although investigators reported they did not identify any other changes to maternity protocols or procedures during the study period that may have affected breastfeeding rates, this facility was actively striving to improve maternity practices and promote breastfeeding and it is thus likely that confounding interventions existed.

In summary, study results found that delaying newborn bathing by at least 24 hours significantly increased breastfeeding initiation rates in the average risk subgroup but not in the high-risk subgroup or the total population.

5.3 Exclusive Breastfeeding at Discharge (EBFD)

A better indicator of long term breastfeeding success is the measure of exclusive breastfeeding at discharge (EBFD). Studies have shown that supplementation before hospital discharge is associated with shorter breastfeeding duration (AOR 3.9, 95% CI 2.1–7.2) (Blomquist, Jonsbo F, Serenius, & Persson, 1994), and lack of supplementation is associated with longer breastfeeding duration (OR 2.49, 95% CI 1.25–4.98) (Sheehan, et al., 1999). Exclusive breastfeeding at hospital discharge is associated with a markedly

lower risk of weaning by 6 months postpartum (adjusted OR 0.19, 95% CI 0.06–0.65, $P=.008$) (Frota & Marcopito, 2004).

The findings of the current study suggest that there is an association between delayed newborn bathing and increased rates of EBFD in both the total population and average risk subgroup. In the total population, infants bathed after 24 hours of life had odds of exclusive breastfeeding 33% greater than those infants bathed before 24 hours (AOR 1.334, 95% CI 1.049-1.698, $p=0.019$). In the average risk subgroup, infants bathed after 24 hours of life had odds of exclusive breastfeeding 40% greater than those infants bathed before 24 hours (AOR 1.401, 95% CI 1.056-1.857, $p=0.019$). Although not statistically significant ($p=0.528$) there was a 17% increase in EBFD in the high-risk subgroup when bathing was delayed which may be of clinical relevance (AOR 1.176, CI 0.711-1.944).

These data are similar to findings of Preer and colleagues (2013) who reported that exclusive breastfeeding rates increased from 32.7% to 40.2% ($p<0.05$) when bathing was delayed by 12 hours and that those infants in the delayed bath group had odds of exclusive breastfeeding 39% greater than infants in the early bathing group (AOR 1.39, CI 1.02, 1.91). As previously stated comparison of the current study to Preer et. al must consider the differences in bath timing intervention (12 hour delay in Preer versus 24 hour delay in current study) as well as setting.

In summary, results from this study suggest that delayed newborn bathing has the potential to increase breastfeeding rates (both BFI and EBFD) in the average healthy newborn (those >36 weeks gestation, average size for gestational age and born of non-

diabetic mothers) but not in high risk newborns (those born ≤ 36 weeks gestation, babies small or large for gestational age and/or those born of mothers with diabetes).

As a retrospective cohort study, these research findings indicate an association between delayed newborn bathing and increased breastfeeding rates but do not confirm causation. As discussed in the chapter 2 literature review, related data suggests that there are several interconnected mechanisms by which delaying newborn bathing may affect breastfeeding rates. The most evidenced of these mechanisms being skin-to-skin contact (SSC) between mother and child. Eliminating the separation of mother and child required for bathing facilitates extended SSC during the critical first 24 hours of life which has been shown in numerous studies to positively affect breastfeeding (Moore, Bergman, Anderson, & Medley, 2016; Bramson, et al., 2010; Gabriel, et al., 2010). It is possible that the increases in breastfeeding rates observed in this study may be the result of the increase time spent in SSC when bathing is delayed. This study attempted to collect data pertaining to SSC but due to inadequate charting of such information this data was unavailable for analysis.

Breastfeeding rates in Newfoundland and Labrador have been rising gradually over the past thirty years. According to data from the Perinatal Program of Newfoundland and Labrador, breastfeeding rates in the province were rising by between 1-4% per year in the years leading up to and including our study period (2012 to 2016) (Perinatal Program Newfoundland and Labrador, 2016). Increases in breastfeeding rates observed in this study would thus include increases that would presumably have been seen if the delayed bath policy had not been instituted.

5.4 Hypothermia

The current study suggests that delayed bathing is associated with an increase in the rates of hypothermia. In the total population, infants receiving a delayed bath were 2.5 times more likely to experience a hypothermic event than those bathed early (AOR 2.524, $p=0.011$). Those infants in the high-risk subgroup were 3.8 times more likely to experience hypothermia (AOR 3.860, $p=0.028$) and although not significant, those in the average risk subgroup were also at increase risk of hypothermia (AOR 1.958, $p=0.1470$).

Chi squared tests of association found no statistically significant associations between hypothermia and any other study variable but as a retrospective cohort study, detailed data on hypothermic events was limited. Information around factors like room temperature, skin-to-skin contact, and clothing/blanketing were not available.

Additionally, standardized measurement timing, techniques and instruments were not in place.

Further investigation into these incidences of hypothermia was conducted to understand and explain the circumstances of these events. In total 38/1379 infants experienced a hypothermic event, 12 events occurred in the early bath cohort and 26 in the delayed bath cohort. The observed increases in hypothermia are driven largely by the high risk population in that increased rates of hypothermia were significant in the high-risk and total population but not in the average risk population and 18/38 hypothermic events occurred in high risk babies. The rate of hypothermia was greater in the high risk subgroup (4.7%) than in either the average risk subgroup (2.3%) or the total population (2.8%). This is not surprising as studies have shown late-pre-terms and infant born small for gestational age are at higher risk of hypothermia (Medoff-Cooper, et al., 2012; World

Health Organization, 1997). It is possible that detection bias occurred in high risk babies who are known to be at risk for hypothermia. Nursing practice at this hospital dictate that temperature of high risk babies be measured and recorded every 3-4 hours whereas temperatures of average risk babies are measured and recorded once a day. The more frequent taking of temperatures in high risk babies may have resulted in greater detection of hypothermia than those not at increased risk who may have experienced incidence of hypothermia which resolved undetected and thus unrecorded.

Numerous studies have demonstrated significant temperature decreases during and immediately after newborn bathing (Medves & O'Brien, 2004; World Health Organization, 1997; Smales & Kime, 1978; Penny-MacGillivray, 1996; Varda & Behnke, 2000; Bergström , Byaruhanga , & Okong, 2005; Takayama, Wang, Uyemoto, Newman, & Pantell, 2000). Based on these data it was hypothesized that delayed bathing would decrease the incidence of post bath hypothermia. Data from this study did not support this hypothesis. Results found that regardless of whether infants received an early or delayed bath, most (24/38, 63.2%) hypothermic events *occurred before* infants were bathed. The majority (23/26, 88.5%) of hypothermic events observed in the delayed bath cohort *occurred before* infants were bathed. These data may suggest that early bathing mitigates the risk of hypothermia or, more likely, that these hypothermic events were unrelated to bathing. Discussion with neonatal nursing staff and nursing management revealed several potential reasons for the rates of hypothermia observed in this study which support the conclusion that these incidences were unrelated to bath timing. These will be discussed below.

Careful examination of the charts of each participant who experienced hypothermia revealed possible explanations for many of the incidences reported in this study. It was found that in six of the thirty-eight cases, hypothermia was reported immediately after the newborn was transferred from the delivery room and thus temperature drop occurred during transfer. There is a significant distance between the delivery room and the maternity ward in this study hospital. Hospital procedure (both pre- and post bath policy change) is for mother and baby to have skin-to-skin (SSC) contact for 1-2 hours post delivery after which baby is wrapped in a blanket and transferred in a cot to the maternity ward. This break in SSC combined with exposure to the varying temperatures of the hospital corridors and elevators in older hospital buildings are possibly responsible for these incidences of hypothermia and may be unrelated to bath timing. Staff are currently considering implementation of a practice change to transport mother and baby in skin-to-skin contact which may reduce the incidences of hypothermia occurring during infant transfer.

The observed differences in hypothermia rates may also be related to nursing practice and procedures before and after the implementation of the delayed bathing policy. Prior to the bath policy change babies were brought from the case room to the nursery. They were then bathed, dried and either wrapped in warm blankets or placed under a radiant warmer (figure 3.2). Subsequent to the bath policy change babies were wiped dry with a towel post delivery, wrapped and brought to mothers in the maternity ward where room temperatures vary and are cooler than either the nursery or delivery room (figure 3.3). Towel drying of babies post delivery may not always result in babies being completely dry. The combination of a potentially damp baby and cooler ambient

room temperatures may have led to the higher rates of hypothermia observed pre-bath in the delayed bathing cohort. Nursing staff also report that increased emphasis on skin-to-skin contact has resulted in looser wrapping of babies to allow SSC and observation of breastfeeding cues. These poorly wrapped babies are then often passed around to visiting family and friends. This may further contribute to the environmental cold stress responsible for hypothermic incidences.

As the first, and to date, the only study to examine the effects of delayed bathing by 24 hours on incidence of hypothermia there are no comparative studies. Previous studies on the effect of bathing on infant temperature compared bathing times of between one and six hours of life and measured rectal or axillary temperatures and not incidence of hypothermia as measured in the current study (Behring , Vezeau, & Fink, 2003; Alizadeh Taheri, Fakhraee , & Sotoudeh, 2007; Varda & Behnke, 2000; Penny-MacGillivray, 1996). These previous studies found that temperature decreases did occur post bath but were not sustained and of no clinical consequence.

Additional study is required to investigate the effects of longer delays in bath timing, the potential for an optimal bath time as well as the clinical relevance of bathing induced temperature decreases in infants which will be further discussed in the following chapter.

5.5 Hypoglycemia

The current study found no association between delayed newborn bathing and rates of hypoglycemia among any of the cohort comparisons. Sample size calculation determined that 1300 study participants would be required to evaluate this outcome. After

removal of study subjects who were not bathed within the time frame dictated by the policy at the time of birth the remaining sample size was 1225 and thus insufficient to detect difference. Sample size calculation was based on a yet unpublished study by McInerney and Gupta (2015). Minimal details of this study were reported in Journal of Obstetric, Gynecologic, & Neonatal Nursing, as a poster presentation at the 2015 Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) convention. Limited study information on which to base sample size calculation may have results in an inadequately low calculated sample size.

As hypoglycemia is a relatively rare event, a much larger cohort or alternative study design may be required to detect any association between bathing and hypoglycemia. Additionally, the high rates of supplementation and formula feeding in the study population may have influenced results as infants receiving formula are less likely to experience hypoglycemia (Hawdon, Ward Platt, & Aynsley-Green, 1992; Fatos, et al., 1997).

5.6 Secondary Analysis

Primary analysis compared infants bathed before 24 hours to those bathed after 24 hours and excluded 154 infants who were not bathed within the timeframe dictated by the policy at the time of their birth. Secondary analysis compared those infants born pre-policy change to those born post policy change in the total population. This analysis included all infants despite non-adherence to bathing policy at the time of birth (total n=1379, n=721 born pre-policy change, n=658 born post policy change). Results of the pre/post policy change analysis were similar to the primary analysis for the outcomes of

breastfeeding initiation, hypothermia and hypoglycemia. The only difference in results observed was with respect to exclusive breastfeeding at discharge (EBFD). Primary analysis results found that babies bathed after 24 hours had a significant increase in EBFD compared to those bathed before 24 hours. Secondary analysis results found that babies born post policy change had a non-significant increase in EBFD. In other words, when pre- and post policy change measures are compared, EBFD results are not significant but when bath timing is compared EBFD results are significant. This is explained by the fact that pre/post policy analysis included 154 infants who were not bathed at the proper time. More specifically 41 infants born pre-policy change were bathed after 24 hours and 113 infants born post policy change were bathed before 24 hours. The misclassification of exposure (bath) is reflected in the results. The difference in results in the primary and secondary analysis highlights the influence of bath timing. The majority (113/154) of misclassifications were in infants born post policy change who should have received a delayed bath but were in fact bathed early leading to a non-significant increase in EBFD and suggests that delayed bathing, in fact, positively impacts breastfeeding rates.

Misclassification of exposure is an inherent challenge in the conduct of pre/post intervention studies, especially when done retrospectively. Although in this study a three-month window of time was left on either side of the policy change in order to minimize non-adherence, there remained participants non-compliant to the policy. These incidences of non-compliance to bathing policy were not a reflection of staff policy adherence but due to parents' requests for early or late bathing. Bathing practice remains the parents' choice but there may be opportunity to provide parental education around the timing of a

newborns first bath, especially with respect to reducing complications such as hypothermia.

5.7 Summary

Data from this study suggests that delaying newborn bathing may aid in breastfeeding. Whether due to the decrease in separation of mother and child, the maintenance of biological cues or the decrease in infant stress from early bathing, delaying bathing may play a key role in providing the best possible conditions for breastfeeding. When instituting delayed bathing practices care must be taken to ensure that infant temperature is maintained. There are numerous reasons to delay a newborns first bath beyond the outcomes examined in this study. Decisions regarding newborn bath timing should include consideration of the benefits and risks observed in this study as well as all other factors impacted by newborn bathing.

Chapter 6: Strengths and Limitations, Clinical Implications and Knowledge Translation, Future Research, and Conclusions

This chapter summarizes the strengths and limitations, clinical implications, knowledge translation and future research associated with this study. The first section includes a description and discussion of the strengths and limitations of this study. The second section outlines the clinical implications of this research. Knowledge translation of the research findings are outlined in the third section and section four describes proposals for future research on this topic. The final section summarizes the conclusions of this chapter.

6.1 Strengths and Limitations

This study had both strengths and limitations, some of which are inherent to the study design. This study was a retrospective cohort study which collected data from patient in-hospital charts. Data collection was thus limited to the available information recorded and relied on the accuracy of these records. As a cohort study, only association and not causation can be inferred from the results. The retrospective study cohort design was chosen as it was most suitable to the timing of study inception. This study was designed three months before implementation of the delayed bathing policy at the study hospital and thus timing did not allow for prospective study. Future research in this area would benefit from a prospective cohort or randomized control trial study design.

Strengths of this study were the large sample size and the large number of data variables observed allowing investigation of potential confounders. Data collected

through chart reviews was validated against similar data collected by the Perinatal Program of Newfoundland and Labrador (PPNL) to insure accuracy. These validated variables included: gestational age, size for gestational age, gender, weight, hypoglycemia, breastfeeding initiation, exclusive breastfeeding at discharge, labour type, augmentation of labour and maternal diabetes. Sampling bias was minimized through the use of computer generated random sampling. To insure the required sample size was achieved, a total of 1542 charts were selected and reviewed to identify those meeting inclusion/exclusion criteria which represented 65% of the total births during the study period. This resulted in a sample very representative of the population of Newfoundland and Labrador and generalizable to many populations due to the broad inclusion criteria.

Study limitations were predominantly due to the retrospective nature of the study and the limitation to previously recorded data. Attempt was made to collect data on skin-to-skin contact (SSC) but inconsistent charting of this information prevented analysis of SSC as a potential confounder. Similarly, data related to infant temperature like ambient room temperature and specific clothing and blanketing of infants was not recorded and thus could not be assessed as confounders. Differences in temperature monitoring procedure between full term and late pre-term infants resulted in a potential detection bias in incidences of hypothermia. Analyses conducted in this study have relied on the accuracy of in-hospital records which consist of paper records written by physicians and nurses which are later manually coded into electronic records by hospital coders and may thus contain errors.

Based on the numerous interconnected factors influencing breastfeeding it is not possible to attribute the increases in breastfeeding observed in this study to the sole intervention of delayed bathing. It is possible that delaying a newborn's bath allows for increased time spent skin-to-skin (SSC) which may be independently responsible for the increases in breastfeeding. It is also not possible to separate the influences of bio-fluids and olfactory cues from SSC. There have been no studies examining the removal of bio-fluids and its impact on SSC and/or breastfeeding. The interconnected nature of the outcomes of this study as well as the role of SSC, bio-fluids and olfactory cues make it impossible to attribute the results of this study to the sole intervention of delayed bathing. Instead, bath timing must be considered as part of a larger goal of providing an optimal environment for mother and baby to breastfeed.

6.2 Clinical Implications

This study will inform hospital staff, policy makers and parents of the potential benefits and limitations of delayed bathing procedures and policies. Being the first, and at the time of this writing, the only study evaluating the specific recommendation of the World Health Organization (WHO) to delay newborn bathing until at least 24 hours of life, this study will add clinical evidence to the WHO's guidelines.

Previous studies examined much shorter intervals of delayed bathing from 1-12 hours post delivery (Preer, Pisegna, Cook, Henri, & Philipp, 2013; McInerney & Gupta, 2015; Penny-MacGillivray, 1996; Varda & Behnke, 2000; Smales & Kime, 1978; Takayama, Wang, Uyemoto, Newman, & Pantell, 2000; Bergström, Byaruhanga, &

Okong, 2005; Nako, et al., 2000). This study provides the only currently available data examining the effects of a 24-hour delay in bathing as recommended by the WHO. The addition of data from this study provides evidence for longer delays in bath timing.

As an increasing number of hospitals adopt delayed bathing policies, this research will provide policy makers with evidence to inform their decisions and aid in policy development. This study contributes to the body of evidence in support of practices and policies that minimize separation of mother and baby and limit health care providers intervention to that which is medically necessary.

6.3 Knowledge Translation

The results of this study have been presented internationally at the Healthy Children Project and UCLAN's 2018 International Conference on the Theory and Practice of Human Lactation Research. Locally, research findings were disseminated through presentations to relevant hospital staff and management, the Clinical Epidemiology Seminar Series and the Breastfeeding Research Working Group. Additional knowledge translation activities have been planned to present locally at the 2018 Primary Healthcare Partnership Forum (PriFor). Papers will be submitted to peer-reviewed journals for publication.

6.4 Future Research

As this is the first, and to date, the only study examining the effects of delaying newborn bathing by at least 24 hours, as recommended by the WHO, future research on

this subject is required. Additional studies evaluating the recommended 24-hour delay in newborn bathing to support or refute results found in this study are required to make definitive determination of the potential benefits of the recommendation. Randomized control trials comparing differing bath times could provide insight into optimal bath timing. Further research which includes evaluation of skin-to-skin contact in addition to bath timing are needed to assess the impact of each intervention and the potential for each as an independent contributor to breastfeeding. Randomized control trials are required to assess the effect of bath timing on hypothermia rates controlling for all influencing factors like ambient room temperature, bathing procedure, temperature measurement and measurement timing. Quality improvement initiatives with prospective and standardized measurement of relevant outcomes could also address some of the research gaps. Continued research on the impact of newborn bath timing will inform policy and future guidelines.

6.5 Conclusions

The WHO's recommendation to delay newborn bathing by at least 24 hours is driving an increasing number of hospitals to adopt delayed bathing policies. Some hospitals are opting for policies directly in line with the WHO's recommendation but others are choosing to institute 8-12 hour delay policy. The lack of definitive evidence on optimal bath timing is reflected in the diversity of policy timing. Future research will aid in the adoption of the best possible delayed bathing policies.

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APPENDIX A: ETHICAL APPROVAL



Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

November 17, 2015
Ms Susan Warren
31 Monkstown Road
St. John's, NL
A1C 3T2
Dear Ms Warren

Reference #15.254

Re: In full term healthy babies born at the Janeway in NL, does a new delay the bath policy, implemented March 2015, affect in-hospital breastfeeding rates, thermoregulation and glycemic control?

Your application received an expedited review by a Sub-Committee of the Health Research Ethics Board. **Full approval** of this research study is granted for one year effective **November 17, 2015.**

This is your ethics approval only. Organizational approval may also be required. It is your responsibility to seek the necessary organizational approval from the Regional Health Authority or other organization as appropriate. You can refer to the HREA website for further guidance on organizational approvals.

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Letter of request, acknowledged
- List of variables, approved

MARK THE DATE

This approval will lapse on November 17 2016. It is your responsibility to ensure that the Ethics Renewal form is forwarded to the HREB office prior to the renewal date; you may not receive a reminder. The Ethics Renewal form can be downloaded from the HREA website <http://www.hrea.ca>. Ms S Warren Reference #15.254 Page 2 Nov 17 2015 email: info@hrea.ca Phone: 777-6974 FAX: 777-8776

If you do not return the completed Ethics Renewal form prior to date of renewal:

- ***You will no longer have ethics approval***
- *You will be required to stop research activity immediately*
- *You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again*
- ***Lapse in ethics approval may result in interruption or termination of funding***

You are solely responsible for providing a copy of this letter, along with your approved HREB application form; **to the Office of Research Services** should your research depend on funding administered through that office.

Modifications of the protocol/consent are not permitted without prior approval from the HREB. **Implementing changes without HREB approval may result in your ethics approval being revoked, meaning your research must stop.** Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREA website) and submitted to the HREB for review.

The Health Research Ethics Board operates according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, the Health Research Ethics Authority Act and applicable laws and regulations.

You are responsible for the ethical conduct of this research, notwithstanding the approval of the HREB.

We wish you every success with your study.

Sincerely,

Dr Fern Brunger (Chair, Non-Clinical Trials Health Research Ethics Board)

Ms. Patricia Grainger (Vice-Chair, Non-Clinical Trials Health Research Ethics Board)

CC: L. Twells

APPENDIX B: DATA ABSTRACTION FORM

In full term healthy babies born at the Janeway in NL, does a new delay the bath policy, implemented March 2015, affect in-hospital breastfeeding rates, thermoregulation and glycemic control?

Mother Study Number: _____(use unique ID)

Infant Study Number: _____

MATERNAL DATA EXTRACTION FORM

INVESTIGATIONS DURING PREGNANCY:

Prenatal Care: ☐ YES ☐ NO

Drug use during pregnancy:

- ☐ Illicit Drugs _____
- ☐ Methadone
- ☐ Expected illicit drug use post-delivery thus breastfeeding contraindicated.

Breastfeeding intention:

- ☐ Yes
- ☐ No
- ☐ Undecided

Serology/genital culture Reports:

- ☐ HIV _____
- ☐ Hepatitis B _____
- ☐ Hepatitis C _____
- ☐ Methacillin-resistance MRSA _____
- ☐ HPV _____
- ☐ Herpes _____ Acyclovir given? ☐ YES ☐ NO
- ☐ **GBS Status:** Neg: _____, Pos: _____ not measured/recorded _____
 - ☐ ABX given ☐ YES ☐ NO

Maternal Diabetic history:

- ☐ Type I
- ☐ Type II
- ☐ Gestational
- ☐ Unknown type

LABOUR:

- ☐ No Labour
- ☐ Spontaneous
- ☐ Induced:
 - ☐ Oxytocin
 - ☐ Prostaglandin
 - ☐ Augmented after labour started

Medications during labour: ☐ YES ☐ NO

- ☐ Ampicillin
- ☐ Gentamycin
- ☐ Clindamycin
- ☐ Kefzol
- ☐ Cephalosporins
- ☐ Pen-G
- ☐ Anti-Nausea _____
- ☐ Atasol (other pain medication)_____
- ☐ Other (Please list): _____
- ☐ Antibiotics given to mother number of hours prior to delivery?
_____ (hrs)

DELIVERY:

Mode of delivery:

- ☐ Vaginal Birth
- ☐ C-Section
 - ☐ Emergency
 - ☐ Elective

Operative Deliveries:

- ☐ Vacuum
- ☐ Forceps
- ☐ Combo

Pain Management:

- ☐ Epidural
- ☐ spinal
- ☐ General Anesthetic
- ☐ Narcotics

Complications of Labour and Delivery:

- ☐ Maternal ICU admission
- ☐ Meconium at delivery:
- ☐ Infant corded

INFANT DATA EXTRACTION FORM**Infant Study Number:** _____ **DOB:** _____**Gestational age at delivery:** _____ **weeks**

Birth weight: _____ Length: _____ HC: _____

Apgars 1 min _____ 5 min _____

☐ **Resuscitation required? Details**

HOSPITAL STAY:

- ☐ 5 North B LOS: _____
- ☐ NICU admission
 - ☐ NICU admission due to hypothermia
 - ☐ NICU admission due to hypoglycemia

HYPOTHERMIA:Jaundice requiring phototherapy ☐ YES ☐ NO☐ **Symptomatic hypothermia requiring treatment** (Infant temperature <36.5) ☐ YES☐ NO

- ☐ Pre bath
- ☐ post bath

Treatment given

- ☐ Skin to skin
- ☐ Extra blanket

- ☐ Infant care center
☐ Not charted

HYPOGLYCEMIA:

☐ Medications given in hospital? _____

☐ **Symptomatic hypoglycemia requiring treatment:**

Glucose level of less than 2.6 mmol/L in the first 24 hours of life ☐ YES ☐ NO

Glucose level of less than 2.6 mmol/L after 24hrs of life. ☐ YES ☐ NO

Lowest blood sugar level: _____ Age in hours at this time: _____

Infant temperature at time of lowest blood sugar level: _____

Hypoglycemia occurred:

- ☐ Pre bath
☐ Post bath

Infant at risk for Hypoglycemia:

- Small for gestational age (see definition below): ☐ YES ☐ NO
- Large for gestational age (see definition below): ☐ YES ☐ NO

| 10 th and 90 th percentile cut-offs for birthweight at term in Canadian infants: | | | | |
|--|-----------------------------|--------|-----------------------------|--------|
| Gestation (completed weeks) | Birthweight (g) | | | |
| | 10 th percentile | | 90 th percentile | |
| | Male | Female | Male | Female |
| 37 | 2552 | 2452 | 3665 | 3543 |
| 38 | 2766 | 2658 | 3877 | 3738 |
| 39 | 2942 | 2825 | 4049 | 3895 |
| 40 | 3079 | 2955 | 4200 | 4034 |
| 41 | 3179 | 3051 | 4328 | 4154 |
| 42 | 3233 | 3114 | 4433 | 4251 |

CPS Position statement (FN
2004-01)

SKIN TO SKIN:

- ☐ Skin to skin immediately post delivery
Length of SSC post delivery _____
Time after birth when SSC initiated _____
- ☐ Skin to skin during ward stay
- None
 - Few

- Frequently
- At all times

IN-HOSPITAL BATHING: ☐ YES ☐ NO

Time to first bath _____

Second bath ☐ YES ☐ NO

Time to second bath _____

- ☐ Parents requested delayed bathing
- ☐ Parents requested early bathing
- ☐ Symptomatic hypothermia post bath
- ☐ Symptomatic hypoglycemia post bath requiring treatment
(lowest blood sugar level): _____
- Treatment for hypoglycemia:
 - ☐ IV dextrose _____ (%) and amount
 - ☐ PO (milk or glucose)
 - ☐ NG (milk or glucose)
- ☐ Symptoms of hypoglycemia (jittery, seizures, lethargy etc. _____)

FEEDING:

Breastfeeding initiation ☐ YES ☐ NO

Time to breastfeeding initiation _____

- ☐ Exclusive breastfeeding in hospital
 - ☐ Exclusive formula feeding in hospital
 - ☐ BF and formula feeding
 - ☐ BF at discharge
 - ☐ Hospital supplementation
Reason for required
supplementation _____
- Supplement given _____