

Mount Saint Vincent University
Department of Applied Human Nutrition

In-Hospital Feeding Practices of Infants Born to Mothers with Gestational Diabetes Mellitus or Type 2 Diabetes Mellitus: Evaluating Policy Implementation Effectiveness

by
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Abstract

Title: In-Hospital Feeding Practices of Infants Born to Mothers with Gestational Diabetes Mellitus or Type 2 Diabetes Mellitus: Evaluating Policy Implementation Effectiveness

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Introduction: Women with diabetes mellitus (DM) in pregnancy may experience unique breastfeeding challenges, including delayed onset of lactogenesis II and neonatal hypoglycemia. There is evidence that routine, non-medically indicated formula supplementation may be provided in hospital to overcome these challenges. A policy directing supplemental feeding practices for breastfeeding children was introduced at a tertiary level health centre providing services for women and children to promote evidence-based practice.

Objectives: This study aimed to (1) describe feeding practices of infants born to mothers with gestational diabetes mellitus (GDM) and type 2 diabetes (T2DM); (2) compare feeding practices before and after policy introduction.

Methods: A retrospective chart audit of mother-infant pairs (n=120) was performed, n=60 each ~12 months before and after policy introduction. The primary outcome was provision of breast milk at discharge; a chi-square test was completed to compare pre- and post-policy groups. Secondary outcomes included participant and infant feeding characteristics.

Results: There was no significant difference in the number of infants receiving breast milk at discharge between pre- (58% [35/60]) and post-policy (58% [35/60]) groups ($p=0.64$). The number of infants exclusively breastfed throughout the hospital stay also did not differ by group (37% [22/60] before, 43% [26/60] after; $p=0.39$).

Conclusion: Additional research that examines impacts and efficiency of in-hospital policies to support breastfeeding among women with GDM and T2DM in pregnancy is needed. Our findings suggest that this policy was not effective in facilitating breastfeeding or limiting supplementation. Using an integrative knowledge translation action framework, these initial findings indicate future opportunities to explore provider knowledge, perceptions, and barriers to *Policy* adoption.

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List of Abbreviations

B

BFI *Baby-Friendly Initiative*

C

CPS Canadian Paediatric Society
CPG Clinical Practice Guidelines

D

DM Diabetes mellitus

G

GDM Gestational diabetes mellitus

H

HMO Human milk oligosaccharide

I

IR Insulin resistance
IV Intravenous

K

KTA Knowledge-to-action

M

MODY Maturity-onset diabetes mellitus in the young

N

NICU *Neonatal intensive care unit*

P

PG Plasma glucose

O

OGTT Oral glucose tolerance test

T

TPB Theory of planned behavior
T1DM Type 1 diabetes mellitus
T2DM Type 2 diabetes mellitus

W

WHO World Health Organization

1.0 Introduction

Breast milk provides optimal nutrition to support healthy childhood growth and development during the first six months of life (1,2). The World Health Organization (WHO) (2002), Health Canada (2015), the Canadian Paediatric Society (CPS) (2015), Dietitians of Canada (2015), and the Breastfeeding Committee for Canada (BCC) (2015) recommend that infants are exclusively breastfed for the first six months of life, with the subsequent introduction of complimentary foods and continued breastfeeding for up to two years and beyond (1,2). Despite this recommendation, rates of breastfeeding in Canada are low. In 2017, 90% of Canadian mothers initiated breastfeeding, while only 32% were exclusively breastfeeding at six months (3).

Such low rates of breastfeeding may be attributed to a number of factors (4). For instance, previous research has identified the following as factors interfering with breastfeeding duration: low milk supply, infant health problems, physical problems with latching, delivery by caesarean section, return to work, a lack of family and provider support, and low maternal self-efficacy (4). Mothers with diabetes mellitus (DM) during pregnancy may be more likely to encounter a number of unique challenges that interfere with breastfeeding, including neonatal hypoglycemia, macrosomia, delivery by cesarean section, shoulder dystocia, and delayed onset of lactogenesis II (5–7). Increased maternal body weight, a risk factor for type 2 diabetes mellitus (T2DM) and gestational diabetes mellitus (GDM), has also been associated with difficulties with infant latch (8,9).

In the early 1900s, women with DM were discouraged from breastfeeding as it was thought to increase the risk of infant mortality and interfere with DM management (10). Breastfeeding is now supported for women with DM, however, challenges experienced in-hospital may interfere with the establishment of breastfeeding (11). For instance, supplementation with infant formula may be provided due to maternal and healthcare provider perceptions of inadequate colostrum and the belief it will prevent neonatal hypoglycemia (12,13). Furthermore, routine admission to special care units may be more common in infants born to mothers with DM during pregnancy (11). Such practices can be problematic for women with DM intending to breastfeed their infants. Delays in the first feed, limited skin-to-skin contact, mother-infant separation, and

formula supplementation can result in decreased milk supply, impacting breastfeeding initiation and duration (11).

The in-hospital period is a critical time for women to establish breastfeeding. Early success builds maternal confidence and increases the likelihood of achieving long-term breastfeeding intentions (14). Hospital policy reflective of evidence-informed infant feeding practices may support breastfeeding for women with DM in pregnancy. There is a need for research that examines the impacts and efficiency of in-hospital policies to support breastfeeding in women with GDM and T2DM in pregnancy. Although studies have evaluated the effectiveness of policy in supporting breastfeeding in healthy and at-risk infants, little recent research has focused on mothers with GDM or T2DM and their infants (15). The aim of this study was twofold: 1) to describe in-hospital feeding practices of infants born to mothers with GDM and T2DM in pregnancy, and 2) to evaluate the effectiveness of the *Supplemental Feedings for Breastfeeding Children Policy* in facilitating in-hospital breastfeeding at the Izaak Walton Killam (IWK) Health Centre.

2.0 Literature Review

2.1. Diabetes Mellitus in Pregnancy

Diabetes mellitus in pregnancy is characterized by periods of hyperglycemia (16). Onset of DM can occur either prior to (pre-existing) or during pregnancy (GDM) (9). The following section provides an overview of pre-existing DM and GDM (9). Although these conditions are discussed separately, there is overlap in recommended management principles for all women with DM in pregnancy (9).

2.1.1. Type 1 and Type 2 Diabetes Mellitus

The term pre-existing DM refers to DM existing before pregnancy and includes type 1 diabetes mellitus (T1DM) and T2DM (9). In T1DM, immune-mediated destruction of pancreatic beta cells results in a loss of insulin production and secretion (17). Type 2 diabetes mellitus, on the other hand, is characterized by impaired insulin secretion from beta cells and increased insulin resistance (IR) to insulin action (17). Diagnostic criteria of DM, as outlined in Diabetes Canada 2018 Clinical Practice Guidelines (CPG), are as follows: fasting plasma glucose (PG) ≥ 7.0 mmol/L, hemoglobin A1C $\geq 6.5\%$ (to be used in adults without factors known to affect the accuracy of A1C; not recommended for use in individuals with suspected T1DM), two-hour PG in a 75g oral glucose tolerance test (OGTT) ≥ 11.1 mmol/L, and random PG ≥ 11.1 mmol/L (17). When symptoms of hyperglycemia are evident, diagnosis of DM is made if a single test result is in the DM range (17). In the absence of symptoms of hyperglycemia, a repeat test (preferably the same test) on a different day is needed to confirm diagnosis. A random PG ≥ 11.1 mmol/L in an asymptomatic individual should be confirmed with an alternative test (17).

A number of management principles during pregnancy have been associated with improved outcomes for women with pre-existing DM (9). In particular, achieving optimal glycemic control has been associated with decreased risk of fetal and maternal complications. The majority of women with pre-existing DM should strive for the following targets: fasting and pre-prandial PG < 5.3 mmol/L, one-hour postprandial PG < 7.8 mmol/L, two-hours postprandial PG < 6.7 mmol/L, and hemoglobin A1C $< 6.5\%$ ($\leq 6.1\%$ by the third trimester, if possible) (9). Self-monitoring of

blood glucose, with fasting, pre-prandial, and postprandial PG checks performed four to seven times per day, is essential to achieving glycemic control (9). For women receiving insulin therapy, blood glucose monitoring overnight may also be advised to reduce the risk of nocturnal hypoglycemia. The use of a continuous glucose monitor may assist women with pre-existing DM to meet blood glucose targets (9).

For women with pre-existing DM receiving pharmacology therapy, medications should also be reviewed to assess their safety for use during pregnancy (9). Regimens should be tailored and may need to be adjusted throughout pregnancy with changes in placental hormone levels. Women with pre-existing DM should also be supported to achieve a healthy weight gain during pregnancy as per guidelines from the Institute of Medicine (IOM) based on maternal pre-pregnancy Body Mass Index (BMI) (9). Weight gain within recommended ranges has been associated with lower risk of macrosomia, large for gestational age, and caesarean deliveries. When provided by an inter-professional healthcare team, such care has been associated with improved pregnancy outcomes for women with pre-existing DM (9).

2.1.2. Gestational Diabetes Mellitus

Gestational diabetes mellitus refers to DM that is diagnosed during pregnancy and is often transient in nature (9). Hormones released during pregnancy cause IR to ensure adequate glucose is shunted to the fetus (16). In a state of normoglycemic pregnancy, IR is compensated for by increased insulin secretion from pancreatic beta cells. Consequently, blood glucose remains within physiological range, or even below pre-pregnancy levels (16). In women with GDM, beta cells are unable to secrete sufficient insulin to overcome gestational IR. Furthermore, peripheral tissues, including fat and muscle, exhibit greater IR than in normoglycemic pregnancy. These changes in metabolism result in periods of hyperglycemia (16). The pathogenesis of GDM may also be related to increased release of pro-inflammatory cytokines associated with chronic-low grade inflammation, however, further research is needed to understand this relationship (18). Women who develop GDM often display greater pre-pregnancy IR as compared with women who do not develop GDM (18,19). Given the similarity in pathogenesis, women with GDM are at greater risk of developing T2DM later in life (19). For instance, it is estimated that in the 16-

year period following delivery, approximately 40% of women with prior GDM will develop T2DM (9).

Symptoms of GDM frequently go unnoticed, often diagnosed during standard screening procedures (9). For this reason, universal screening is recommended for all pregnant women between 24 to 28 weeks gestation (9). Early screening at <20 weeks is recommended for women with a history of GDM and those at high-risk of T2DM (9). Diabetes Canada 2018 CPG outline two methods for screening and diagnosis: a preferred approach and alternative approach. The preferred approach consists of two-steps: a 50 g glucose challenge test, followed by a 75 g OGTT if one-hour PG is between 7.8 to 11.0 mmol/L. Diagnosis of GDM is made when 50g glucose challenge test >11.1 mmol/L, or 75g OGTT fasting PG \geq 5.3 mmol/L, one-hour PG \geq 10.6 mmol/L, and two-hour PG \geq 9.0 mmol/L (9). The alternative approach includes administration of a 75g OGTT. Diagnosed of GDM is made when fasting PG \geq 5.1 mmol/L, one-hour PG \geq 10.0 mmol/L, and two-hour PG \geq 8.5 mmol/L (9).

As with pre-existing DM, frequent self-monitoring of both fasting and post-prandial blood glucose is essential to achieve glycemic control and to assess the need for changes in therapy (9). Glycemic targets for women with GDM are the same as those for women with pre-existing DM (outlined in section 2.1.1.). Women on insulin therapy should aim to maintain blood glucose >3.7 mmol/L to minimize the risk of recurrent hypoglycemia (9). Appropriate weight gain as per IOM guidelines may also improve pregnancy outcomes. Discussion and care should be provided to assist women with weight management during pregnancy (9). In terms of therapy, first-line treatment for GDM involves lifestyle modification, with changes to diet and exercise. Specific dietary interventions include moderate carbohydrate intake and incorporation of low glycemic index (GI) foods in place of high-GI foods (9). When glycemic targets cannot be reached within one to two weeks with diet and physical activity alone, insulin or oral anti-hyperglycemic medication (e.g. Metformin) is typically initiated (9).

2.1.3. Rates of Diabetes in Pregnancy

Rates of pre-existing DM and GDM in Canada are on the rise (20). As evident from Table 1, the rate of T1DM has remained relatively stable from 2004/2005 to 2010/2011, whereas rates of

T2DM and GDM have increased (20). Specific risk factors for these conditions, including advanced maternal age and rising rates of overweight/obesity, are proposed to be related to the increase in rates over time (9,20,21). According to data from 2010/2011, T1DM and T2DM accounted for approximately 4% and 7% of cases of DM in pregnancy, respectively. Gestational diabetes mellitus, on the other hand, accounted for the majority of cases (89%) of DM in pregnancy (20).

Table 1. Rates of maternal diabetes mellitus in Canada (per 1,000 deliveries) 2004 to 2011

	<u>2004/2005</u>	<u>2005/2006</u>	<u>2006/2007</u>	<u>2007/2008</u>	<u>2008/2009</u>	<u>2009/2010</u>	<u>2010/2011</u>
T1DM	3.0	2.7	3.1	2.7	3.0	2.8	2.7
T2DM	2.9	3.0	3.6	3.7	3.5	3.9	4.3
GDM	40.8	41.5	44.9	45.1	48.8	52.4	54.5

Adapted from Public Health Agency of Canada (2014)

T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; GDM, gestational diabetes mellitus

Data source: Canadian Institute for Health Information, Discharge Abstract Database (DAD).

Data from the province of Quebec not included, since it does not contribute to the DAD.

2.2. Infant Feeding Options

2.2.1. Human Breast Milk

Human breast milk is the sole food required to provide optimal nutrition for healthy infant growth and development to six months of age (1). The WHO (2002) recommends that infants are exclusively breastfed for the first six months of life, at which time complimentary foods should be introduced with continued breastfeeding for up to two years and beyond (1). Breast milk is a dynamic fluid and its composition evolves to meet an infant's nutritional and developmental needs (22). The content of maternal breast milk gradually changes through lactation and is referred to as colostrum, transitional milk, and mature milk (23). Colostrum is a yellow, thick milk secreted in small amounts during the first few days post-partum (24). Colostrum is higher in total protein than mature milk and is composed predominantly of whey protein, with negligible amounts of casein protein (23,24). Colostrum is also rich in bioactive components that support early immunity and maturation (22). Thus, breast milk not only provides nutrition, but also supports infant health and development (22).

Such bioactive components in breast milk include growth and immunological factors (22). For instance, colostrum is rich in epidermal growth factor, neuronal growth factors, insulin-like growth factor, vascular endothelial growth factors, erythropoietin, calcitonin, somatostatin, adiponectin, as well as other hormones (22). These growth factors serve diverse roles, including intestinal epithelial maturation and healing, enteric nervous system development, angiogenesis, red blood cell proliferation, intestinal tight junction closure, growth regulation, and energy metabolism (22). Breast milk also contains human cells (e.g. macrophages, T cells, stem cells, and lymphocytes), cytokines, chemokines, immunoglobins, defensins (e.g. lactoferrin and lactadherin), and nucleotides (22,25). These components promote development of the infant's immature immune system, serve as communicator between cells (to either stimulate or inhibit inflammation), and offer protection against pathogens (22,25).

Breast milk is also rich in live bacteria and human milk oligosaccharides (HMOs) that are proposed to influence gut barrier and immune function in infants (22,26). In particular, human milk is a source of bifidobacteria, and the flora of breastfed infants tend to have greater compositions of lactobacilli and bifidobacteria species than formula fed infants (26). These bacteria assist in establishing the infant microbiome shortly after birth (26). Similarly, HMOs act to influence the composition of an infant's gut bacteria (27). These components serve as fermentable compounds that alter the composition and/or activity of microbiota in a manner that benefits the host (27). The profile of HMO's in human breast milk is genetically determined and its concentration is greatest in colostrum (23).

Colostrum gradually transitions to more mature milk from approximately five days to two weeks post-partum (22). During this time, breast milk production and secretion substantially increases (22). Referred to as transitional milk, this milk contains greater amounts of carbohydrate and fat, and a lesser amount of protein. It is also less concentrated in bioactive components than colostrum. At approximately four to six weeks, milk becomes fully mature and its macronutrient composition tends to remain stable through the remainder of lactation (22). Mature milk has a higher lactose content than colostrum, and lactose concentration is greatest between four to seven months (23). Mature milk also contains a greater amount of fat than colostrum, with this amount

increasing over the course of lactation. These changes in breast milk composition through lactation accommodate the nutritional needs of the growing infant (23).

The nutrient profile of breast milk changes not only over the course of lactation, but also throughout a day and even within the same feeding (22,23). Breast milk from afternoon and early evening feeds typically contain a greater amount of fat, as compared with morning and night feeds (22,23). The length of time between feeds can also influence fat content. As the duration of time between feeds increases, the concentration of fat in breast milk decreases (23). The composition of breast milk also changes within a feeding, with a gradual increase in fat content as a feed progresses (22,23). Milk composition also differs between women delivering at term and preterm (22). Higher concentrations of protein, growth factors, and HMOs have been reported in maternal preterm breast milk. It is proposed that preterm milk contains greater concentrations of these factors to support the developmental needs of premature newborns (22).

The macronutrient profile of breast milk is presented in Table 2. The energy content of breast milk, ranges from 65 to 70kcal/dL varying according to fat content (22). The majority of fats are present in the form of triglycerides, with mostly palmitic and oleic fatty acids (28). Triglycerides also contain essential fatty acids, linoleic acid (LA) and α -linolenic acid (ALA), that promote healthy growth, development, and immunity (28). Protein is the most diverse macronutrient of breast milk and over 400 different types have identified from human milk (23). As compared with milk of other mammals, human breast milk has a higher ratio of whey to casein proteins (28). This ratio is advantageous since whey proteins are more easily digested and absorbed by infants (28). The most abundant carbohydrates in breast milk are lactose and HMOs (22,23).

Table 2. Macronutrient content of human breast milk

<u>Macronutrient</u>	<u>Content in breast milk (g/dL)^a</u>
Fat	3.2 to 3.6
Protein	0.9 to 1.2
Carbohydrate	
Lactose	6.7 to 7.8
Oligosaccharides	~1.0

^aSource: Ballard and Morrow (2013).

The nutrient composition of human breast milk can vary according to maternal dietary intake (22,29,30). In terms of macronutrient composition, the fatty acid content of breast milk, including trans-fatty acids, oleic acid, LA, ALA, and docosahexaenoic acid (DHA), is influenced to a large extent by maternal type of dietary fat intake (29,31). The composition of free amino acids and vitamins in breast milk have also been found to vary according to maternal intake; vitamins most impacted by diet include thiamine, riboflavin, vitamin B6, vitamin B12, and choline (30). When maternal stores are inadequate, maternal intake of vitamin A becomes an important source for breast milk. For vitamin D, dietary intake has been shown to influence breast milk concentrations of total vitamin D, but not 25(OH)D and generally, limited amounts are passed from maternal circulation into breast milk (30). The mineral composition of breast milk is not typically influenced by maternal intake, exceptions include iodine and selenium. The iodine and selenium content of breast milk vary according to soil content of these minerals. Additionally, iodine content may be impacted by salt iodization (30). For calcium, in cultures where intake is typically low, breast milk concentrations may be more impacted by dietary intake (30).

In the Society of Obstetricians and Gynaecologists Clinical Practice Guidelines (2016), it is recommended that women consume a variety of nutrient-dense foods throughout lactation (32). To meet the energy requirements of lactation, a modest increase in energy intake (approximately 300 to 450kcal/day in addition to pre-pregnancy requirements) is also advised. A multivitamin supplement containing 0.4mg of folic acid is recommended for all women of childbearing age prior to, during pregnancy, and throughout lactation (32). Folic acid supplementation before and early in pregnancy reduces the risk of neural tube defects in offspring. Multiple micronutrient supplementation during pregnancy and lactation also promotes adequate intake of nutrients that

may be limited in the diets of some women. Throughout lactation, women are also advised to consume 150g, the equivalent of two servings of fatty fish per week to increase the DHA content of breast milk (32). Docosahexaenoic acid is a principal fatty acid in retina and grey matter cell membranes and plays an essential role in infant neurodevelopment (31). Although DHA can be synthesized from ALA, the conversion rate is less efficient. For this reason, maternal dietary intake of foods rich in DHA, such as fish and marine oils, is often recommended (31). For vegan and vegetarian women, including foods high in ALA (e.g. walnuts) in the diet can result in more efficient conversion of ALA to DHA (33). Research has found that serum DHA levels in infants vary according to its concentration in breast milk, which in turn depends on maternal dietary intake. Western dietary patterns are typically low in DHA and consequently, education of DHA rich food sources and ways to incorporate these foods in a diet during lactation is important (31).

In general, there is little risk of nutrient deficiencies in healthy infants receiving breast milk from adequately nourished women (34). Exceptions include vitamin D and vitamin K, where the content in breast milk often does not meet Dietary Reference Intakes (DRIs) (28,32). It is recommended that breastfed infants receive a daily Vitamin D supplement containing 10µg (400IU) (2,34). Maternal stores of vitamin D are often low and infant exposure to sunshine is typically minimal (34). An intramuscular injection of vitamin K is also routinely provided post-birth to prevent hemorrhagic disease (35).

2.2.2. Infant Formula

In circumstances when a mother cannot or chooses not to breastfeed, commercial infant formula is recommended (1,2). Infant formula is nutritionally complete and formulated to meet the nutritional requirements of healthy infants (2,28). Standard formula is cow-milk based and has evolved considerably since it was first introduced (2,28,36). The first cow-milk based formulas were available in 1867 and composed of wheat flour, cow milk, malt flour, and potassium carbonate (36). Today, infant formula is designed to mimic the composition of breast milk. Cow milk is diluted and vegetable oils, vitamins, and minerals are added to alter the nutrient profile (28). It is also reformulated to have a ratio of whey to casein protein that more closely resembles breast milk (36). Yet, it is important to note that this ratio in breast milk fluctuates according to an infant's age (28). Formula is available in liquid (ready-to-feed or concentrated) and powdered

forms (2). In Canada, commercial infant formulas must meet total energy, nutritional, and labelling requirements as outlined in Canada's Food and Drug Regulations. Furthermore, only those food additives outlined in regulations are permitted for use (2). A number of companies meeting such regulatory requirements provide formula in Canada, including: Earth's Best Organic, Mead Johnson, Perrigo Nutritionals, Abbott, Nestlé, and Nutricia (37).

Alternative formulas are available for use in specific pediatric populations requiring medical nutrition therapy (2). The proteins from cow-milk based formulas can be hydrolyzed into smaller peptides and amino acids. Partially hydrolyzed formulas may be beneficial to reduce the risk of allergic reaction associated with whole cow milk protein. Extensively hydrolyzed formulas are recommended, over more common intact protein formulas, for use in infants with food allergies and malabsorptive conditions (2). For infants at high risk of atopic dermatitis, hydrolyzed formulas may also reduce the risk of developing the disease, when compared with non-hydrolyzed alternatives (2). Specialized formulas higher in protein, iron, DHA, and arachidonic acid (ARA) have been formulated for preterm infants (2,37). Soy-milk based formulas are also available and suitable for infants who have been diagnosed with galactosemia or cannot consume dairy products (e.g. cow's milk allergy) (2).

Bioactive components including DHA, ARA, nucleotides, prebiotics, and probiotics, are also added to some infant formulas to more closely resemble their concentrations in human breast milk (37). Although the addition of DHA and ARA is not mandatory in Canada, many formula manufacturers have added these fatty acids to their products in response to research highlighting their importance in neurodevelopment (37). This exchange between research evidence and clinical decision making can be illustrated using the Evidence-Based Practice Model by Satterfield et al. (2009) (38). For instance, research pioneered by Dr. Sheila Innis, registered dietitian, led to a better understanding of concentrations of fatty acids in human breast milk and infant formula and their role in retinal and brain development (31,39). This work led to recommendations for intake of DHA rich food sources during lactation, as highlighted above, along with the addition of DHA and ARA to infant formulas (32,37).

Dietary intake of DHA and ARA may also be important for growth in preterm infants (40). During the final trimester of pregnancy, the fetus accumulates DHA and ARA, and thus fetal

plasma levels of these fatty acids are higher than term infant and maternal levels. Premature infants who are fed formulas without DHA and ARA show a greater decrease in plasma levels of these fatty acids, as compared with infants fed human milk with these fatty acids (40). Research has found that infants fed formula with added DHA and ARA have a significantly faster weight gain during preterm formula feeding, than infants fed formula without added DHA and ARA (Mean=34.7g/day versus 30.7g/day, respectively, $p=0.004$) (40). These findings indicate the potential benefits of formulas with added DHA and ARA on infant growth in this pediatric population (40).

Nucleotides have also been added to some infant formulas (37). The exact concentration associated with beneficial health outcomes to formula fed infants is uncertain (25). It has been estimated that supplementation of formula with a minimum of 33mg/L of nucleotides and up to 72mg/L may improve immune development and decrease the risk of infantile diarrhea, as compared with formula with no added nucleotides (25).

Manufacturers have also added prebiotic compounds to some infant formulas to mimic the effects of HMOs (27). Galacto-oligosaccharides (GOSs) and polydextrose (PDX) are currently the most common prebiotics added to infant formulas (37). There is evidence that infant formulas containing GOS (4.0g/L) or a mixture of GOS/PDX (2.0g/L each) may improve stool consistency in infants, particularly in infants with hard stools, when compared with formula with no prebiotics (27). A number of formulas, however, contain <4.0g/L of GOS or GOS/PDX and have not demonstrated the same beneficial effect on stool consistency (37).

Along with prebiotics, formulas are also available with added probiotics. The species *Bifidobacterium animalis* subspecies *lactis* and *Lactobacillus rhamnosus* GG are those most commonly added (37). Research suggests that infant formulas with probiotics may prevent against acute infectious diarrhea and certain infections, as compared with formulas with no added probiotics; however, the effects of probiotic use are disease and strain-specific (26). Further research is needed to understand doses and specific strains associated with beneficial health outcomes (26,37).

There are few circumstances in which a woman should not breastfeed (41,42). Infants diagnosed with galactosemia, maple syrup urine disease, and phenylketonuria require specialized formula (41). Infants with very low birth weight (<1500g), born premature (<32 weeks of gestational age), and showing signs or symptoms indicative of low milk intake may require supplementation with donor breast milk, infant formula, or other breast milk substitutes (41). Supplementation may also be indicated in some cases of hyperbilirubinemia and hypoglycemia that is unresponsive to more frequent feeds at the breast (41–43). Maternal conditions in which breastfeeding may temporarily be avoided are severe illness, herpes simplex virus type 1, the use of certain medications, and delayed onset of lactogenesis II with inadequate infant intake (41,42). Supplementary feedings may also be indicated in cases of maternal primary glandular insufficiency or extreme pain when breastfeeding that remains unresolved with prior intervention (42). In Canada, it is recommended that women with HIV (human immunodeficiency virus) infection not breastfeed their infants to reduce the risk of transmission (44). In summary, the majority of women can successfully breastfeed and there are few situations in which supplementation is medically-indicated (41,42).

2.2.3. Infant Feeding Terminology

A number of terms in the literature are used to describe characteristics of infant feeding. For instance, breast milk options have been described as ‘breast milk’, ‘human milk’, and ‘human breast milk’, and formula options as ‘infant formula’, ‘formula milk’, ‘breast milk substitute’, and ‘human milk substitute’ (2,22,23,45). Numerous terms are also used to describe infant feeding and these include ‘formula feeding’, ‘bottle-feeding’, ‘mixed feeding’, ‘exclusive breastfeeding’, ‘partial breastfeeding’, ‘predominant breastfeeding’, ‘any breastfeeding’, and ‘full breastfeeding’ (14,46–53). Exclusivity is commonly used to differentiate between these feeding descriptions (52). The term ‘exclusive breastfeeding’, defined by the WHO as the “infant receives only breast milk... No other liquids or solids are given – not even water – with the exception of oral rehydration solution, or drops/syrups of vitamins, minerals or medicines” is widely accepted in literature (54).

Limitations of these definitions for infant feeding have been previously discussed (52,53,55). For instance, definitions often focus on how the infant was fed, as opposed to what the infant was fed

(52). Furthermore, terms such as ‘partial breastfeeding’ and ‘any breastfeeding’ may not indicate the relative amounts of breast milk and formula that an infant received (52). Breastfeeding indicators may also differ with respect to time (53,55). For example, exclusive breastfeeding can be measured by point-in-time data, often using a 24-hour recall method, or by lifelong data (since birth) (53,55). When describing these indicators, the phraseology used should be carefully considered (55). For example, exclusive breastfeeding ‘to’ six months and exclusive breastfeeding ‘at’ six months are often used interchangeably, however they do not reflect the same outcome (55). ‘First’ or ‘regular’ may also be used synonymously to describe the introduction of liquids/foods other than breast milk, yet these terms have different meanings (55).

Future research may consider exploring the advantages and disadvantages of definitions to identify clear and precise terminology. For providers, standard terminology may be beneficial in assessing infant growth and health, and also in communicating how an infant is fed to other providers (52). Statisticians and policy makers may also benefit from standard definitions of infant feeding. The direction of future public health initiatives is often determined based on population data of infant feeding. Data of infant feeding is also used in policy development and evaluation phases (52). In research, the diversity of definitions limits the ability to interpret and compare results between studies. Inconsistencies in terminology also limits the translation of research findings into practice-based solutions, and vice versa, how problem identification can inform future research (52). There is an opportunity for future studies to examine how language and terminology impacts research and practice of infant feeding.

2.3 Breastfeeding and Health

Breastfeeding is associated with beneficial maternal and infant health outcomes (56). A comprehensive report prepared in 2006 for the *United States Office on Women’s Health* by Ip et al. (2007) found that for mothers, breastfeeding had a protective effect against developing T2DM, breast and ovarian cancer, as well as post-partum depression. In infants, breastfeeding is associated with reduced risk of certain infections, atopic dermatitis, sudden infant death syndrome, necrotizing enterocolitis, childhood asthma, childhood leukemia, obesity, T1DM, and T2DM (56). Although the report was comprehensive, incorporating findings from 115 studies,

the majority of the studies were observational (56). Conclusions drawn from such observational research are subject to bias due to selection, confounding, and reverse causality (57,58).

To overcome limitations of observational designs, the *Promotion of Breastfeeding Intervention Trial (PROBIT)*, a cluster-randomized trial (CRT) of healthy breastfed infants, was conducted (57,58). The trial aimed to determine the effects of breastfeeding on infant health outcomes (57,58). Hospitals from Belarus (n=31) were randomized to the intervention group, adopting the *Baby-Friendly Initiative (BFI)*, and the control group, continuing with existing infant feeding practices (57,58). Infants born at intervention sites were significantly more likely to be exclusively breastfed at three and six months and, at one-year follow-up, less likely to experience gastrointestinal infection and atopic eczema. No significant reduction in respiratory tract infections was seen in infants born at intervention sites (58). Also, at 6.5-year follow-up, no reduction in measures of childhood weight or adiposity was found in the intervention group, as compared with the control group (57).

In addition to beneficial health outcomes in the general obstetric population of infants, breastfeeding is proposed to have positive outcomes for infants born to mothers with DM in pregnancy. For instance, breastfeeding is thought to decrease the risk of neonatal hypoglycemia in the early post-partum period (59). A prospective pilot study was conducted in 2009 to describe and compare blood glucose values between breastfed and formula fed infants born to mothers with GDM (59). The study sample included n=84 term mother-infant pairs. Those infants who received breast milk as the first feed had significantly higher mean blood glucose levels than those who received formula (3.20 mmol/L versus 2.68 mmol/L respectively, $p=0.002$). These results suggest that breast milk may be more effective than infant formula in supporting glycemic control in the early post-partum period (59).

Research has also examined the long-term protective effects of breastfeeding on the development of childhood overweight and T2DM (60–62). Two large studies, the *Nurses' Health Study of Offspring* and a study of German mothers with GDM and their infants, aimed to evaluate the association between breastfeeding and rates of childhood overweight for infants born to mothers with DM in pregnancy (60,61). In the *Nurses' Health Study of Offspring*, there was no association between exclusively breastfed, versus never breastfed, infants born to mothers with

DM and odds of childhood overweight (odds ratio (OR)=0.63, 95% confidence interval (CI)=0.24-1.60) (60). Results from the German study found an association between exclusive breastfeeding for >3 months and decreased risk of childhood overweight, although these findings were only significant for children of obese mothers (OR=0.52, 95% CI=0.32-0.85) (61). In terms of future development of T2DM, results are also uncertain (62). The majority of research has focused on specific population groups, such as Pima Indians and Indigenous Canadians, and results might not be generalizable to other populations since T2DM is more common in these groups (62). In summary, the link between breastfeeding and prevention of childhood overweight/obesity and later development of T2DM in infants born to mothers with DM in pregnancy is inconclusive (62). Further prospective studies are needed to evaluate these associations (62).

In terms of maternal benefits, breastfeeding has may support short- and long-term metabolic health (62,63). In the early post-partum period, lactation has been associated with improved lipid profiles, glucose tolerance, insulin sensitivity, and beta-cell function in women with GDM (62). Lactation may also be protective against the development of metabolic syndrome (63). Results from a long-term prospective observational cohort study, the *Coronary Artery Risk Development in Young Adults (CARDIA) Study*, found an inverse relationship between duration of lactation and incidence of metabolic syndrome in women with GDM (n=50) (63). Longer duration of lactation (>9 months) was associated with a relative risk (RR)=0.09 (95% CI=0.02-0.37, $p=0.01$) of developing metabolic syndrome as compared with shorter duration of lactation (≤ 1 month) (63).

Lactation may also be protective against the development of T2DM in women with GDM (64). A recent systematic review explored the association between lactation and the development of T2DM in women with GDM. After performing a meta-analysis of 13 studies, there was a significantly lower risk of developing T2DM with lactation, as opposed to no lactation (RR=0.66, 95% CI=0.48-0.90, $p<0.001$). Lactation may prevent later T2DM by shifting maternal metabolism (64). Specifically, increased lipolysis, increased energy expenditure, and alterations in carbohydrate metabolism associated with lactation may be protective against the progression to T2DM (64).

Given the potential short- and long-term benefits, organizations have adopted specific breastfeeding recommendations for women with DM in pregnancy. Diabetes Canada (2018) recommends that mothers with pre-existing DM and GDM breastfeed immediately after delivery to reduce the risk of neonatal hypoglycemia (9). It is also recommended that mothers be encouraged to continue breastfeeding for a minimum of four months to prevent later childhood obesity and DM, and for women with GDM, to reduce the risk of developing T2DM (9). Likewise, the Pregnancy and Diabetes Working Group of Nova Scotia (2014) recommends that women with GDM and pre-existing DM breastfeed for at least six months and up to two years and beyond (65). Also, if possible, breastfeeding should occur within the first hour following delivery and feeds at the breast be encouraged over bottle feeds to stimulate maternal milk production (65).

2.3.1. Infant Feeding Discourse

A number of public health campaigns have been launched internationally and within Canada to promote breastfeeding. Promotional discourse for such campaigns can be framed from a preventative lens, highlighting the protective effects of breastfeeding against risks to infant and later childhood health (66–68). For example, breastfeeding has been promoted as “best for babies everywhere”, “for the best possible start in life”, and “the best food you can offer” (66,67). When making infant feeding decisions women therefore balance the risks and benefits of breastfeeding and formula feeding (68). There is evidence that mothers internalize these messages and feel morally obligated to provide what is best for their infants (68). Consequently, some women choosing to formula feed their infants may question their identity and capability as a mother (68).

Internal responses associated with infant feeding choices have been explored in qualitative research. For some women, formula feeding or breastfeeding difficulties have been interpreted as failure (68–71). In particular, research has found that for some women the experience of breastfeeding is often different from expectations (72,73). Breastfeeding is at times described as something “natural”, that all mothers can do easily (72). Consequently, some women encountering breastfeeding challenges may internalize this as failure and experience feelings of inadequacy (72,73). Research has also found that the decision to formula feed may, in some cases, be accompanied with feelings of guilt and embarrassment (68–71). Women formula

feeding their infants may choose not to disclose this to healthcare providers due to feelings of embarrassment (70). As a result, mothers may turn to less credible sources of information for formula feeding support (72). There is also evidence that some women formula feeding their infants may not receive sufficient post-partum information and education on how to do so (73).

Results from these studies have important implications for those providing support to mothers. Support should involve encouragement to breastfeed, while also respecting a mother's personal choice of how to feed her infant (70). This involves working collaboratively with the mother to develop personalized goals that are realistic and achievable. Providers should also be honest and truthful when discussing challenges to ensure women do not view unsuccessful breastfeeding moments as failed attempts (70,73). For women choosing not to breastfeed, credible information and advice on how to safely formula feed should be provided (72). These practices are not intended to undermine breastfeeding, but instead to create an environment where a mother feels supported and confident to safely feed her infant regardless of her choice (73).

2.4. Breastfeeding Challenges

As previously discussed, women with DM in pregnancy and their infants are at greater risk of experiencing complications at birth and in the early post-partum period that can pose as challenges to breastfeeding initiation (5). Furthermore, a number of breastfeeding barriers are risk factors for DM (9). These maternal and infant breastfeeding-related challenges are summarized below.

2.4.1. Maternal Challenges

Women with pre-existing DM, notably those receiving insulin therapy, may experience difficulties with glycemic control in the post-partum period (65,74). Breastfeeding requires an abundant source of glucose, which puts mothers with DM at greater risk of developing hypoglycemia (65). Also, elevated blood glucose increases the likelihood of developing mastitis, nipple yeast infections, and vaginal yeast infections in the post-partum period (65). High blood glucose is thought to provide a favourable environment for bacterial growth (75). These

infections are generally treated with antibiotics safe for use during lactation, yet some mothers may perceive these medications as unsafe while breastfeeding (65).

The transfer of oral pharmacological agents into breast milk while lactating may also be a concern for women with DM (9). Few studies have evaluated the safety of oral agent use during lactation (9). Metformin and glyburide may be considered for use while breastfeeding, since minimal amounts of these agents have been found to pass into breast milk (76). Few studies have evaluated thiazolidinedione, glucagon-like peptide-1 agonist, or dipeptidyl peptidase-4 (DPP-4) inhibitor use throughout lactation, and these agents are not recommended while breastfeeding (76).

Women with T2DM and GDM may also be more likely to encounter weight-related breastfeeding challenges, since pre-pregnancy maternal overweight and obesity are risk factors for these conditions (9). Physical differences, such as a broad areolae and short nipples, may interfere with infant latch (8). Women may also experience difficulties with positioning an infant for latch while holding a large breast (8). Obesity is associated with decreased prolactin levels in response to infant suckling, which can impede milk production (7). Women who are overweight and obese may also be more likely to experience obstetric complications resulting in mother-infant separation that can interfere with breastfeeding initiation (8). There is also evidence that cultural pressures to be “discrete” and “modest” can discourage women with large breasts from breastfeeding in public (8).

Delayed onset of lactogenesis II may have a negative impact on the establishment of breastfeeding in the post-partum period (77,78). Maternal milk volume during the first day following birth is typically low (<100 ml/day) (7). During the 36 to 92-hour period after birth, lactogenesis II occurs with a substantial increase in milk secretion. This increase is often referred to as milk “coming in” (6,7). Hormonal changes in the post-partum period trigger the onset of lactogenesis II. Maternal progesterone, estrogen, and human placental lactogen levels decline following loss of the placenta (78). Specifically, low progesterone levels, along with high prolactin levels, trigger milk secretion (69). Delayed onset of lactogenesis II is typically described as milk secretion occurring after 72 hours post-partum (7).

Maternal metabolic health may influence the timing of lactation (80). A preliminary study from 2012 including primiparas women (n=16) found that higher ratios of serum insulin to glucose following a glucose challenge, and higher adiponectin concentrations, were predictive of earlier onset of lactogenesis II (80). These findings suggest that the timing of lactation is associated with maternal glycemic control. Within the mammary gland, insulin is hypothesized to upregulate transcription of α -lactalbumin, a protein that stimulates lactose production (80). The role of adiponectin in timing of lactation is less clear. Adiponectin may promote closure of tight junctions between mammary cells, dilation of capillaries, and enhance insulin action (80). Despite these findings, there are several limitations to the study. The sample size was small and specific biological mechanisms for these observed findings are still uncertain. Authors also explain that data of metabolic markers was collected prenatally and these markers may differ in the early post-partum period at onset of lactation (80).

Women with DM in pregnancy may be at greater risk of experiencing delayed onset of lactogenesis II, as compared with women without DM (6). A systematic review examined the association between DM status in pregnancy and DLII. All 10 studies included in the review found an association between maternal DM in pregnancy, compared with no DM, and DLII (6). The majority of studies included in the review, however, included participants with T1DM and further studies are needed to evaluate this relationship in women with T2DM and GDM (6). It is possible that women with T2DM and GDM may be more likely to experience DLII. There is overlap between risk factors for DLII, T2DM, and GDM, including maternal overweight/obesity, unplanned surgical delivery, and infant birth weight >3600g (77,81). The compounding effect of these factors, along with alterations in maternal metabolic health, may place women with GDM and T2DM in pregnancy at greater risk of DLII (77,80,81).

There is evidence that delayed onset of lactogenesis II has a negative impact on breastfeeding initiation and duration (77,78). A longitudinal cohort study of first-time mothers (n=438) found that, as compared with infants born to mothers with timely lactogenesis, those with delayed onset of lactogenesis II presented with significantly greater suboptimal feeding behaviour at day seven post-partum as defined by the Infant Breastfeeding Assessment Tool (IBFAT) ($p<0.001$) (77). These infants were also more likely to be supplemented with formula between three and seven

days post-partum ($p < 0.0001$) (77). Timing of lactogenesis may also influence the likelihood of breastfeeding in the long-term. Findings from a large prospective cohort study of mothers ($n = 2,491$) found that delayed onset of lactogenesis II was associated with any breastfeeding and exclusive breastfeeding cessation at four weeks following birth (OR=1.62, 95% CI=1.14-2.31; OR=1.62, 95% CI=1.18-2.22, respectively) (78). These findings suggest that delayed milk secretion not only impairs milk supply in the short-term, but can also negatively impact breastfeeding in the long-term (78).

2.4.2. Infant Challenges

A number of infant-related challenges may also present as barriers to establishing breastfeeding. Previous research examined the sucking patterns of infants born to mothers with GDM and infants born to mothers with normoglycemia (82). As compared with the control group of infants (no DM) ($n=55$), infants of mothers with insulin-treated GDM ($n=16$) had 42 fewer sucks ($p=0.04$) and 5.2 fewer bursts ($p=0.013$) per five minute interval (82). No significant differences were found between infants born to mothers with diet-treated GDM ($n=31$) and the control group. It is proposed that exposure to insulin *in utero* may result in neurodevelopmental immaturity that can interfere with infant reflexes and motor skills required for breastfeeding (82). Differences in sucking patterns for infants born to mothers with DM may interfere with early breastfeeding, yet additional research is needed to confirm these initial findings. Authors explain that data was not available on maternal glucose levels, maternal DM control, and the duration of diet or insulin treatment during pregnancy, which may have impacted results (82).

Exposure to elevated maternal glucose levels in pregnancy also places infants at greater risk of complications (83). For instance, maternal hyperglycemia in pregnancy increases the risk of fetal macrosomia, defined as infant birth weight $>4000\text{g}$ for term infants or $>90^{\text{th}}$ percentile for gestational age (83). In response to maternal hyperglycemia, the fetus produces higher levels of insulin and insulin-like growth factor levels that stimulate fetal growth (84). Approximately 15-45% of infants born to mothers with GDM may present with fetal macrosomia (83). Fetal macrosomia increases the risk of shoulder dystocia, clavicle fractures, and brachial plexus injury and is associated with a greater number of admissions to the *neonatal intensive care unit (NICU)* (74). With higher infant birth weight, women are also more likely to require surgical delivery

(83,85). Mother-infant separation and disruptions in hormone level associated with surgical deliveries may impair milk production in the post-partum period (85).

High maternal blood glucose in the late stages of pregnancy and during delivery also increases the risk of neonatal hypoglycemia (86). It is estimated that between 8-30% of infants born to mothers with DM in pregnancy experience hypoglycemia following birth, compared with 3% of full-term infants born to women with normoglycemia in pregnancy (72). There is no single blood glucose value to define neonatal hypoglycemia; clinically significant episodes requiring intervention are identified by the presence of symptoms and blood glucose values falling outside normative ranges (43). Although there is no standard approach for diagnosis, the CPS (2018) provides an algorithm for screening and management of infants at risk for neonatal hypoglycemia (43).

Screening is not routinely recommended for well, term newborns. For at-risk well infants, however, the CPS (2018) recommends blood glucose be checked before feeds at two hours after birth and every three to six hours thereafter. Such screening is clinically indicated to prevent long-term neurological damage associated with repeated episodes of severe hypoglycemia (43). Early breastfeeding (within one hour of birth) is also recommended to prevent hypoglycemia (43). For infants with repeatedly low blood glucose levels, more frequent feeds at the breast is recommended. Supplementation with expressed maternal milk, human donor milk, or formula may be indicated in cases where low blood glucose levels do not resolve with increased feeds at the breast. Symptomatic infants are to be treated with intravenous (IV) glucose and continued breastfeeding (43). Monitoring and treatment practices that introduce formula over feeds at the breast may impair maternal milk supply (88). Mother-infant separation for management of neonatal hypoglycemia may also interfere with the establishment of breastfeeding (88).

2.5. Breastfeeding Rates Among Women with Diabetes in Pregnancy

Evidently, a number of DM-related challenges have the potential to interfere with breastfeeding initiation. In fact, a number of studies have found that breastfeeding rates differ for women with DM in pregnancy as compared with the general population (46–48). In a study including a sample of women delivering at four Ontario hospitals, women with GDM (n=1,291) were less

likely to breastfeed in-hospital (adjusted OR=0.77, 95% CI=0.68-0.87) and at discharge (adjusted OR=0.75, 95% CI=0.66-0.85) than women without DM (n=23,291) (47). Results from a cross-sectional study of women participating in the *US Infant Feeding Practices Study II* also found that women with GDM (n=119) were less likely to breastfeed at discharge, as compared with women without GDM (n=1,919) (OR=0.59, 95% CI=0.39-0.92) (48). Recent research from Australia found that women diagnosed with GDM (n=361) were much less likely to predominantly breastfeed in-hospital as compared with women without GDM (n=6,442) (OR=0.32, 95% CI=0.27-0.38, $p<0.0001$) (46). Conversely, in a cross-sectional online survey of Australian women with GDM (n=738), 97% of mothers reported initiating breastfeeding, comparable to population-based data (50). However, the study sample was limited to women registered in the National Diabetes Services Scheme in Australia and the response rate for the survey was low (15%). Results are subject to nonresponse bias since women choosing to participate in the study may have differed from other women with GDM (13,47,49).

A number of studies have found breastfeeding rates differ according to maternal DM status (14,49,51). In a cross-sectional study of Ohio Vital Statistics birth certificate data, mothers diagnosed with GDM had the highest breastfeeding initiation rates, followed by women without DM, and women with pre-existing DM (66% [27,455/41,599], 65% [484,184/744,899] and 61% [3,802/6,232] respectively, $p<0.05$) (49). Similar results were found following analysis of data from the *Pregnancy Risk Assessment Monitoring System (PRAMS)*, a survey conducted in 30 states across the United States (51). Breastfeeding initiation rates were comparable between women without DM (82% [53,185/64,702]) and women with GDM (81% [5,374/6,652], $p=0.20$), yet significantly lower for women with pre-existing DM (78% [1,098/1,401], $p=0.03$) (51). Research from the United Kingdom found maternal DM type to be the most significant predictor of breastfeeding initiation ($p<0.05$) (14). Breastfeeding rates statistically differed by DM type at birth ($p=0.022$), 1-week ($p=0.049$) and 2-weeks ($p=0.042$) post-partum, from lowest to highest: T1DM (n=15), T2DM (n=11), and GDM (n=68) (14). A proposed reason for this difference is that women with pre-existing DM in pregnancy often exhibit greater disease severity and risk of complications at birth than women with GDM (14). Furthermore, women with pre-existing DM may experience greater DM-related breastfeeding challenges in the post-partum period since GDM often resolves after birth (49).

Despite these findings, there are a number of limitations that make it difficult to compare between studies and draw conclusions. Terms to describe breastfeeding varied from ‘any’ to ‘predominant’ to ‘exclusive’; outcome variables also differed between studies and included ‘breastfeeding at discharge’, ‘breastfeeding in-hospital’, and ‘breastfeeding initiation’ (14,46–51). Clear definitions for these terms and outcomes were not always provided (14,46–51). It is also possible that diverse methods were used to diagnose GDM, resulting in differences in study inclusion criteria (14,89). Furthermore, the generalizability of study findings may be limited due to differences in cultural norms of infant feeding and national breastfeeding policies. Studies collecting data retrospectively were also subject to maternal recall bias of infant feeding practices (14,48,51). In spite of the limitations, these studies indicate that breastfeeding rates may differ for women with DM in pregnancy, as compared with women without DM in pregnancy.

2.6. Risk Factors for Breastfeeding Cessation

A number of studies have examined specific risk factors and determinants of breastfeeding cessation in women with DM (14,50,90–92). Maternal BMI has been found to be negatively associated with breastfeeding in the early post-partum period and at six months (14,92). Complications during and after pregnancy have also been found to impact breastfeeding initiation and duration. Specifically, admission to the *NICU* has been associated with lower rates of breastfeeding initiation and exclusive breastfeeding at six months for women with pre-existing DM and GDM (90,92). Delivery by caesarean section has also been linked to breastfeeding cessation before three months in women with GDM (50). Concern for adequate milk production has been shown to be a particularly influential factor associated with early breastfeeding cessation for women with DM in pregnancy. Research has found that women commonly cite this as the primary reason for stopping breastfeeding (50,91,92). Factors associated with longer breastfeeding duration include maternal intention to breastfeed and higher parity (14,90,92).

Several limitations make it difficult to compare risk factors between studies. For instance, inclusion criteria for maternal DM differed between studies, with some studies examining risk factors in women with pre-existing DM and others GDM (50,90,92). The timeframe for the outcome variable also differed. Some studies examined breastfeeding initiation and others, breastfeeding at three and six months post-partum (14,50,90,92). Low response rates were

reported for two studies, which may have resulted in response bias, such that the study sample was not representative of the population (14,50). As described previously, results of studies examining infant feeding practices may not be generalizable due to differences in cultural norms and national breastfeeding policies (14,50,90–92).

2.7. Maternal Feeding Experiences: Qualitative Findings

Few studies have explored infant feeding experiences of women with DM in pregnancy to better understand the challenges to breastfeeding (12,91). A study from 2008 in the United Kingdom examined breastfeeding experiences among women with DM in pregnancy (n=94) by administering a survey (91). Open ended responses from the survey were organized into themes including: “information and advice”, “support versus pressure”, “classification and labelling”, and “expectations” (91). Many women were grateful for the advice from healthcare providers, however, some stated they could have benefited from additional information. Women differed in how they perceived efforts to encourage breastfeeding; some women felt supported, while others felt pressured (91). Several women in the study felt that the classification of their diabetic condition, particularly those with GDM, negatively influenced their delivery experience and care they received. In terms of continuity of care, many women felt that although they received adequate prenatal support, this support did not follow through to the post-partum period (91).

A more recent study conducted in 2015 explored breastfeeding practices of women with GDM (n=27) attending hospitals and clinics in the Midwest and Atlantic regions of the United States (12). In-depth focus groups and interviews were carried out and maternal narratives were transcribed. Following content analysis, three main themes emerged: “breastfeeding challenges and support”, “milk supply challenges”, and “concern for infant health” (12). Women described family, friends, and caregivers as supportive of breastfeeding, yet in the face of challenges, this network could advise women to supplement with formula (12). Technical breastfeeding challenges, such as infant latch and positioning, DLII, and concern for milk volume were commonly expressed by mothers (12). In terms of care, women often felt that the focus was centered around infant health, with less time directed towards breastfeeding support (12). Also, monitoring and treatment of infant complications, such as hypoglycemia and weight loss, frequently led to mother-infant separation and supplementation with formula (12). Results from

these studies portray the feeding experiences of women with DM in pregnancy and suggest the need for tailored breastfeeding support. It should be considered, however, that findings may not be generalizable to other regions since healthcare practices and policies differ among countries. Yet, research in this form of exploration is effective in portraying patient experiences, and other methods can offer insight into broader community-based experiences (e.g. clinicians, partners, and family).

2.8. In-Hospital Feeding Practices

Evidently, a mother's experience in-hospital after birth influences the establishment of breastfeeding. The early post-partum period is an important time where health care providers have the opportunity to educate and assist mothers to successfully breastfeed. For women with DM in pregnancy, early support is essential since breastfeeding for the first feed has been shown to significantly predict long-term breastfeeding (14). Previous research has identified potential practices that may interfere with breastfeeding for mothers with DM in pregnancy, including routine admission to special care units and formula supplementation, overfeeding, delayed skin-to-skin contact, delayed first feed, and premature blood glucose monitoring and treatment (11). Such practices are often intended to prevent complications, yet they may negatively impact maternal milk supply, breastfeeding initiation, and duration (13).

Several studies have examined in-hospital feeding practices of infants and their mothers with DM in pregnancy. An early study from 1993 in the United States compared practices between three groups of women: a group receiving insulin therapy (n=33), a control group (similar to women receiving insulin therapy with respect to method of delivery, prior lactation experience, and gestational age, n=33), and a healthy reference group (n=11) (93). Results from the study found that women receiving insulin therapy had a significantly greater length of time between delivery and the first breastfeed, as compared with control and reference groups (26.1±2.8, 11.4±2.7, 4.6±4.7 hours respectively, p<0.05) (93). Furthermore, women receiving insulin therapy had the least number of breastfeeds in the 12 hours following birth (0.5±0.2, 1.0±0.2, 1.4±0.3 feeds respectively, p<0.05) and supplemented with formula significantly more by day two (157.4±22.9mL, 28.8±22.4mL, 0.0 ± 0.0mL respectively, p<0.01) than control and reference

group (93). Though these findings provided initial insight into feeding practices of mothers with DM receiving insulin therapy, they may not be reflective of current clinical practices since these data are 25 years old.

A more recent study from the United States in 2014 examined in-hospital formula use in first-time mothers intending to breastfeed. Results from the study found that a significantly greater number of women with DM (n=29) compared to women without DM (n=378) used formula during their hospital stay (72.3% and 44.5% respectively, $p=0.006$) (94). It is not clear whether these findings differed according to DM classification, since DM type was grouped as a single category (94).

Further research from the United States in 2016 found that, although women with GDM (n=34) had similar breastfeeding initiation rates as women without DM (n=398), they were more likely to introduce formula in the first two days of life (79.4% versus 53.8%, $p<0.01$; adjusted OR=3.48; 95% CI=1.47-8.26) and began pumping four days earlier ($p<0.05$) (95). Though the number of women experiencing breastfeeding difficulties did not differ between the two groups (OR=2.08; 95% CI=0.78-5.52), women with GDM resorted to formula use more often when experiencing challenges as compared with women without DM in pregnancy (95).

Similar findings were evident from results of a 2017 United States population-based survey of women with recent live births (n=157,187) (96). As compared with women without DM in pregnancy, women with GDM were less likely to breastfeed in the first hour (adjusted OR=0.83, 95% CI=0.73-0.94), feed their infants exclusive breast milk while in hospital (adjusted OR=0.73, 95% CI=0.65-0.82), and feed on demand (adjusted OR=0.86, 95% CI=0.74-0.99) (96). Women with GDM were also more likely to be provided with a pump (adjusted OR=1.28, 95% CI=1.07-1.53) and a formula package (adjusted OR=1.17, 95% CI=1.03-1.34), as compared with women without DM in pregnancy (96).

Findings from these studies indicate that women with DM in pregnancy may encounter delays in the first breastfeed, introduce formula earlier, and supplement with formula more often than women without DM in pregnancy (93–96). Formula is often provided by healthcare providers due to perceptions of inadequate colostrum and beliefs that it will prevent dehydration,

hypoglycemia, hyperbilirubinemia, and infant weight loss (13). Other reasons for formula supplementation include breastfeeding problems, infant behaviour, and maternal fatigue (13). Maternal reports of the most common reasons for in-hospital formula use include perceived inadequate milk supply, signs of inadequate intake (such as infant weight loss or hypoglycemia), poor infant feeding behavior, and mother-infant separation (94). In summary, supplementation with formula may be provided for a number of routine, non-medically indicated reasons and interfere with maternal breastfeeding intentions.

2.9. Hospital Initiatives to Support Breastfeeding

In-hospital initiatives and policies may promote healthcare practices that support and facilitate breastfeeding. This will more effectively support implementation of WHO guidelines. In 1991, the *BFI* was launched by the United Nations International Children's Emergency Fund (UNICEF) and WHO to provide international standards for infant feeding and promote optimal infant nutrition (97). The *BFI* outlines *Ten Steps to Successful Breastfeeding*, established from evidence-based practices, that serve as a guide for establishing breastfeeding-friendly environments in healthcare facilities and promoting practices that encourage and enable breastfeeding (97). Currently, 50 centers in Canada have *BFI* designation, with the IWK Health Centre recently granted status in July 2018 (98,99).

Several practices from the *Ten Steps to Successful Breastfeeding* have been associated with greater likelihood of mothers achieving their breastfeeding intentions. A study by DeClercq, Lobbok, Sakala and O'Hara (2009) found that among first-time mothers (n=338), those experiencing six of the seven steps evaluated in the study were six times more likely to reach their breastfeeding goals, as compared with mothers experiencing one or no practices (86% [291/338] versus 14% [47/338] respectively, $p<0.01$). Those practices significantly associated with achieving breastfeeding intentions were “helping mothers get started”, “hospital staff not supplementing with formula or water”, “telling mothers about community resources for breastfeeding support”, and “staff not giving the baby a pacifier” (100).

The overall effectiveness of the *BFI* in promoting exclusive breastfeeding has been previously studied on a large scale in the *PROBIT* (58). As introduced in section 2.3, the *PROBIT* was a

cluster-randomized trial conducted in the Republic of Belarus in which hospital sites were randomly assigned to the intervention group, with *BFI* status, and the control group, with continuation of current practices (58). Infants born at sites with *BFI* designation were more likely to be breastfed exclusively at three months (43% [3,812/8,865] versus 6.4% [526/8,181], $p<0.001$) and at six months (7.9% [700/8,865] versus 0.6% [49/8,181], $p<0.01$) of life, as compared with infants born at non-*BFI* sites ($n=8,181$) (58).

The impact of *BFI* has also been studied in at-risk infants (101,102). A retrospective chart review performed in 2003 found that, following *BFI* designation, breastfeeding initiation rates for infants admitted to the *NICU* of the Boston Medical Centre ($n=227$) increased significantly from 35% [38/110] to 74% [87/117] ($p<0.001$) (102). Moreover, the percentage of infants receiving any breast milk increased from 28% [12/43] to 66% [27/41] after *BFI* implementation ($p<0.001$) (102). Additional research from Brazil at the Odete Valadares Hospital found that exclusive breastfeeding at discharge among infants admitted to the *NICU* increased from 36% [90/250] to 55% [134/245] ($p<0.01$) following implementation of *BFI* (101). Strengths of these studies included describing infant feeding using multiple categories (exclusive breast milk, mostly breast milk, mostly formula, and exclusively formula), and defining exclusive breastfeeding at discharge as the 72-hour period prior to discharge (101,102). These descriptions accounted for circumstances in which medically-indicated supplementation may be required.

There is little recent research evaluating the effectiveness of healthcare policies and practices to support breastfeeding for mothers with DM. A study by Tozier (2013) aimed to determine the effectiveness of a new algorithm for managing hypoglycemia in infants born to mothers with DM. The new algorithm addressed in this study was developed by a newborn committee based on a review of the literature (15). Guidelines were also introduced to promote hand expression of colostrum and skin-to-skin contact. A retrospective chart review of infants born to mothers with T1DM and GDM ($n=163$) was performed to compare neonatal blood glucose levels and feed type (colostrum or formula) before and after implementation of the algorithm and guidelines (15).

Results from the study found no significant difference in blood glucose levels by feed type, although less variability in blood glucose was reported for the colostrum fed group in the post-

intervention period, compared with the pre-intervention period (15). The number of babies receiving colostrum and formula pre-intervention (colostrum, n=25; formula, n=50) was reversed post-intervention (colostrum, n=52; formula, n=21). Fewer transfers to the *NICU* for hypoglycemia treatment were also documented post-implementation (6.5% [5/77]), as compared with pre-intervention (18.8% [16/85]) ($\chi^2=5.44$, $df=1$, $p=0.020$) (15). These findings provide preliminary insight of the effectiveness of policy and guidelines to support breastfeeding in women with DM, a topic largely unexplored, however, there were a number of study limitations. For instance, sampling methods were not described, feedings were only collected and described for the first six hours after birth, and mothers were not grouped or analyzed according to DM type (15).

2.10. Theoretical Framework

The theoretical framework by Graham et al. (2006), referred to as the knowledge-to-action (KTA) process, was used as the foundation for the following study (103). The KTA process explains the relationship between two key concepts: knowledge creation and action (see Figure 1) (103). Although knowledge creation and action are represented as being distinct, there is much overlap between the two concepts (103). The KTA process is also dynamic, and movement between the phases is not always sequential (103). The process is ongoing and advances in knowledge are continuously integrated into the phases of the action cycle (103).

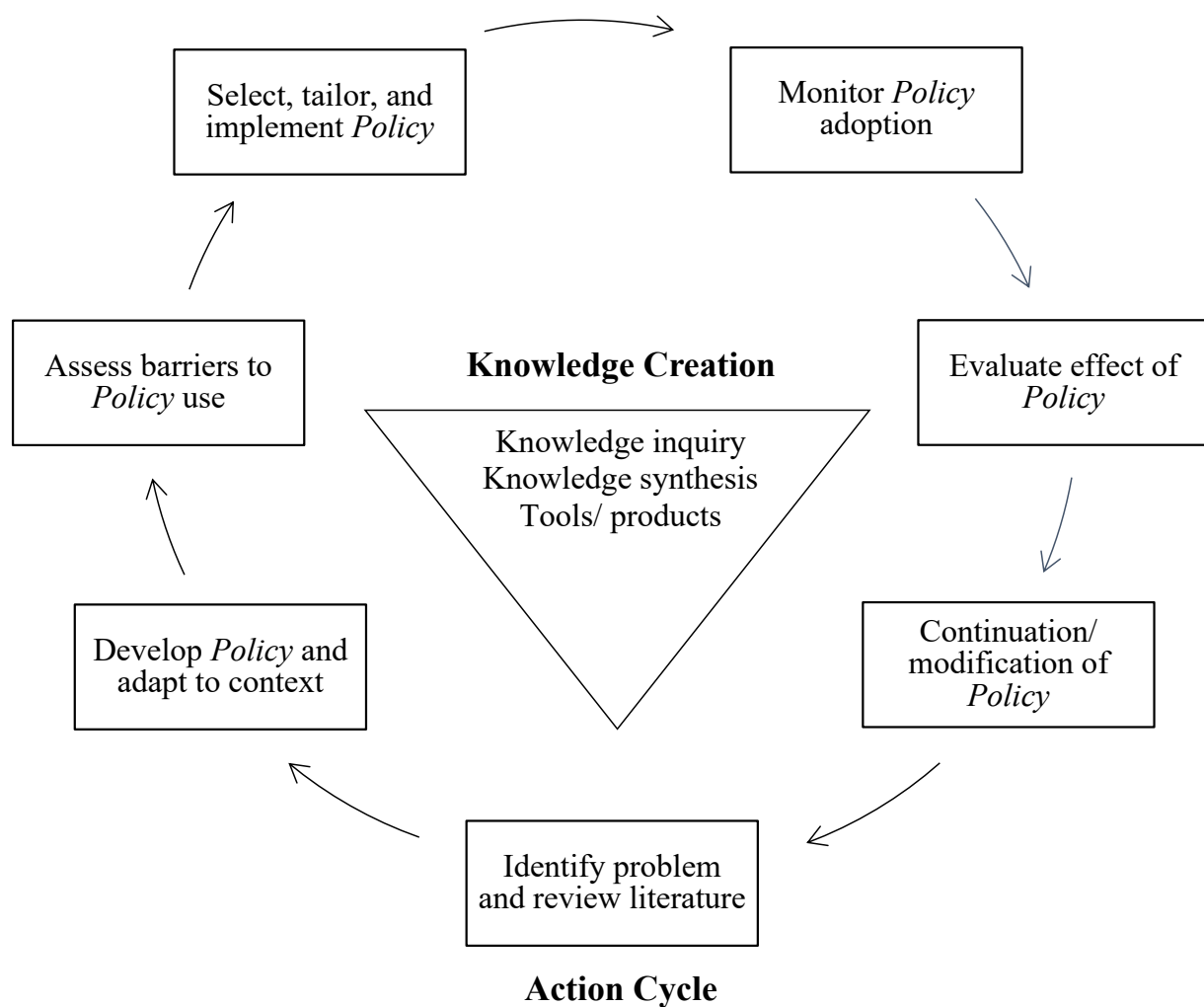


Figure 1. Knowledge-to-action process adapted from Graham et al. (2006) (103)

Knowledge creation is represented as a funnel throughout which information becomes increasingly refined (103). Knowledge inquiry comprises the abundance of initial research findings and information that is available, and synthesis refers to the assembly and refinement of this information (103). Knowledge is then transformed into applicable tools/products, as represented in the bottom section of the funnel (103). Throughout various phases of the action cycle, this knowledge is continuously applied and tested/evaluated (103). The action cycle is based on planned-action theory and classical behaviour change theory, and assists the change

facilitator in recognizing factors that influence the change process (103). In phases of the cycle, deliberate activities are carried out to achieve specific goals or outcomes (103).

Recent efforts to promote and support breastfeeding at the IWK Health Centre led to the development of the *Supplemental Feedings for Breastfeeding Children Policy* (referred to as *Policy* hereon in) (see Appendix A) (104). The evidence-informed *Policy* outlines a specific protocol for healthcare providers when providing supplemental feedings to breastfeeding children. This work was led by a senior clinical nurse specialist (Dr. Glenda Carson) with the IWK Health Centre and can be interpreted using the KTA process. Specifically, previous work completed the “identify a problem” to the “select, tailor, and implement *Policy*” phases of the action cycle. Results of this study further addressed the “knowledge inquiry” phase, by providing a descriptive account of in-hospital infant feeding, and the “monitor *Policy* adoption” and “evaluate effect of *Policy*” phases. At the monitoring phase, the extent to which the *Policy* was adopted by IWK Health Centre staff and providers was reviewed by assessing the completeness of chart documentation of the feeding plan. At the evaluating effects phase, an exploration of infant feeding practices among women with GDM and T2DM in pregnancy provided an indication of the impact of the *Policy* in facilitating breastfeeding for this group of women. Such findings may provide direction for future work at the IWK Health Centre.

3.0 Rationale, Research Questions, Objectives, and Hypothesis

3.1. Rationale

Breast milk exclusively provides energy and nutrients to support healthy infant growth and development during the first six months of life (1,2). For mothers with DM in pregnancy, breastfeeding has been associated with improved short- and long-term metabolic health, and for women with GDM reduced risk of developing T2DM (62–64,105). Infants who are breastfed may also be at lower risk of experiencing neonatal hypoglycemia (59). Despite these benefits, there is evidence that women with DM in pregnancy may be less likely to initiate breastfeeding, as compared with the general population (46–49).

Women with DM in pregnancy may experience unique breastfeeding challenges, including delayed onset of lactogenesis II, neonatal hypoglycemia, and mother-infant separation following birth (6,7,12,106). Healthcare providers may inadvertently provide non-medically indicated formula supplementation to prevent or manage these conditions (12,13,107). For instance, formula supplementation may be provided due to perceptions of low milk supply and the belief it will prevent hypoglycemia (12,13,107). Maternal fatigue, infant behaviour, and breastfeeding problems are also commonly cited reasons for supplementing with formula (13). These practices may be problematic for women intending to breastfeed their infants, since formula supplementation can result in decreased maternal milk supply and interfere with breastfeeding duration (42,94).

The in-hospital period is an important time to establish breastfeeding. Early success builds maternal confidence and increases the likelihood of achieving long-term breastfeeding intentions (14). The introduction of hospital policy to promote evidence-based infant feeding practices may support breastfeeding for women with DM in pregnancy. There is a need for research that examines impacts and efficiency of in-hospital policies to support breastfeeding in women with GDM and T2DM in pregnancy. The aim of this study is to describe infant feeding practices and explore the effectiveness of the *Policy* in facilitating breastfeeding from birth to hospital discharge at the IWK Health Centre. Results from this study will be used to inform future *Policy* implementation efforts.

3.2. Research Questions

This study aimed to address the following questions:

- 1) What were the in-hospital feeding practices of infants born (between January 5th, 2016 and November 24th, 2017) to mothers with GDM and T2DM in pregnancy at the IWK Health Centre in Halifax, Nova Scotia?
- 2) Did in-hospital infant feeding practices differ pre- and post-introduction of the *Policy* (effective November 29th, 2016) for infants born to mothers with GDM and T2DM in pregnancy?

3.3. Objectives

Study objectives were to:

- 1) Describe in-hospital infant feeding practices for infants born (between January 5th, 2016 and November 24th, 2017) to mothers with GDM and T2DM in pregnancy at the IWK Health Centre in Halifax, Nova Scotia.
- 2) Evaluate in-hospital infant feeding practices pre- and post-introduction of the *Policy* for infants born to mothers with GDM and T2DM.

3.4. Hypothesis

It was hypothesized that there will be an increase in the number of infants receiving breast milk at discharge following introduction of the *Policy*. This prediction was based on previous literature evaluating the effectiveness of in-hospital initiatives to support breastfeeding for mothers of healthy and at-risk infants (58,100–102).

4.0 Methodology

4.1. Intervention: *Supplemental Feedings for Breastfeeding Children Policy*

The intervention is the *Supplemental Feedings for Breastfeeding Children Policy* developed and implemented by a senior clinical nurse specialist (Dr. Glenda Carson) at the IWK Health Centre (see Appendix A). The evidenced-informed *Policy* applies to IWK Health Centre staff and physicians providing care for breastfeeding children and families. As described in the *Policy*, the goal for the supplementation for breastfeeding children is to “provide medically-indicated nutrition while optimizing the maternal milk supply, breastfeeding exclusivity and duration” (Appendix A, p. 90).

The *Policy* provides guidance to healthcare providers and staff for supplementation decisions and practices. The *Policy* emphasizes the importance of completing extensive maternal and child health and breastfeeding assessments when considering the need for supplementation. Specific circumstances in which supplementation should and should not be considered are also outlined. The *Policy* includes guidelines for providers to ensure parents are fully informed of decisions to supplement. The IWK Health Centre *Breastfeeding Policy* is provided for further reference of situations in which breastfeeding should not be considered. Lastly, further direction is provided for developing the supplemental feed plan. This includes choosing the type, amount and method of supplementation, documenting the plan, discontinuing/decreasing the amount of supplement, and preparing for discharge.

The *Policy* was approved October 18th, 2016 and effective November 29th, 2016. As discussed in communications with the senior clinical nurse specialist from the IWK Health Centre, *Policy* implementation initiatives were carried out from March to July 2017. The *Policy* was brought forward by educators to teams in the *Women’s and Newborn Health Program* (104). It was also introduced in huddles, meetings, and education sessions with individual teams. A message was sent from the director to inform providers of the *Policy*. *Child Health* teams were also approached, and it was determined that *Policy* implementation would be carried out during a later timeline due to competing priorities (104). The dynamic nature of *Policy* implementation was discussed following data collection and analysis.

4.2. Design

This research involved a retrospective chart audit of mothers with GDM and T2DM in pregnancy and their infants (n=120). Feeding and supplementation practices were examined for infants born in the period prior to (n=60) and following (n=60) introduction of the *Policy*, on November 29th, 2016. Figure 2 describes the retrospective timeline of study periods with reference to infant birth dates and date of *Policy* introduction. The impact or effect of *Policy* was evaluated by comparing the number of infants from pre- and post-*Policy* groups receiving breast milk at discharge.

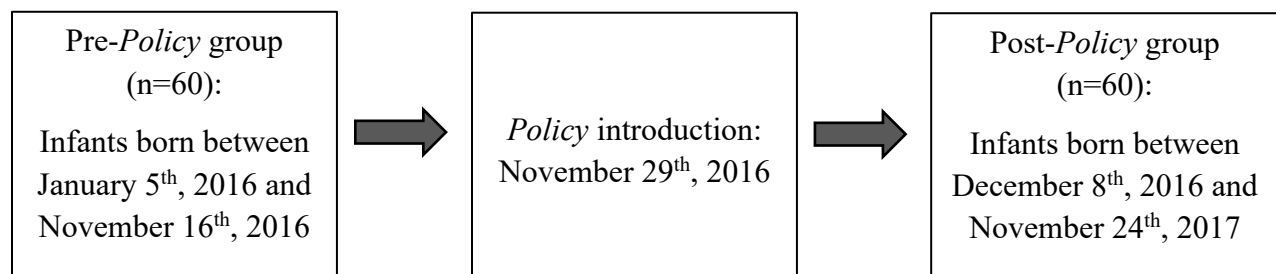


Figure 2. Retrospective timeline of study periods before and after the date of *Policy* introduction

4.3. Sample

4.3.1. Participants

The study sample included mothers with GDM and T2DM in pregnancy and their infants (n=120). Inclusion criteria were as follows:

- 1) Women attending the *IWK Pregnancy and Diabetes Clinic*
- 2) Women diagnosed with either GDM or T2DM as indicated in maternal charts
- 3) Women delivering a live singleton infant

Diagnosis of GDM and T2DM were assumed to be made in accordance with diagnostic criteria outlined in the Diabetes Canada 2018 CPG (9).

Exclusion criteria for the study included multiple births, since the study sample was described as the “mother-infant pair”. Multiples could be confounding, having a negative impact on the likelihood of breastfeeding. Mothers diagnosed with T1DM and maturity-onset diabetes mellitus in the young (MODY), were also excluded from the study since the pathogenesis of these conditions differs from T2DM and GDM. The study aim was to evaluate outcomes in a specific maternal profile, characteristic of T2DM and GDM.

The site of *Policy* introduction (IWK Health Centre) is a large hospital centre serving women, children, youth, and families in the Canadian Atlantic region. The health centre provides primary, secondary, and tertiary care services, and is a leading centre for teaching and research (108). Recent statistics of hyperglycemia in pregnancy for women attending the *IWK Pregnancy and Diabetes Clinic* were presented at the IWK Health Centre Obstetrics and Gynaecology Grand Rounds (September 26, 2018) (109). The prevalence of hyperglycemia is comparable to global estimates (16.9% of live births) (109,110).

Ethics for the proposed research was approved by the IWK Health Centre Research Ethics Board (#1022327) and the MSVU Research Ethics Office (#2017-082). Additionally, all research team members were required to complete the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics (TCPS 2: CORE).

4.3.2. Sample Size Calculation

A power analysis was performed using results from two studies, with similar research designs and cross-sectional measures of breastfeeding to the present study. A cross-sectional measure of breastfeeding was selected as the primary outcome for this study to estimate the sample size. Given the exploratory objective of this study, this outcome was chosen primarily for power analysis purposes, to determine the sample size required to observe the effect of the *Policy*.

The first study selected compared infant feeding practices in a sample of *NICU* infants before and after introduction of *BFI* (102). Breastfeeding initiation rates, described as an infant receiving any breast milk in the first week of feeds, were 34.6% (38/110) and 74.4% (87/117) for pre- and post-*BFI* groups of mother-infants pairs, respectively (102). The second study aimed to

determine the number of infants born to mothers with DM in pregnancy receiving colostrum prior to and following introduction of a new algorithm and practice guidelines to prevent neonatal hypoglycemia and facilitate breastfeeding (15). Results from this study found that 33.3% (25/75) of infants were fed colostrum before, and 71.2% (52/73) after introduction of the algorithm and guidelines (15).

Power analysis calculations were performed using software developed by David Schoenfeld, with support from the Massachusetts General Hospital Mallinckrodt General Clinical Research Centre (updated in 2015) (111). Software was accessed in October and November 2017. The study type selected was a parallel, success or failure design, and a Fisher Exact Test was used to determine statistical power (two-sided with a p -value of 0.05). Using results and sample sizes from each of the above studies, it was determined there was a 100% chance of detecting if there is a significant difference in the primary outcome before and after *Policy* introduction.

Sample size estimations were also calculated using an equation for binary data described by Campbell, Julious, and Altman (2005) (112). It was calculated that a sample size of $n=50$ and $n=56$ mother-infant pairs, for each study respectively, was required to achieve a 5% significance level and 90% power (see Appendix B). Consequently, a sample size of $n=120$ participants was selected for this exploratory study. The sample size was chosen as a conservative estimate to provide sufficient power to evaluate whether there was a significant difference in the primary outcome before and after *Policy* introduction.

4.4. Study Outcomes

The primary outcome for the study was the provision of solely breast milk at discharge, with binary outcomes of yes/no. For the following study, the discharge period was defined as the final recorded feed prior to discharge. This cross-sectional measure of breastfeeding was chosen primarily for the purposes of power analysis calculations. Also, this measure was selected since women with DM are an at-risk group and may encounter complications at birth requiring medically-indicated supplementation; thus exclusivity may not accurately reflect feeding practices for this group.

Secondary outcome variables were as follows:

Participants characteristics:

- 1) Maternal DM type, including GDM and T2DM in pregnancy.
- 2) Unit at discharge, defined as the unit from which the infant was discharged from the health centre, including *Family Newborn Unit* and *NICU*.
- 3) Length of hospital stay, recorded to the nearest day.
- 4) Infant birth weight, recorded to the nearest gram.

Infant feeding characteristics:

- 1) Type of infant feed, defined as the category of nutrition that the infant received for the feed. Categories of infant feed included: breast milk, formula, IV fluid, and combinations thereof.
- 2) Source of breast milk, including mother's milk and donor milk.
- 3) Method of infant feeding, defined as the means by which the infant received nutrition. Methods included: breast, bottle, finger/syringe, cup, gavage, IV route, and combinations thereof.
- 4) Feeding description, defined as the subjective measure of how well the infant was fed. Descriptions included: good, fair, and poor.
- 5) Infant state, defined as the infant behavior during the feed. Categories included: awake/quiet, crying, fussy, and sleeping.
- 6) Intravenous volume, defined as the amount of IV fluid received each feed, recorded to the nearest 0.01mL.
- 7) Oral volume, defined as the amount of formula or expressed breast milk received orally each feed, recorded to the nearest 0.01mL.
- 8) Total volume, defined as the sum of IV fluid and oral volume received each feed, recorded to the nearest 0.01mL.

4.5. Chart Screening and Data Management

4.5.1. Procedures

Medical records were searched using MEDITECH software program. MEDITECH is an electronic software program designed for healthcare organizations to store patient health records (113). The Research Coordinator/Master of Science (MSc) Student (EC) and Research Assistant/Research in Medicine (RIM) Student (TR) screened maternal records for women diagnosed with GDM and T2DM in pregnancy attending the *IWK Pregnancy and Diabetes Clinic*. Maternal Fetal Assessment Records were reviewed to identify diagnosis (see Appendix C for screening procedures). All women attending clinics between December 2nd, 2015 and June 1st, 2016, and December 7th, 2016 and April 12th, 2017 were screened for inclusion.

Maternal data were linked to their infants' data using the birth record since this document is located in both mother and infant charts. Information from the birth record (maternal delivery date, infant birth date, time of birth, sex, and weight) were cross-referenced from both charts to confirm the mother-infant pair. As each pair was identified, they were added to the study target list. Each mother-infant pair was de-identified by assigning a participant ID.

Infant and maternal charts were then searched using patient identification K numbers. The data spreadsheet was completed by recording information from charts. Data of infant feeding from health records was documented by both providers and parents/caregivers. It was not known whether records were completed by either providers or parents/caregivers. Data for each feed was recorded and entered as a new row in the data spreadsheet. The day of life was referenced according to the infant time of birth. Data not available was entered as n/a, while data not applicable was recorded as N/A (see Appendix D for data collection procedures). Data for the pre-*Policy* sample was previously recorded by Research Assistant (TR) as part of a Dalhousie University RIM project. Data for the post-*Policy* sample was recorded by the Research Coordinator/MSc Student (EC).

4.5.2. Data Collection Tools

The original target list form and data collection form were developed by Research Assistant (TR), for a Dalhousie RIM project (see Appendix E and F). Dropdown options were created to increase efficiency and accuracy of data entry. The Research Coordinator/MSc Student (EC) updated the target list form to include the infant K number. The data collection form was also revised to include additional outcomes and a more exhaustive list of dropdown options.

4.5.3. Data Review

All data was double-checked to ensure accuracy. The Research Coordinator/MSc Student (EC) reviewed data collected previously for the Dalhousie University RIM project. Trained Research Assistants (JL and JP) double checked remaining data. Inconsistencies were resolved by assessing the original chart.

4.5.4. Data Storage and Sharing

Study target list and data collection forms were stored as password-protected spreadsheets in separate folders on the IWK Health Centre's secure electronic server. Data collection forms containing de-identified participant data were transferred to Mount Saint Vincent University (MSVU). All data was held in password-protected spreadsheets and stored on the MSVU protected server. Target list and data collection forms are to be stored and subsequently deleted following retention periods as per IWK Health Centre and MSVU Research Ethics Board protocols.

4.5.5. Data Management

Data was organized and represented by either individual feeds or participants. When discussing results throughout the remainder of this thesis, it will be clarified whether data is being described by feeds or participants.

In preparation for analysis, nominal data was coded using numerical values. For the outcome “provision of breast milk at discharge”, feeds of solely breast milk were categorized as “yes”,

while formula/IV fluid and mixed feeds were grouped as “no”. In-hospital type of feeding was also determined for each participant (n=120) to indicate the primary type of feed an infant received throughout the hospital stay. This was calculated for each participant by tallying the frequencies of each feed type (see Appendix G for example calculation). Participants were categorized as receiving the following based on the type of feed they received over the entire hospital stay:

- 1) Exclusive breast milk (100% of feeds breast milk)
- 2) Mostly breast milk (>75% of feeds breast milk)
- 3) Mixed feeding (25-75% of feeds breast milk)
- 4) Mostly formula/IV fluid (>75% of feeds formula/IV fluid)
- 5) Exclusive formula/IV fluid (100% of feeds formula/IV fluid)

An overall method of feeding was also determined for each participant (n=120):

- 1) “Breast”: The infant was fed exclusively at the breast for all feeds in hospital.
- 2) “Breast and other”: The infant was fed by a combination of breast and other methods while in hospital.
- 3) “Other”: The infant was fed exclusively by methods other than breast for all feeds while in hospital.

Feeding volumes (oral, IV, and total) were summed for each participant (n=120) to represent the volumes that each participant received throughout the hospital stay.

4.6. Statistical Analysis

All descriptive and inferential analysis were completed using IBM SPSS Software (Version 25; IBM Corp, Armonk, New York). Descriptive analyses were computed for the pre- and post-*Policy* participant and feeding characteristics data. Nominal data was described using counts (*n*) and percents (%) and continuous data by means (*Mean*) and standard deviations (*SD*). Inferential statistics were performed to evaluate whether there were any differences in outcomes between the pre- and post-*Policy* study groups.

4.6.1. Pearson's Chi-Square Test

For nominal outcomes, Pearson's chi-square test with two-sided significance was performed to determine if there was an association between *Policy* groups and outcomes. The term association, also referred to as independence, will be used throughout the remainder of the thesis to indicate whether there is a relationship between variables. An association between variables indicates the variables are in some way related and the observed distribution is not likely due to chance (114).

To meet sample size assumptions for Pearson's chi-square test, expected frequencies of each cell of 2 x 2 contingency tables were ≥ 5 (114). For larger tables, no more than 20% of cells had frequencies < 5 . For larger tables not meeting this assumption, similar categories were collapsed. Collapsing categories increased the frequencies of cells, such that the expected counts met the above assumption (114).

Specifically, for the outcomes "provision of breast milk at discharge" and "final feed type at discharge", the category 'not available' was excluded from analysis, since the frequencies of cells were < 5 and similar categories could not be collapsed.

Categories were collapsed for the following outcomes: "type of infant feeding", "method of infant feeding", and "in-hospital type of feeding". Specifically, for "type of infant feeding" each feed was categorized as either "breast milk", "mixed feeding" and "formula/IV". The category "mixed feeding" was used to describe feeds for which an infant received a combination of breast milk and either formula, or IV fluids. For the outcome "method of infant feeding" each feed was categorized as either "breast", "breast and other", and "other". The category "breast and other" was used to describe feeds for which an infant was fed by combination of breast and other method(s) (e.g. bottle, finger/syringe, cup, gavage, or IV). For "in-hospital type of feeding", the categories "mostly formula/IV fluid" and "exclusive formula/IV fluid" were combined for analysis to meet sample size assumptions.

For outcomes where a significant Pearson's chi-square test ($p < 0.05$) was found, z-scores (standardized residuals) were calculated. A p -value was determined for each cell according to z-

scores (114). The Pearson's chi-square test statistic (χ^2), degrees of freedom (df), significance value (p), and contingency table were reported for results of analysis. The p -value was reported for z-scores.

A large enough sample was not obtained for "source of breast milk", "infant state", and "feeding description" to meet minimum cell frequencies for analysis, therefore inferential analysis was not performed.

4.6.2. Fisher Exact Test

A Fisher's exact test was performed in circumstances where 2 x 2 contingency tables did not meet sample size assumptions (114). To meet minimum cell frequencies for the outcome "unit at discharge", a Fisher's exact test with two-sided significance was performed. The p -value was reported for results.

4.6.3. Independent T-Test

Independent t-tests were performed to assess whether there were statistically significant differences for continuous outcomes between pre- and post-*Policy* groups. Data were not normally distributed for several outcomes, as evidenced by the distribution of quantile-quantile (Q-Q) plots and the Shapiro-Wilk (S-W) tests. According to the Central Limit Theorem, for sample sizes >5 or 10 , parametric tests can be used regardless of whether data are normally distributed (115). The assumption of normality is often understood to mean that the data must be normally distributed, however, for significance tests it is the sampling distribution that must be normal and not necessarily the data itself (114). With sufficiently large samples, the means from the sample will be normally distributed irrespective of the shape of the original distribution (115). Parametric tests were performed on non-normal continuous data since sample sizes were sufficiently large. The *Mean*, *SD*, mean difference, CI, t-statistic (t), df , and significance value (p) were reported for results of independent t-tests.

5.0 Results

5.1. Participant Characteristics

Table 3. Participant characteristics (n=120) by *Policy* group

Characteristic	Pre-policy	Post-policy	<i>p</i>
	<i>n</i> (%) <i>Mean</i> (\pm <i>SD</i>) n=60	<i>n</i> (%) <i>Mean</i> (\pm <i>SD</i>) n=60	
Maternal diabetes type			
GDM	48 (80%)	44 (73%)	0.39 ^a
Type 2 diabetes	12 (20%)	16 (27%)	
Unit at discharge			
<i>Family Newborn Unit</i>	57 (95%)	57 (95%)	1.00 ^b
<i>NICU</i>	3 (5%)	3 (5%)	
Length of hospital stay (days)	3.1 (\pm 4.0)	2.1 (\pm 1.1) ^c	0.09 ^d
Infant birth weight (g)	3495 (\pm 536)	3312 (\pm 576)	0.08 ^d

SD, standard deviation; GDM, gestational diabetes mellitus; *NICU*, neonatal intensive care unit

^a Derived by chi-square analysis.

^b Derived by Fisher exact test analysis.

^c Data not available from charts for n=1 participant.

^d Derived by independent t-test analysis.

The target sample was reached, and the final sample included n=120 mother-infant pairs. A total of n=2,064 feeds were recorded from charts (pre-*Policy*: n=992 feeds; post-*Policy*: n=1,072). Participant characteristics by *Policy* group are described in Table 3. Approximately three-quarters of women were diagnosed with GDM and one-quarter with T2DM. No association was found between *Policy* group and maternal DM type, $\chi^2(1)=0.75$, $p=0.39$ (see Table H.1.). The majority of infants were discharged from the *Family Newborn Unit*, with no association between *Policy* group and unit at discharge ($p=1.00$) (see Table H.2.). On average, the mean length of hospital stay did not differ significantly between *Policy* groups (pre-*Policy*: *Mean*=3.1 days, (*SD*)=4.0; post-*Policy*: *Mean*=2.1 days, *SD*=1.1, *Mean* difference=0.91 days, 95% CI [-0.15, 2.0], $t(68.69)=1.71$ $p=0.09$). Mean infant birth weight was 3495g (*SD*=536) for the pre-*Policy* group, and 3312g (*SD*=576) for the post-*Policy* group. No significant difference was found between groups (*Mean* difference=183g, 95% CI [-18.4, 383.9]; $t(118)=1.80$, $p=0.08$).

5.2. Provision of Breast Milk at Discharge

Table 4. Provision of breast milk at discharge for each participant (n=120) by *Policy* group

	<u>Pre-<i>Policy</i></u>	<u>Post-<i>Policy</i></u>	<i>p</i>
	<u><i>n</i> (%)</u>	<u><i>n</i> (%)</u>	
	n=60	n=60	
Provision of breast milk at discharge ^a			
Yes	35 (58%)	35 (58%)	0.46 ^{b,c}
No	24 (40%)	18 (30%)	
Not available	1 (2%)	7 (12%)	

^a Provision of breast milk at discharge is defined as the provision of solely breast milk for the final recorded feed before discharge.

^b Derived by chi-square analysis.

^c “Not available” excluded from analysis, therefore n=59 for pre-*Policy* and n=53 for post-*Policy* groups.

As shown in Table 4 and Figure 3, 58% (35/60) of infants in both *Policy* groups received breast milk for the final feed before discharge. Data was for the final feed was unavailable from charts more frequently for the post-*Policy* group (12% [7/60]), as compared with the pre-*Policy* group (2% [1/60]). No association was found between *Policy* group and the provision of breast milk at discharge, $\chi^2(1)=0.54$, $p=0.46$ (see Table H.3.). Results do not support the hypothesis that the number of infants receiving breast milk at discharge will increase following *Policy* introduction.

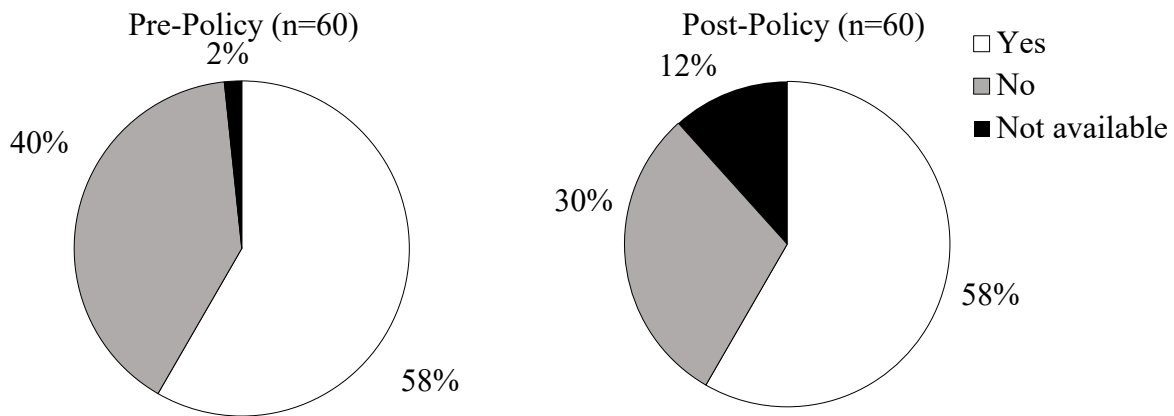


Figure 3. Provision of breast milk at discharge for each participant (n=120) by *Policy* group. Provision of breast milk at discharge is defined as the provision of solely breast milk for the final recorded feed before discharge. “No” includes infants who received formula and/or intravenous fluids, as well as those who received a mixed feed of breast milk and formula/intravenous fluid. “Not available” refers to data not recorded in charts.

5.3. Type of Infant Feeding

Table 5. Type of infant feeding by *Policy* group

	<u>Pre-Policy</u>	<u>Post-Policy</u>	<i>p</i>
	<u><i>n</i> (%)</u>	<u><i>n</i> (%)</u>	
Type of feeding at discharge ^a	n=60	n=60	
Breast milk	35 (58%)	35 (58%)	0.32 ^{b,c}
Mixed feeding ^d	13 (22%)	6 (10%)	
Formula/IV fluid	11 (18%)	12 (20%)	
Not available	1 (2%)	7 (12%)	
In-hospital feeding type ^e	n=60	n=60	
Exclusive breast milk	22 (37%)	26 (43%)	0.39 ^{b,f}
Mostly breast milk	12 (20%)	10 (17%)	
Mixed feeding ^d	18 (30%)	21 (35%)	
Mostly formula/IV fluid	3 (5%)	2 (3%)	
Exclusive formula/IV fluid	5 (8%)	1 (2%)	
Total number of feeds by type ^g	n=992	n=1,072	
Breast milk	596 (60%)	651 (61%)	0.09 ^b
Mixed feeding ^d	161 (16%)	207 (19%)	
Formula/IV fluid	175 (18%)	165 (15%)	
Not available	60 (6%)	49 (5%)	

IV, intravenous

^a Type of feeding at discharge is defined as the type of feed the infant received for final recorded feed before discharge.

^b Derived by chi-square analysis.

^c “Not available” excluded from analysis, therefore n=59 for pre-*Policy* and n=53 for post-*Policy* groups.

^d Mixed feeding is defined as the provision of breast milk and formula/IV fluid during the same feed.

^e In-hospital feeding type is defined as the primary feed type infants received throughout the entire hospital stay. Categories are defined as follows: exclusive breast milk (100% of feeds breast milk); mostly breast milk (>75% of feeds breast milk); mixed feeding (25-75% of feeds breast milk); mostly formula/IV fluid (>75% of feeds formula/IV fluid); exclusive formula/IV fluid (100% of feeds formula/IV fluid).

^f Categories mostly formula/IV fluid and exclusive formula/IV fluid combined for chi-square analysis.

^g The total number of feeds by type represents data for each feed for the entire dataset (n=2,064).

5.3.1. Type of Feeding at Discharge

The type of feeding each infant (n=120) received at discharge is presented in Table 5. Breast milk was the most common feed type provided to infants in both groups (pre- and post-*Policy*: 58% [35/60]). No association was found between *Policy* group and the type of feeding infants received at discharge, $\chi^2(2)=2.31$, $p=0.32$ (see Table H.4.).

5.3.2. In-Hospital Type of Feeding

The overall type of feeding infants (n=120) received throughout the entire hospital stay is shown in Table 5 and Figure 4. Throughout the hospital stay, infants were most commonly fed exclusive breast milk (pre-*Policy*: 37% [22/60]; post-*Policy*: 43% [26/60]). Following *Policy* introduction, a greater number of infants received exclusive breast milk and fewer infants were fed exclusive formula/IV fluid (pre-*Policy*: 8% [5/60]; post-*Policy*: 2% [1/60]). Despite these findings, there was no association between *Policy* group and in-hospital type of feeding, $\chi^2(3)=3.02, p=0.39$ (see Table H.5.).

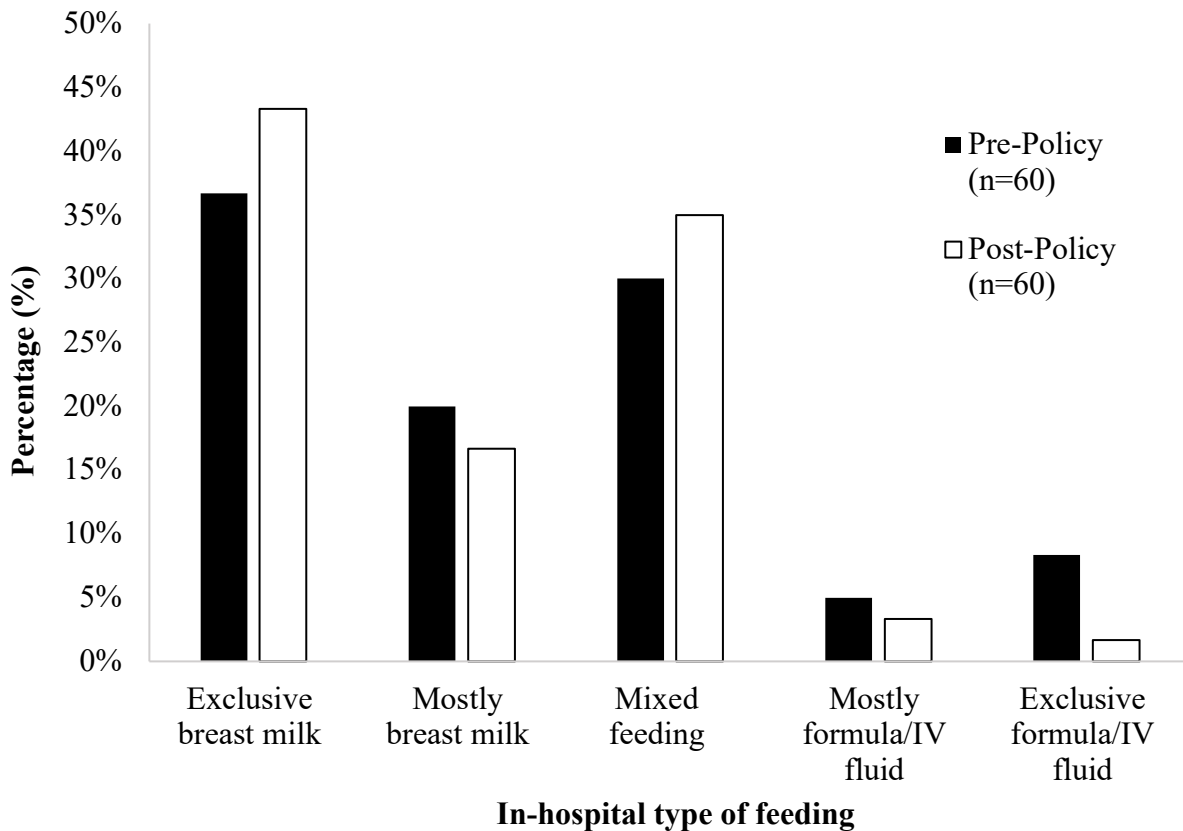


Figure 4. In-hospital type of feeding for each participant (n=120) by *Policy* group. In-hospital feeding type is defined as the primary feed type infants received throughout the entire hospital stay. Categories are defined as follows: exclusive breast milk (100% of feeds breast milk); mostly breast milk (>75% of feeds breast milk); mixed feeding (25-75% of feeds breast milk); mostly formula/IV fluid (>75% of feeds formula/IV fluid); exclusive formula/IV fluid (100% of feeds formula/IV fluid). IV, intravenous.

5.3.3. Total Type of Feeding

The type of feeding infants received for the total number of feeds (n=2,064) is presented in Table 5. Both pre- and post-*Policy* groups of infants most frequently received breast milk, accounting for approximately two-thirds of all feeds (pre-*Policy*: 60% [596/992]; post-*Policy*: 61% [651/1,072]). No association was found between *Policy* group and total type of feeding, $\chi^2(3)=6.49$, $p=0.09$ (see Table H.6.).

5.4. Source of Breast milk

Table 6. Source of breast milk for each participant (n=120) by *Policy* group

Source of breast milk	<u>Pre-Policy</u>	<u>Post-Policy</u>
	<u>n (%)</u> n=60	<u>n (%)</u> n=60
Mother's milk	55 (92%)	58 (97%)
Donor milk	0 (0%)	0 (0%)
Mother's milk/Donor milk	0 (0%)	1 (2%)
Not applicable ^a	5 (8%)	1 (2%)

^a Not applicable refers to infants who received formula and/or intravenous fluid exclusively throughout the entire hospital stay.

Table 7. Source of breast milk for each feed (n=2,064) by *Policy* group

Source of breast milk	<u>Pre-Policy</u>	<u>Post-Policy</u>	<i>p</i>
	<u>n (%)</u> n=992	<u>n (%)</u> n=1,072	
Mother's milk	756 (76%)	823 (77%)	
Donor milk	0 (0%)	2 (0%)	
Mother's milk/Donor milk	0 ^b (0%)	32 ^b (3%)	<0.001 ^a
Not applicable ^c	176 (18%)	163 (15%)	
Not available ^d	60 (6%)	52 (5%)	

^a Derived by chi-square analysis.

^b $p < 0.001$, post-hoc z-scores for standardized residuals of individual cells.

^c Not applicable refers to feeds for which the infant received formula and/or intravenous fluid.

^d Not available refers to data that was missing from records.

As shown in Table 6, one infant of the total sample received donor breast milk while in hospital (1% [1/120]). Of the total number of feeds (n=2,064), donor milk accounted for 0% (2/2,064) and a combination of mother's milk and donor milk for 2% (32/2,064) of feeds (Table 7). For the overall model, an association was found between *Policy* group and source of breast milk, $\chi^2(4)=34.86$, $p < 0.001$ (see Table H.7.). Following post-hoc analysis, it was determined that there was a significantly greater number of mother's milk/donor milk feeds for the post-*Policy* group as compared with the pre-*Policy* group ($p < 0.001$; see Table I.1.). The OR could not be calculated since the pre-*Policy* count for the category mother's milk/donor milk resulted in a zero denominator.

5.5. Method of Infant Feeding

Table 8. Method of infant feeding for each participant (n=120) by *Policy* group

Method of feeding ^a	<u>Pre-Policy</u>	<u>Post-Policy</u>	<i>p</i>
	<u><i>n</i> (%)</u> n=60	<u><i>n</i> (%)</u> n=60	
Breast alone	10 (17%)	14 (23%)	0.50 ^b
Breast and other ^c	42 (70%)	41 (68%)	
Other alone ^c	8 (13%)	5 (8%)	

^a Defined as the overall method by which the infant received nutrition throughout the entire hospital stay.

^b Derived by chi-square analysis.

^c Other includes: bottle, finger/syringe, cup, and intravenous route.

In Table 8, the overall method by which each infant (n=120) was fed throughout the entire hospital stay is presented. While in hospital, few infants were fed at the breast alone (*pre-Policy*: 17% [10/60]; *post-Policy*: 23% [14/60]). The majority of infants were fed by a combination of breast and other methods, including bottle, finger/syringe, cup, and IV route (*pre-Policy*: 70% [42/60]; *post-Policy*: 68% [41/60]). No association was found between *Policy* group and the method of feeding, $\chi^2(2)=1.37$, $p=0.50$ (see Table H.8.).

Table 9. Method of infant feeding for each feed (n=2,064) by *Policy* group

Method of feeding ^a	<u>Pre-Policy</u>	<u>Post-Policy</u>	<i>p</i>
	<u><i>n</i> (%)</u> n=992	<u><i>n</i> (%)</u> n=1,072	
Breast alone	420 (42%)	539 (50%)	<0.001 ^b
Breast and other ^c	178 ^d (18%)	60 ^d (6%)	
Other alone ^c	43 ^d (4%)	120 ^d (11%)	
Not available	351 (35%)	353 (33%)	

^a Defined as the method by which the infant received nutrition for each feed (n=2,064).

^b Derived by chi-square analysis.

^c Other includes: bottle, finger/syringe, cup, and intravenous route.

^d $p<0.001$, z-scores for standardized residuals of individual cells.

Table 9 summarizes the method of infant feeding for the total number of recorded feeds (n=2,064). For the overall model, there was an association between *Policy* group and the method of infant feeding, $\chi^2(3)=106.71$, $p<0.001$ (see Table H.9.). Following post-hoc analysis, it was determined there was a significantly greater number of ‘other’ feeds and lesser number of ‘breast and other’ feeds for the *post-Policy* group, as compared with the *pre-Policy* group ($p<0.001$; see

Table I.2.). The odds of an infant fed by combination of breast and other method during the same feed was 0.27 times less in the post-*Policy* group, as compared with the pre-*Policy*. Infants in the post-*Policy* were more likely to be fed by other method alone (OR=2.78) than infants in the pre-*Policy* group (see Appendix J).

5.6. Infant State and Feeding Description

Subjective clinical measures of infant state and feeding description for each feed (n=2,064) are presented in Table 10. These measures were missing from charts for the majority of feeds (infant state: pre-*Policy*: 96% [955/992], post-*Policy*: 97% [1,036/1,072]; feeding description: pre-*Policy*: 96% [954/992], post-*Policy*: 97% [1,033/1,072]).

Table 10. Infant state and feeding description for each feed (n=2,064) by *Policy* group

	<u>Pre-<i>Policy</i></u>	<u>Post-<i>Policy</i></u>
	<u><i>n</i> (%)</u>	<u><i>n</i> (%)</u>
	n=992	n=1,072
Infant state^a		
Awake/Quiet	0 (0%)	0 (0%)
Crying	0 (0%)	0 (0%)
Fussy	4 (0%)	5 (1%)
Sleeping	33 (3%)	31 (3%)
Not available ^b	955 (96%)	1,036 (97%)
Feeding description^c		
Good	36 (4%)	34 (3%)
Fair	1 (0%)	3 (0%)
Poor	1 (0%)	2 (0%)
Not available ^b	954 (96%)	1,033 (96%)

^a Infant state is defined as the infant behavior during the feed.

^b Not available refers to data that was missing from records.

^c Feeding description is defined as the subjective measure of how well the infant was fed.

5.7. Feeding Volumes

The feeding volumes (IV, oral, and total) received by each participant (n=120) throughout the hospital stay by *Policy* group are presented in Table 11 and Figure 5. The mean IV volumes for the pre- and post-*Policy* groups were 90mL (*SD*=321) and 131mL (*SD*=797), respectively. The mean difference between groups (-41mL, 95% CI [-261, 179]) was not statistically significant, $t(118)=-0.37$; $p=0.71$. Mean oral volumes for the pre- and post-*Policy* groups were 470mL (*SD*=1,943) and 517mL (*SD*=3,121), respectively. The difference between oral volume means (-47mL, 95% CI [-987, 893]) also did not statistically differ between *Policy* groups ($t(118)=-0.99$, $p=0.92$). Average total volumes were determined to be 560mL (*SD*=2,211) for the pre-*Policy* group and 648mL (*SD*=3,915) for the post-*Policy* group. This mean difference (-88mL, 95% CI [-1,237, 1,061]) was not statistically significant between groups ($t(118)=-0.15$, $p=0.88$).

Table 11. Feeding volumes (intravenous, oral, and total) received by each participant (n=120) throughout the hospital stay by *Policy* group

	<u>Pre-<i>Policy</i></u> <u>Mean (\pm<i>SD</i>)</u> n=60	<u>Post-<i>Policy</i></u> <u>Mean (\pm<i>SD</i>)</u> n=60	<i>p</i>
IV volume (mL)	90 \pm 321	131 \pm 797	0.71 ^a
Oral volume (mL)	470 \pm 1,943	517 \pm 3,121	0.92 ^a
Total volume ^b (mL)	560 \pm 2,211	648 \pm 3,915	0.88 ^a

SD, standard deviation; IV, intravenous

^a Derived by independent t-tests.

^b Total volume is equal to the sum of IV and oral volume.

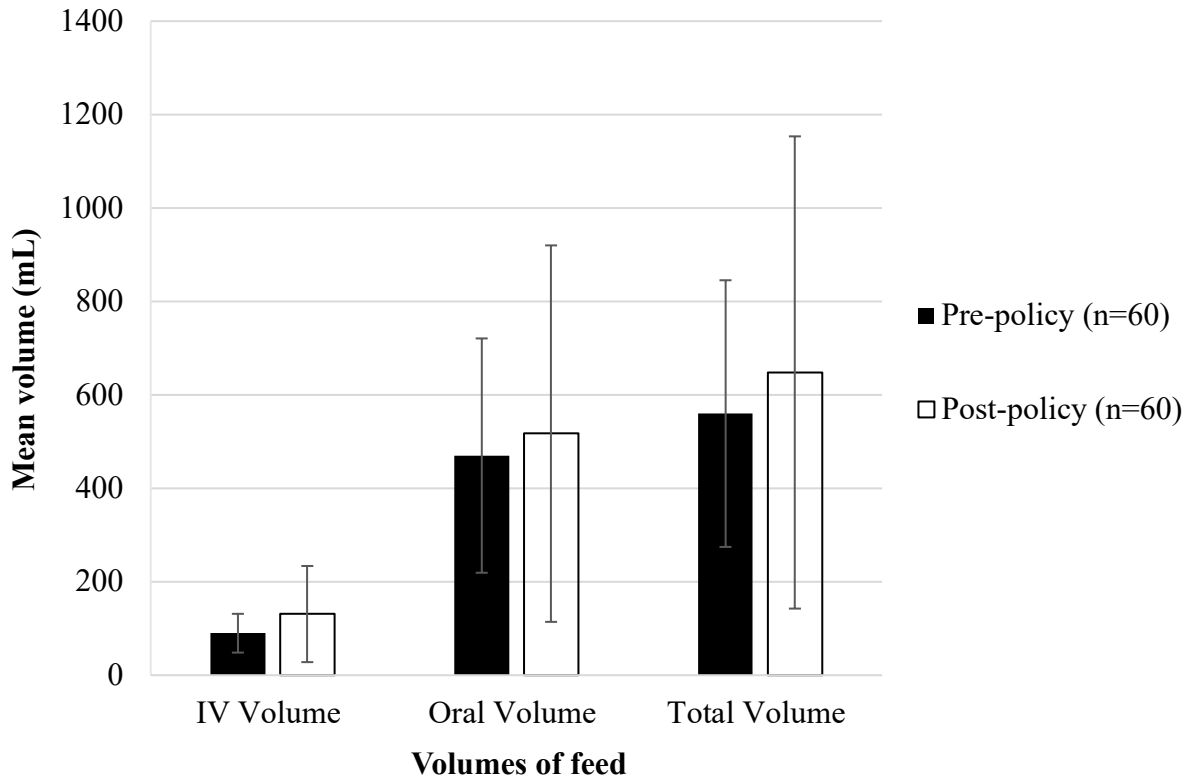


Figure 5. Volumes of feed (intravenous, oral, and total) received by participants (n=120) throughout the hospital stay by *Policy* group recorded in mL. Total volume is equal to the sum of intravenous and oral volume. Errors bars represent standard error. IV, intravenous.

6.0 Discussion

6.1. Introduction

In this retrospective chart audit of mothers with GDM and T2DM and their infants, 58% (35/60) of infants in pre- and post-*Policy* groups received breast milk as their last feed at discharge; no association was found between *Policy* group and the provision of breast milk at discharge ($\chi^2(1)=0.54, p=0.46$). Results do not support the hypothesis that following introduction of the *Policy*, more infants would receive breast milk as their final feed. No association was found between *Policy* group and the overall feed type infants received throughout the entire hospital stay ($\chi^2(3)=3.02, p=0.39$). Despite these findings, results of this study provide a description and exploration of feeding practices among this group of mother-infant pairs at the IWK Health Centre. These findings may also not be reflective of the *Policy* itself, but instead by a number of factors that will be considered below.

Descriptive results of infant feeding practices will first be interpreted and compared to previous literature. The effectiveness of the *Policy* in facilitating breastfeeding in-hospital for women with GDM and T2DM will then be discussed. Explanations for study findings will also be explored. Study strengths and limitations will be presented, and lastly, conclusions and suggestions for future directions will be proposed. The KTA process will be used as a framework to guide discussion and interpretation of results (103).

6.2. Knowledge-to-Action Process

6.2.1. Knowledge Creation Funnel

This study completes the KTA process at the “knowledge inquiry” phase by providing a descriptive account of infant feeding practices for women with GDM and T2DM in pregnancy (see Figure 1) (103). Of the sample of mother-infant pairs included in the study, 95% (114/120) of infants received some breast milk in hospital. This finding suggests that the majority of women with GDM or T2DM initiated breastfeeding, for at least one feed, in the early post-partum period. Although the majority of mother-infant pairs initiated some breastfeeding, the rate of “exclusive” breastfeeding was lower as compared with the general maternal population.

In 2013, in Nova Scotia, approximately 62% of mothers exclusively breastfed from birth to hospital discharge (116), while in our current study, 40% (48/120) exclusively breastfed throughout the hospital stay.

Results from previous studies have come to similar conclusions. Rates of “any” breastfeeding were found to be comparable for women with GDM, women without DM during pregnancy, and population-based rates (46,50). Yet, research suggests that women with GDM or pre-existing DM are less likely to exclusively breastfeed at discharge, as compared with women without DM in pregnancy (46–48). One possible explanation for this finding is the provision of formula supplementation in-hospital to prevent/manage complications that are more common among women with DM in pregnancy and their infants (11). For instance, healthcare providers and mothers have cited perceptions of inadequate colostrum or beliefs it will prevent neonatal hypoglycemia as reasons for supplementing with formula (12,13,107). The theory of planned behaviour (TPB), as applied in previous work by RIM Student (TR), will be used below as a framework to explore healthcare provider behavior of supplementation practices.

Another interesting finding in this study is the discrepancy between the number of infants who received exclusive breast milk in hospital and the number who were fed only at the breast. Specifically, 40% (48/120) of infants received breast milk exclusively in hospital and only 20% (24/120) were fed exclusively at the breast. Comparable findings have been found in previous research. For instance results from one study found that, as compared with mothers without DM, mothers with GDM were more likely to pump exclusively in hospital and initiate pumping sooner after birth (*median*=3.0 days versus 7.0 days following birth, respectively, $p<0.05$) (95,96). These results may indicate that women experienced physical breastfeeding challenges and pumped as a means to increase milk supply. Breastfeeding difficulties may be related to maternal overweight and obesity, a risk factor for GDM and T2DM (8). For instance, mothers with large breasts may experience difficulties with infant latch and positioning for breastfeeding (8). Metabolic and hormonal differences characteristic of DM have also been associated with delayed onset of lactogenesis II (7,80). The possibility that women proactively pumped in hospital, knowing they were at greater risk of experiencing such challenges, should also be

considered. This finding may also be reflective of healthcare provider efforts to encourage pumping to provide infants with expressed breast milk rather than formula.

6.2.2. Action Cycle

“Monitor Policy Adoption”

Study findings can also be interpreted using phases of the action cycle (see Figure 1) (103). The “monitor *Policy* adoption” phase of the action cycle describes the extent to which the *Policy* had been adopted by IWK Health Centre staff and providers. Adoption refers to changes in practice or behaviour that are in accordance with the *Policy*. Results of this study provide an indication of *Policy* adoption by evaluating the completeness of chart documentation. As stated in the *Policy*, the supplemental feeding plan is to be documented in the child’s health record.

After reviewing *Newborn Nutrition/Elimination Records* and *NICU 24 Hour Intake Summary Sheets*, information for each feed was found to be frequently missing from charts for the following outcomes: infant state (96% [1,991/2,064] of feeds), feeding description (96% [1,987/2,064] of feeds), and method of feeding (34% [704/2,064] of feeds). In particular, information was frequently missing for formula fed infants. For instance, feeding volumes were often reported but the method (e.g. bottle) was not available. Infrequent chart documentation suggests that at the monitoring phase of the action cycle, the *Policy* was not entirely adopted by healthcare providers and staff.

These pieces of information provide an indication of the success of the feeding plan. As outlined in the *Policy*, a description of the feeding and infant state are components of the breastfeeding assessment. These measures indicate the “quality and effectiveness” of breastfeeding (see Appendix A, p. 92). The method of feeding is also essential to document since certain methods, such as teats or artificial nipples, may interfere with the establishment and duration of breastfeeding (42).

In terms of record keeping, previous research has identified documentation of infant feeding as a potential area for practice improvement (107). A study from 2011 explored breastfeeding knowledge and in-hospital practices of nurses employed in Colorado hospitals (107). Although

nurses recognized the benefits and importance of charting, documentation was inconsistent and lacked appropriate detail (107). Nurses described relying on verbal exchanges of infant feeding at shift change rather than through written records (107). Nurses from the study also acknowledged this as gap, and stated they would benefit from additional education on the best methods for documenting feeds (107). Although these results may not be generalizable to other healthcare centres, they provide insight into the potential barriers and opportunities to improve record keeping.

Recording details of infant feeding is essential for a number of reasons. Charting serves as a primary method of communication between healthcare providers (117). Quality communication between providers can increase the likelihood of mothers receiving consistent care and advice (74). Documentation also services as a tool to evaluate the quality of care and as a legal record narrating the history of care (117). At the IWK Health Centre, further work may include exploring healthcare provider feedback regarding documentation forms. Specific questions may explore barriers to record keeping and the ease of completing documentation of infant feeding using the current forms. Such exchanges with providers could potential identify beneficial changes to existing forms.

“Evaluate Effect of Policy”

Results from the current study also address the “evaluate effect of *Policy*” phase of the KTA process (see Figure 1) (103). A comparison of infant feeding practices before and after *Policy* introduction provided an indication of *Policy* impact. We found no association between *Policy* group and breastfeeding rates at discharge ($\chi^2(1)=0.54, p=0.46$).

Results from past studies also offer insight into the effectiveness of initiatives to facilitate breastfeeding (15,58,101,102). Previous research evaluating the impact of *BFI* status have reported increased breastfeeding rates in healthy newborn populations and *NICU* infants following implementation (58,101,102). The *PROBIT*, a large cluster-randomized trial, was conducted from June 1996 to December 1997 in the Republic of Belarus to evaluate the effect of the *BFI* in increasing exclusive breastfeeding rates (58). Hospital sites were randomized to the intervention group (adopting *BFI*) and the control group (continuing with existing practices).

Results from the study found that exclusive breastfeeding rates were significantly greater for infants born at intervention hospital sites at both three months (43% [3,812/8,865] versus 6.4% [526/8,181], $p<0.001$) and six months (7.9% [700/8,865] versus 0.6% [49/8,181], $p<0.01$) following birth, as compared to infants born at control hospital sites (58).

Other research has examined the impact of *BFI* status on breastfeeding rates in a *NICU* population of infants (101,102). At the Boston Medical Centre, breastfeeding rates among infants admitted to the *NICU* were compared between 1995 (before implementation of *BFI*) and 1999 (when *BFI* status was granted) (102). Breastfeeding initiation rates, defined as the infant receiving any breast milk in the first week following birth increased significantly from 1995 to 1999 (35% [38/110] and 74% [87/117], respectively; $p<0.001$) (102). Similar research was conducted at the Odete Valadares Hospital in Brazil between 1998-2000 (101). Exclusive breastfeeding rates at hospital discharge (defined as the 72-hour period prior to discharge) were compared between sub-samples of infants born before and after *BFI* status. Exclusive breastfeeding rates at discharge increased significantly from 36% [90/250] to 55% [134/245] ($p<0.01$) following implementation of *BFI* (101).

Other research has evaluated the impact of hospital guidelines in facilitating breastfeeding in a sample of women with DM in pregnancy (15). A study by Tozier in 2013 evaluated the impact of the introduction of a newborn hypoglycemia clinical algorithm on breastfeeding rates and blood glucose control among infants born to mothers with DM. The sample included $n=163$ infants and their mothers, diagnosed with GDM or T1DM (15). A greater number of infants received colostrum following introduction of algorithm (colostrum, $n=52$ versus formula, $n=21$) as compared to the time period before introduction (colostrum, $n=25$ versus formula, $n=50$) (15).

There are limitations, however, to comparing results of previous research to findings of this study. The populations studied in research discussed above included healthy newborn infants and infants admitted to the *NICU* (58,101,102) and few studies have focused on infants born to mothers with GDM or T2DM. Moreover, the in-hospital initiatives introduced in these studies differed from the *Policy* introduced in this study. For instance, in research by Tozier (2013) the goal of the algorithm was to guide management of neonatal hypoglycemia (15); whereas in this study, the aim of the *Policy* was to provide direction regarding supplemental feedings. The

context in which these initiatives were introduced may also limit generalizability of results. Organizational policies and workplace cultures likely differ between health care centres, which may impact infant feeding practices. Also, broader country-specific breastfeeding policies and cultural norms of infant feeding should be taken into consideration when interpreting findings.

It is also important to consider that missing data from records in this study could potentially have affected the primary outcome. For the pre-*Policy* group, data for the final feed at discharge was missing for 2% (1/60) of participants, and for the post-*Policy* group 12% (7/60) participants. Should some of these missing feeds have been breast milk, then a more positive effect would have been observed for the primary outcome. It is possible that changes in practice occurred following *Policy* introduction, yet this change was not captured due to information of feeds that were not recorded in health records. Furthermore, *Policy* implementation was carried out from March to July 2017. Given the timeframe of inclusion of mother-infant pairs in this study, it is possible that providers had not yet been introduced or received training regarding the *Policy*.

In terms of the in-hospital feeding type, a further proposed analysis will be performed as a goal for dissemination. Specifically, for in-hospital type of feeding, categories “mostly breast milk”, “mixed feeding”, “mostly formula/IV fluid”, and “exclusive formula/IV fluid” will be collapsed and compared with “exclusive breast milk”. This analysis will be performed to determine if there was an association between *Policy* group and exclusive breastfeeding throughout the entire hospital stay.

An association was found between *Policy* group and method of feeding for each feed ($n=2,064$) ($\chi^2(3)=106.71, p<0.001$). Although the post-*Policy* group of infants were more likely to be fed by “other” methods (e.g. bottle, cup, etc.) ($p<0.001$), the method of feeding did not reflect the type of feed an infant received. For instance, infants fed by bottle could have received expressed breast milk. A significantly greater number of mother’s milk/donor milk feeds was also provided following *Policy* introduction ($p<0.001$), however donor milk was only provided to one infant in the post-*Policy* group. It should be noted that donor milk is only available to infants admitted to the *NICU*. This is an important consideration for future recommendations as this can impact whether an infant receives breast milk exclusively.

Results in this study may not be reflective of the *Policy* itself, but instead attributed to other factors. Previous research has highlighted the complexity of translating evidence into practice change at an organizational level (118). Behaviour change in healthcare is particularly complex and research often reveals gaps between evidence and practice (118). The case of healthcare provider hand-hygiene practices is an excellent example to illustrate this complexity (118). Although the benefits of hand hygiene in reducing the rates of hospital-acquired infections are well known, research has found that compliance with organizational handwashing guidelines is often less than desirable (118).

A number of factors have been found to influence the success of practice change (103,118). For example, barriers at multiple levels including individual, social, and organizational levels act as obstacles to change. Furthermore, differences in the setting and target populations can also determine adoption of change (103,118). Thus, achieving successful practice change is not a one-size fits all approach and is shaped by several influencing factors (103,118). Future directions at the IWK Health Centre will be explored using the KTA process, specifically the “assessing barriers to *Policy* use” and “select, tailor, and implement *Policy*” phases (see Figure 1) (103).

“Assess Barriers to Policy Use”

Future research at the IWK Health Centre may explore specific barriers/facilitators to *Policy* adoption. A mixed methods approach to gather provider feedback and insight may be an effective method to explore such factors. Findings from research could inform further methods to investigate these factors. The TPB, a framework to explain and predict human behavior, can be used to understand previous findings from the literature (119). This framework was selected and applied previously by TR, RIM student, to interpret results of feeding practices of infants born in the pre-*Policy* time period of this study. The TPB proposes that three variables shape our intention to perform a specific behaviour: 1) attitude toward the behaviour, 2) subjective norm, and 3) perceived behavioural control (see Figure 6) (119). Our intentions, along with perceptions of control, then determine whether the actual behaviour is performed (119). Each of these variables will be discussed in the context of previous literature exploring healthcare provider infant feeding practices.

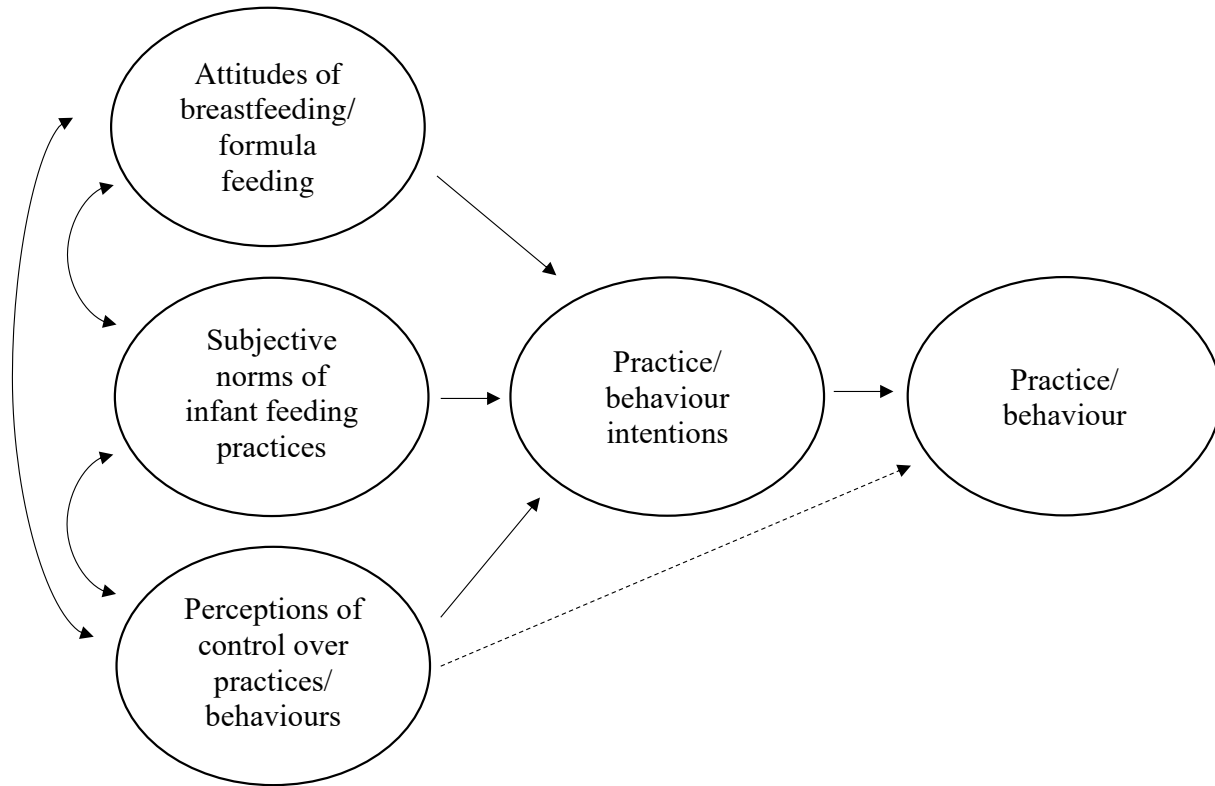


Figure 6. Theory of planned behaviour adapted from Ajzen (1991) (119)

Attitudes refer to the extent to which an individual has a positive or negative assessment of a specific behaviour (119). Research has found that healthcare providers hold positive and supportive attitudes of breastfeeding (120,121). Providers recognize health benefits associated with breastfeeding and the importance of establishing breastfeeding shortly after birth (120,121). Nurses also acknowledge their role of providing support and assistance for breastfeeding mothers while in hospital (120,121). These findings indicate that the majority of providers hold favourable beliefs and attitudes, and other variables may be more likely to mediate behaviour.

Subjective norms are understood as social expectations to conform with a particular behaviour (119). Provider relationships have been found to influence practice behaviour in a manner that either supports, or conflicts with breastfeeding support (122). Research suggests that workplace cultures and routines may lead to feelings of pressure to conform with certain non-evidence based practices (123). There is evidence to suggest that supplementation with formula is commonly provided for a number of non-medically indicated reasons (12,13,107). For instance,

infant formula is commonly provided due to perceived low milk supply and the belief it will prevent hypoglycemia (12,13,107). Health care providers have also cited breastfeeding problems, infant behaviour, and maternal fatigue as reasons for supplementing (13). Formula feeding during the overnight hours may also be a common practice in some centres (13,107).

Perceived behavioural control refers to an individual's "perception of the ease or difficulty of performing the behaviour of interest" (119). This variable includes access to resources, such as money, time, and skills that enable action of the behaviour. It also refers to an individual's confidence or self-efficacy with performing the action. Perceptions of behavioural control can vary according to the situation and/or context (119). At the organizational level, nurses have reported being busy, overworked, tired, and having insufficient staffing as limitations to delivering the best care (13,122). Both mothers and nurses have also described breastfeeding support as being rushed, with little time to establish proper positioning and latch (122).

A number of factors identified using the TPB framework have the potential to influence in-hospital infant feeding practices. Findings from the above studies offer an overview of potential barriers/facilitators to *Policy* adoption, although results may not be reflective of practices and environments at the IWK Health Centre. Future efforts at the IWK Health Centre could include gathering feedback and engaging in dialogue with providers to determine specific barriers/facilitators to practice change. With an understanding of such factors, implementation plans could be tailored to facilitate change.

"Select, Tailor, and Implement Policy"

Future directions may also be explained by the "select, tailor, and implement *Policy*" phase of the KTA process (see Figure 1). Interventions can be carried out using a number of strategies including implementation, diffusion, and dissemination (103). Implementation, which refers to planned efforts to encourage change adoption, has been found to be most effective for enabling larger-scale change (103). A number of strategies for implementation exist, including educational, feedback and reminder, patient-focused, and organizational strategies (124). Those most relevant to future work at the IWK Health Centre may include feedback and reminders, as well as education and training activities.

Feedback involves communicating information regarding performance to providers, teams, and/or the organization, while reminders are prompts directed at providers to elicit specific actions/decisions (124). These strategies are useful since behaviours are often routine, and it can be difficult to objectively self-evaluate performance (124). In relation to the following study, the audit of infant feeding practices offers information to providers and leaders regarding the extent of *Policy* adoption. This feedback can be useful to establish new patterns of behaviour (124). Study results bring forward awareness of current infant feeding practices, and this awareness can often be a motivator for change (124). Research indicates that feedback may be most effective when presented with specific change objectives and an actionable plan (124). Future dialogue and exchange with healthcare providers may also inform opportunities for education and training. Depending on feedback from providers, areas of focus may include charting methods and supplementation practices.

In summary, organizational behaviour change is complex and research has found that translating best-evidence into practice is particularly challenging (124). Compliance with new change is often mediated by the complexity of the change (118). For example, approaches to care requiring the acquisition of new skills and broader organizational change can be difficult to achieve (118). Implementation efforts must also overcome multiple barriers at individual, social, and organizational levels (124). Using the KTA process as a framework, results from the following study suggest that further efforts may address the “assess barriers to *Policy* use” and “select, tailor, and implement *Policy*” phases of the cycle (103).

6.3. Strengths and Opportunities

Strengths of the following study include collaboration between researchers and decision makers at the IWK Health Centre. This involved the exchange of knowledge throughout the planning and data collection phases of research. The research question was tailored to specifically monitor adoption of the *Policy* and evaluate its impact on infant feeding practices. Findings from this study can be directly used to guide future work at the IWK Health Centre.

There are some considerations that highlight opportunities for future research. Results are specific to mothers delivering at the IWK Health Centre in Halifax, Nova Scotia, and may not be

generalizable to other health care centers or regions across Canada. Breastfeeding policies and practices likely differ between health care institutions. Also, the primary outcome was defined as the final recorded feed, which may not necessarily predict future feeds in-home. For this study, the final recorded feed was chosen as a cross-sectional measure of breastfeeding to estimate the required sample size. Also, given the increased risk of complications at birth and in the early post-partum period for women with DM in pregnancy, exclusive breastfeeding may not be reflective of the group. To support this primary outcome, infant feeding data from the entire hospital stay was provided. Future studies may explore feeding practices in the broader post-partum period and health care provider or caregiver reasons for formula supplementation.

Data available from charts was limited by the completeness and accuracy of records of infant feeding practices. Missing data for final feed prior to discharge may have impacted results of the primary outcome. A greater effect may have been observed had some of the missing feeds been breast milk. Parents and caregivers are also encouraged to document in charts and may have little experience or training with documentation. In terms of volumes of feed, oral and total amounts included both expressed breast milk and formula. Therefore, volumes do not distinguish between these two feed types. Volumes were also not available from charts for all feeds, particularly feeds in which expressed breast milk was provided.

Staff training and education took place in the spring of 2017, overlapping the timeframe for inclusion of mother-infant pairs (104). It is possible that staff and providers were unaware of the *Policy* and/or did not yet receive training. Also, collecting data during a timeframe immediately following *Policy* enactment might not have provided an appropriate buffer period for staff to become comfortable with the change. The impact of other hospital policies introduced during the study period should also be considered. *Guidelines for Neonatal Glucose Monitoring* were introduced on June 1st, 2016 at the IWK Health Centre. Implementation of these guidelines overlapped with the pre-*Policy* window of this study. It is possible that practice changes associated with the guidelines led to reduced supplementation in the pre-*Policy* group.

7.0 Conclusions and Future Directions

The following study involved a retrospective chart audit of mothers diagnosed with GDM and T2DM and their infants (n=120) born at the IWK Health Centre in Halifax, Nova Scotia between January 5th, 2016 and November 24th, 2017. The objectives were to describe and compare in-hospital feeding practices of infants born before and after *Policy* introduction. In summary, there was no association between *Policy* group and the provision of breast milk at discharge ($p=0.46$); 58% (35/57) of infants from both pre- and post-*Policy* groups received breast milk for the final feed. Data on several outcomes were infrequently documented in charts for each feed: feeding method (34% [704/2,064]), infant state (96%, [1,991/2,064]) and feeding description (96%, [1,987/2,064]).

These results may be related to other factors, and not necessarily indicative of the *Policy* itself. As a first step at the IWK Health Centre, feedback could be gathered from health care providers to understand knowledge/perceptions of the *Policy*. This step may facilitate knowledge exchange between researchers/decision makers and clinicians. Such exchanges may enable meaningful collaboration between stakeholders and highlight directions for effective and meaningful change (103). This dialogue may also capture the values of clinicians to better understand buy-in of *Policy* goals and objectives. As discussed earlier, according to the TPB provider attitudes of initiatives to facilitate breastfeeding have the potential to shape practice and behavior (119). Such insight may also indicate potential barriers/facilitators to change. Identifying these specific factors can assist with developing a tailored implementation plan (103).

Another strategy may include the provision of study feedback to healthcare providers. Results from the study could be summarized and presented to teams during small group meetings for their thoughts and ideas. When presented in an encouraging, engaging, and participative approach, such feedback may increase the opportunities for individuals to be motivated to adopt new behaviours (124). Ongoing feedback that is incorporated into the monitoring process can also promote sustained change (124). Results from this study also indicate the opportunity for additional education and training of documentation procedures. Chart documentation serves as a primary method of communication between healthcare providers, ensuring consistent and coordinated care (117). An initial strategy to improve record keeping may include gathering

health care provider and patient feedback of current documentation forms. Such dialogue may highlight the opportunity for patient training of documentation methods. Alternatively, providers may choose to review and sign off on records completed by patients. Exchanges with providers and patients may also highlight potential areas for improvements to existing forms and records.

Potential next steps:

Re-evaluate *Policy* implementation plan and strategies.

Engage in dialogue with healthcare providers to better understand motivation to implement *Policy*.

Explore healthcare provider perspectives and knowledge of the *Policy*.

Examine potential barriers and facilitators to *Policy* adoption and practice.

Gather feedback from healthcare providers and patients regarding documentation to identify opportunities for changes in charting methods and tools.

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CLINICAL MANUAL Policy/Procedure

TITLE:	Supplemental Feedings for Breastfeeding Children	NUMBER: 685A
Sponsor:	Director Women's and Newborn Health Program	Page: 1 of 18
Approved by:	Medical Advisory Committee	Approval Date: October 18 th , 2016 Effective Date: November 29 th , 2016
Applies To:	All IWK Health Centre Health Care Staff and Physicians Providing Care for Breastfeeding Children and Families	

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POLICY STATEMENTS

For the purpose of this policy, a breastfeeding child is anyone whose mother is breastfeeding or has expressed the intent to breastfeed prior to or upon admission to the IWK Health Centre regardless of the child's gestation at birth or age. The terms preterm, newborn, infant and child may be used intermittently throughout this document when the content is pertinent to specific ages.

Whenever a medical need for the interruption, cessation or supplementation of breastfeeding is considered, the risks posed by the presenting medical condition must be weighed against the risks posed by breastfeeding supplementation and the use of human milk substitutes.

All mothers will be supported to make an informed decision regarding supplementation of their breastfeeding babies. If supplementary feedings are necessary, maternal verbal consent for supplementation and the type of supplement will be obtained and documented. If the mother is not able to provide consent, this can be done through another parent or identified substitute decision maker for the baby.

GUIDING PRINCIPLES AND VALUES

The primary goal for the supplementation of breastfeeding children is to provide medically indicated nutrition while optimizing the maternal milk supply, breastfeeding exclusivity and duration.

The IWK Health Centre strives to meet the standards set to support exclusive breastfeeding by the World Health Organization (WHO) and UNICEF in the Baby-Friendly Hospital Initiative, the Health Canada Accreditation Standards and the Nova Scotia Provincial Breastfeeding Policy.

The World Health Organization states that all babies should be exclusively breastfed from birth until six months of age. Breastfeeding should be sustained for up to two years or longer with appropriate complementary feeding. The protective effect of early introduction of potentially allergenic foods at four to six months of age remains under investigation. Documented benefits of introducing complementary feedings at 4-6 months are largely limited to infants at high risk of developing allergies. High risk infants are those with a first degree relative (parent or sibling) who has an allergic condition such as atopic dermatitis, a food allergy, asthma or allergic rhinitis.

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Inappropriate and routine supplementation of breastfeeding can interfere with a mother's milk supply and effective milk transfer by her infant. This may have a negative impact on their ability to exclusively breastfeed and may shorten the duration of the breastfeeding experience.

The IWK Health Centre embraces a philosophy that protects and supports the continuum of families' breastfeeding experiences, while acknowledging individual decision making and cultural differences. It is important for staff to work collaboratively with parents, other professionals and community networks to achieve a culture supportive of exclusive breastfeeding while maintaining the dignity of and supporting those who are unable to or choose not to breastfeed.

Parents have the right to make an informed decision regarding the use of human breast milk substitutes, such as infant formula, based on accurate and unbiased information about the risks and costs of breast milk substitutes.

PROTOCOL

Determining the Need for Supplemental Feedings:

All supplemental feeding plans are based on comprehensive maternal and child health and breastfeeding assessments.

- **Maternal Assessment:** The maternal health and breast assessment will include factors that may predispose the mother to experience breastfeeding challenges including:
 - Prenatal, birth and medical health history
 - Maternal breast anatomy and milk production
 - Psychological aspects of breastfeeding
- **Child assessment:** The child health assessment will include factors that may indicate a medical need for supplementation, including:
 - Infant stability related to the infant's response routine care and handling without experiencing severe apnea, desaturation or bradycardia.
 - Developmental (gestational) age.
 - Ability to feed directly at breast.
 - Ability to attain a sufficient volume of breast milk at breast to meet their nutritional requirements.
 - Hydration status.

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- Weight loss assessed within the context of the complete clinical scenario and consistent with the World Health Organization (WHO) indications.
- Frequency and colour of stools.
- Blood glucose levels. *Refer to IWK Health Centre Policy -#40036 Guidelines for Neonatal Glucose Monitoring.*
- Breastfeeding assessment. The assessment will be by direct observation of the quality and effectiveness of the breastfeeding by an experienced health professional, as well as discussion with the mother and her support people regarding their perceptions of the experience. The assessment will include:
 - Baby sleep/wake patterns and general nature of infant state.
 - Frequency and duration of feeding on each breast
 - Effective and comfortable positioning and latch (Refer to Appendix B, LATCH Assessment Tool).
 - Signs of effective milk ejection reflex
 - Signs of effective milk transfer.
 - Effectiveness of the infant's suck.

Situations in which supplemental feedings should not be considered:

The following situations do not require supplemental feedings unless it is the mother's informed independent decision to provide supplementary feedings. The mother and baby must receive individualized breastfeeding support that is based on best practice interventions supportive of healthy feeding outcomes and which will aid in the prevention of early weaning.

- The sleepy newborn not feeding a minimum 8 times per 24 hours within the first 48 hours of life and who:
 - Is a healthy term newborn
 - Has no signs of illness
 - Is adequately hydrated and
 - Has not had the benefit of best practice interventions that facilitate effective breastfeeding for the sleepy infant.
- The healthy, appropriately grown term newborn with bilirubin levels less than 240 micromoles per litre after 72 hours of age who is feeding well, has a normal frequency of bowel movements and a weight loss of less than 10%.
- The infant who is fussy at night or is cluster feeding.
- The infant of a tired or sleeping mother.
- Diagnosis of mastitis accompanied by painful breastfeeding.

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Situations in which supplemental feedings may be considered:

There may be situations in which food is required in addition to or in place of direct feeding from the breast because of a medically indicated concern. The attending physician, nurse practitioner, midwife and/or their delegates must provide an order for all medically indicated breastfeeding supplementation prior to the implementation of supplementation plans. Examples of the above situations include, but are not limited to:

- Newborns weighing less than 1500 grams (very low birth weight) and less than 32 weeks of gestation (very preterm). Newborns 1500 – 2500 grams or 32+1 to 36+6 weeks of gestation require an individualized approach to supplemental feedings.
- Weight loss of 10% in the first 48 hours of life for term and late preterm newborns or significant weight loss beyond 48 hours of life and accompanied by clinical indications such as milk production not being established and/or decreased milk transfer.
- Newborn asymptomatic hypoglycemia confirmed by laboratory blood glucose measurement and is unresponsive to effective, frequent breastfeeding. This includes those babies at risk of hypoglycemia by virtue of impaired metabolic adaptation or increased glucose demand. *Refer to policy #80.46: Guidelines for Neonatal Glucose Monitoring*
- Failure to gain weight by two weeks after birth or less than average weight gain for their age.
- Inability to consistently attain or sustain a successful latch related to situations such as abnormalities of the baby's mouth (cleft palate) or unstable infant.
- Clinical evidence of dehydration.
- Insufficient milk intake as indicated by no bowel movements or fewer than one a day in the first two weeks of life, or meconium five or more days after birth.
- Maternal-child separation and/or maternal illness preventing feeding at breast.
- Maternal breast pathology or prior breast surgery with confirmed low milk production.
- Significantly cracked and fissured nipples or intolerable nipple pain during feedings with or without evidence of co-existing fungal or bacterial infection.
- Diagnosis of a breast abscess when the affected area is directly involved with the feeding.
- Herpes simplex virus type 1 (HSV-1) lesions on the mother's breasts in direct contact with the infant's mouth.
- Maternal medications and substance use: there are very few situations in which breastfeeding would not be safe. For more information, refer to policy 685.1- *IWK Health Centre and Public Health Services, Central Region Breastfeeding Policy.*

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Parental decision to supplement:

It is important to ensure that parents make a fully informed decision to supplement their breastfeeding child.

- In the absence of a medical reason for supplementation, the parents' expressed desire to have supplemental feedings with breast milk or formula must be explored by their primary care provider and/ or team members.
- Parents must be informed of the risks and benefits of breastfeeding supplementation as well as strategies that will preserve the maternal-newborn relationship and milk supply (e.g. skin to skin care).
- If using a breast milk substitute (infant formula) for supplementation, assist, as necessary, the mother and family in choosing what is acceptable, feasible, affordable, sustainable and safe (AFASS) in their circumstances

Situations in which breastfeeding should not be considered:

Refer to policy 685.1- *IWK Health Centre and Public Health Services, Central Region Breastfeeding Policy*.

Developing the Plan for Supplemental Feedings

An inter-professional collaborative plan of care for supplementation that facilitates the best outcomes for breastfeeding will be developed and documented on the child's chart. All supplemental feeding plans will be individualized to the clinical situation and based on best practice guidelines and maternal goals for breastfeeding.

If the health professional does not have experience and knowledge developing supplementation-feeding plans in the given breastfeeding situation, consultation with other team members with breastfeeding expertise needs to occur prior to implementation supplementation. This may include experienced team members as well as Clinical Nurse Specialists and Lactation consultant nurses from the Women's and Newborn Health Program. With consent from the mother, community team members directly involved in a care relationship with the mother may also be included in planning.

1. Choosing the type and amount of supplement:

The first choice is to support exclusive breastfeeding by providing expressed maternal breast milk.

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Donor milk, if available, is the first choice for a supplementary feeding if there is no maternal breast milk available. Donor milk is available for certain populations of children included in the supplementation policy. Breast milk substitutes such as infant formula, will be used if breast milk is not available. Water, glucose water, and other fluids should not be given.

All mothers using breast milk and breast milk substitutes and breast milk as a supplement must know safe preparation, storage and appropriate volumes for feeding. The volume of supplement must comply with those that have been demonstrated to be least likely to interfere with breastfeeding and consistent with the estimated stomach capacity of the baby.

The use of a breast milk substitute, such as infant formula, must comply with the WHO International Code of Marketing of Breast Milk Substitutes. (Appendix D)

All mothers who are breastfeeding or intend to breastfeed must be taught and assisted to express their breast milk by hand and/or by a breast pump. Hand expression is the preferred method of breast milk expression with breast pumps primarily being reserved if mother and baby are separated or the baby is unable to latch for an extended period.

2. Choosing the method of supplementation:

The method should be the mother's informed choice of those that present the least interference with the initiation, exclusivity and duration of breastfeeding and take into consideration:

- The best method to meet the nutritional needs of the baby in the context of the medical condition.
- The baby's anatomical and physiological ability to feed effectively with a particular method. For example, a baby with a tongue-tie may have challenges in effectively cup feeding.
- Meeting maternal breastfeeding goals, including exclusive breastfeeding.
- The ability of the mother and other significant support people to independently and safely carry out the chosen method of supplementation.

Supported methods of supplemental feeding at the IWK Health Centre:

- Hand expression of breast milk into the baby's mouth
- Finger dipping
- Cup or spoon feeding
- Finger feeding with a tube

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- Paced bottle and nipple feeding
- Enteral tube feedings

Syringe feeding is not supported as a method for supplementation at the IWK Health Centre except for the following situations:

- Antenatal colostrum collection.
- Small volumes of colostrum administered by syringe for mouth care.
- Placing colostrum or breast milk on the mother's nipple when helping a baby learn to latch.

Supplemental feeding systems (e.g. Medela Starter SNS) are only to be initiated in consultation with a Lactation Consultant Nurse (LCN) or a Clinical Nurse Specialist who is a lactation consultant.

3. Documenting the Supplemental Feeding Plan:

Document the supplemental feeding plan in the child's health record when being initiated and updated. The method of documentation may be individualized to the needs of the different care areas, such as the NICU.

Important aspects of documentation include:

- The medical indication for supplementation
- The mother's verbal consent and personal reasons to supplement when there is no medical indication for supplementation.
- The type of supplement, the method, the timing, the frequency and the amount of the supplemental feeding.
- Consultation and collaboration that has occurred in the development of the feeding plan.
- Teaching and anticipatory guidance given the mother, her partner and other significant support people.
- The degree of confidence and competence the mother, other parent and support people have with the supplemental feeding plan.

4. Discontinuing or reducing the amount of supplement:

As determined by the individual situation, the supplement may be discontinued or the amount reduced and gradually discontinued.

The rate and volume at which the supplement is discontinued must be individualized to meet weight and nutritional requirements of the child.

5. Discharge planning:

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Ensure the following if supplemental feedings are part of the child's discharge plan:

- Mothers and families are aware of effective breastfeeding and when to seek assistance.
- The parents express and demonstrate competence and confidence in implementing the supplementation feeding plan.
- The parents indicate that they will be able to connect with community resources and supports that they have determined would be helpful to them.
- A plan for follow up assessment is made with the child's community attending medical care provider.
- The plan for breastfeeding supplementation is included on the Public Health discharge referral information.
- A copy of the supplemental feeding plan is given to the parents.

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RELATED DOCUMENTS

Policies

- # 685.1 Breastfeeding (Joint policy CDHA-Public Health Services and IWK)
- # 8551 Enteral Feedings (Initiation and Progression)
- # 8555 Gavage Feeding Via Naso/Oral Gastric Feeding Tube
- # 40036 Guidelines for Neonatal Glucose Monitoring

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Forms

Newborn Nutrition/Elimination Record
Newborn Assessment
Newborn Plan of Care – Individualized Plan of Care
Newborn Plan of Care – Treatments
Order Sheet
Interdisciplinary Progress Notes
Newborn Weight Graph
24 Hour Intake Summary Sheet (NICU)
Discharge Summary for Public Health (NICU)
Interdisciplinary Discharge Note (NICU)
Breast Milk/Formula Administration Record (NICU)
Family Learning Summary (NICU)

Brochures

Breastfeeding Basics (Nova Scotia Public Health)
Breastfeeding & Surgery (A Guide for Nurses) (IWK Health Centre)
Great Reasons to Breastfeed Your Baby (Public Health Agency of Canada)
10 Valuable Tips for Successful Breastfeeding (Public Health Agency of Canada)
Breastfeeding Your Baby in NICU: A Guide for Parents (IWK NICU)
Hints to Increase Your Milk Supply (IWK NICU)
How to Feed Your Baby with Infant Formula (Nova Scotia Public Health)
Feeding Your Baby if You are Using Formula (IWK Clinical Nutrition)
Nova Scotia Department of Health and Wellness, 2012: Loving Care Birth to Six Months
Making Your Baby's Formula Using Powder (IWK Clinical Nutrition)

Appendices

Appendix A – Definitions
Appendix B - Latch Assessment Tool
Appendix C - Information to Assist in the Application of the World Health Organization International Code of Marketing of Breast Milk Substitutes

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Appendix A- DEFINITIONS

The following definitions have been drawn from research and clinical literature as well as those used by the World Health Organization and the Breastfeeding Friendly Initiative.

Breastfeeding: The baby, infant or child is receiving breast milk, either directly from the breast or expressed. This definition may include exclusive, predominant and partial breastfeeding.

Breastfeeding newborn, infant or child: any child, regardless of gestation at birth or age, whose mother is breastfeeding or has expressed the intent to breastfeed prior to or upon admission to the IWK Health Centre.

Partial Breastfeeding: The baby receives a mixture of breastfeeding and some artificial feeds, either milk or cereal, or other food. The maternal goal is never to exclusively breastfeed.

Exclusive Breastfeeding: No food or liquid other than breast milk is given to the child from birth by the mother, health care provider, family member or other support person. Breast milk given to the infant may be by direct feeding on the breast or by providing mother's own expressed breast milk or donor breast milk. Oral vitamins, minerals and medicines are allowed.

Supplementary Feeding: Feedings provided before 6 months of age when exclusive breastfeeding meets the normal nutritional requirements of the full term infant. The feeding occurs in addition to or in place of direct feeding from the breast and may include expressed maternal breast milk, donor or banked breast milk, breast milk substitutes such as formula. With supplementary feeding, the mother's goal is to exclusively breastfeed.

Bottle-feeding: The baby has received liquid or semi-solid food from a bottle with a nipple. This term applies irrespective of the nature of the liquid or semi-liquid.

Breast-milk substitute: Any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose. These foods are often referred to as formula or formula milk.

Formula milk: a breast milk substitute formulated industrially to satisfy nutritional requirements of infants and adapted to meet as many of their physiological characteristics as possible. Formula is often modified cow's milk or modified soy liquid.

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Artificial feeding: The baby who is artificially fed (i.e. infant formula) and receives no breast milk at all.

Complimentary Feeding: Foods or liquids given after 6 months of age as a complement to breastfeeding in order to meet normal nutritional requirements of the infant

Term Gestation: Infant is born at or after 37 0/7 weeks.

Late Preterm Gestation: Infant is born between 33 6/7 weeks and 36 6/7 weeks.

Preterm Gestation: Infant is born before 33 0/7 weeks.

Baby-led or cue based feeding: Feeding occurs as often as the baby wants, day and night, based on infant cues. This approach is most appropriate for healthy term newborns.

Early Weaning: Breastfeeding is discontinued before the mother's breastfeeding goals are met.

Appendix B - Latch Assessment Tool

Score		0	1	2
L	Latch	<ul style="list-style-type: none"> • Too sleepy or reluctant • No sustained latch or suck achieved 	<ul style="list-style-type: none"> • Repeated attempts for sustained latch or suck • Hold nipple in mouth 	<ul style="list-style-type: none"> • Grasps breast • Tongue down • Lips flanged • Rhythmical sucking
A	Audible swallowing	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • A few with stimulation 	<ul style="list-style-type: none"> • Spontaneous • Intermittent • Frequent
T	Type of nipple	<ul style="list-style-type: none"> • Inverted 	<ul style="list-style-type: none"> • Flat 	<ul style="list-style-type: none"> • Everted (after stimulation)
C	Comfort (breast/nipple)	<ul style="list-style-type: none"> • Engorged • Severe discomfort • large blisters or bruises • Cracked, bleeding, scabs, 	<ul style="list-style-type: none"> • Filling • Mild/moderate discomfort • Reddened/small blisters • bruises 	<ul style="list-style-type: none"> • Breasts full but comfortable • Non-tender
H	Hold	<ul style="list-style-type: none"> • Full assist (caregiver holds infant at breast and shapes breast for latch-on; staff hold baby at breast) 	<ul style="list-style-type: none"> • Minimal assist and coaching 	<ul style="list-style-type: none"> • Mother able to position/hold infant without assistance from staff

From: LATCH: a breastfeeding charting system and documentation tool. Journal of Obstetric, Gynecological, and Neonatal Nursing (JOGNN), 23 (1), 27-32.

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Appendix C - Information to Assist in the Application of the World Health Organization International Code of Marketing of Breast Milk Substitutes

What is the international code of marketing of breast milk substitutes?

The Code is a set of minimum standards to regulate the marketing of breast-milk substitutes, feeding bottles and nipples. The Code was formulated in response to the realization that poor infant feeding practices were negatively affecting the growth, health and development of children, and were a major cause of mortality in infants and young children. The 34th session of the World Health Assembly (WHA) adopted the International Code of Marketing of Breast-milk Substitutes in 1981 as a minimum requirement to protect and promote appropriate infant and young child feeding.

The Code aims to contribute to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution. The Code advocates that babies be breastfed. If babies are not breastfed, for whatever reason, the Code also advocates that they be fed safely on the best available nutritional alternative. Breast-milk substitutes should be available when needed, but not be promoted.

The importance of the code:

The Code is an important part of creating an overall environment that enables mothers to make the best possible feeding choice, based on impartial information and free of commercial influences, and to be fully supported in doing so. Improper marketing and promotion of food products that compete with breastfeeding are important factors that often negatively affect the choice and ability of a mother to breastfeed her infant optimally. Given the special vulnerability of infants and the risks involved in inappropriate feeding practices, usual marketing practices are therefore unsuitable for these products.

Aspects of infant feeding covered by the code:

The Code sets out detailed provisions with regard to:

- Information and education on infant feeding.
- Promotion of breast-milk substitutes and related products to the general public and mothers.
- Promotion of breast-milk substitutes and related products to health workers and health care settings.
- Labeling and quality of breast-milk substitutes and related products.
- Implementation and monitoring of the Code.

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Products covered by the Code:

The Code refers to any food or drink promoted to be suitable for feeding a baby as partial or total replacement of breast milk during the first six months, including:

- Breast milk substitutes, including infant formula
- Formulas for infants with special needs.
- Other milk products, foods and beverages, including bottle-fed complementary foods.
- Baby teas, juices and waters
- Feeding bottles, and nipples

Information and education on infant feeding:

Objective and consistent information is to be provided on infant and young child feeding to families and others involved in infant and young child nutrition.

- Informational and educational materials should clearly state the benefits and superiority of breastfeeding, the social as well as financial costs of using infant formula, the health hazards associated with artificial feeding and instructions for the proper use of infant formula.
- There should be no advertising or other form of promotion to the general public. Samples of breast milk substitute products should not be promoted or made available through any type of sales device, including special displays, discount coupons and special sales. No company personnel should seek direct or indirect contact with, or provide advice to pregnant women or mothers.
- Health care workers are prohibited from promoting products. Donations of free or subsidized supplies of breast-milk substitutes or other products, as well as gifts or personal samples to health workers, are not allowed in any part of the health care system. Information provided by manufacturers and distributors to health professionals regarding products should be restricted to scientific and factual matters.

Labeling and quality of breast-milk substitutes:

No pictures of infants or other pictures idealizing the use of breast-milk substitutes are permitted on the labels of the products.

Information on artificial feeding, including that on labels, should explain the benefits of breastfeeding and the costs and dangers associated with the unnecessary or improper use of infant formula and other breast-milk substitutes.

Unsuitable products for feeding infants, such as sweetened condensed milk, should not

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be promoted.

Applying the Code in the context of HIV (See IWK policy # 80.26 Perinatal HIV-1 Transmission Prophylaxis):

The most appropriate infant feeding option for an HIV-infected mother depends on her individual circumstances, including her health status and the local situation, health services available and the counseling and support she is likely to receive. When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected women is recommended.

Applying the Code in complex emergencies:

For the majority of infants and young children in emergency situations, the emphasis should be on protecting, promoting and supporting breastfeeding and ensuring timely, safe and appropriate complementary feeding. Breast milk substitutes should be procured and distributed as part of the regular inventory of food and medicines, in quantities only as needed. There should be clear criteria for the use of breast milk substitutes and education for caregivers about safe and appropriate feeding.

Infants who have a medical indication not to breastfeed:

Infant formula needed for infants for medical reasons should be obtained through normal methods of hospital procurement of supplies.

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
November, 2016	

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Appendix B: Sample Size Calculations

Binary outcome equation from Campbell, Julious and Altman (2005):

$$m = \frac{[z_{1-\alpha/2}\sqrt{2P(1-P)} + z_{1-\beta}\sqrt{p_A(1-p_A) + p_B(1-p_B)}]}{\delta^2}$$

a.) Sample size calculation from Merewood, Philipp, Chawla and Cimo (2003) study:

$$m = \frac{[z_{1-\alpha/2}\sqrt{2P(1-P)} + z_{1-\beta}\sqrt{p_A(1-p_A) + p_B(1-p_B)}]}{\delta^2}$$

$$z_{1-\alpha/2} = 1.96 \text{ (} \alpha = 0.05 \text{ or 5\% level)}$$

$$z_{1-\beta} = 0.90 \text{ (90\% power)}$$

$$p_A = 0.346$$

$$p_B = 0.744$$

$$P = \frac{(p_A + p_B)}{2} = \frac{(0.346 + 0.744)}{2} = 0.545$$

$$\delta = (p_A - p_B) = 0.346 - 0.744 = -0.398$$

$$m = \frac{[1.96\sqrt{2(0.545)(1-0.545)} + 0.90\sqrt{0.346(1-0.346) + 0.744(1-0.744)}]}{-0.398^2}$$

$$m = \frac{[1.96\sqrt{0.49595} + 0.90\sqrt{0.416748}]}{-0.398^2}$$

$$m = 24.3 \text{ participants}$$

b.) Sample size calculation from Tozier (2013) study:

$$m = \frac{[z_{1-\alpha/2}\sqrt{2P(1-P)} + z_{1-\beta}\sqrt{p_A(1-p_A) + p_B(1-p_B)}]}{\delta^2}$$

$$z_{1-\alpha/2} = 1.96 \text{ (} \alpha = 0.05 \text{ or 5\% level)}$$

$$z_{1-\beta} = 0.90 \text{ (90\% power)}$$

$$p_A = 0.333$$

$$p_B = 0.712$$

$$P = \frac{(p_A + p_B)}{2} = \frac{(0.333 + 0.712)}{2} = 0.5225$$

$$\delta = (p_A - p_B) = 0.333 - 0.712 = -0.379$$

$$m = \frac{[1.96\sqrt{2(0.5225)(1-0.5225)} + 0.90\sqrt{0.333(1-0.333) + 0.712(1-0.712)}]}{-0.379^2}$$

$$m = \frac{1.96\sqrt{0.04989875} + 0.90\sqrt{0.427167}}{-0.379^2}$$

$m = 27.1$ participants

Appendix C: Screening Procedures

Screening

1. Log in to MEDITECH
2. Enter OUPATIENT LOCATION
3. Enter DIAB CL
4. Search for Wednesdays, as this is the diabetic screening day
5. “Enter Subject ID” and “Clinic Date” into screening spreadsheet
6. Click on a subject name
7. Enter SCANNED PERSONAL HEALTH RECORDS
8. Enter CONSULTATION RECORDS (or DOCUMENTS EXTERNAL)
9. Enter FATC REFERRAL
10. Identify diagnosis of “Type 2 diabetes” or “GDM”. Subjects with Type 1 Diabetes or MODY are not included.
11. Go back to screen with options
12. Enter OBSTETRICAL RECORDS
13. Enter BIRTH RECORD
14. Scroll to the bottom of the page and take note of the following:
 - a. Infant sex
 - b. Infant weight
 - c. Infant birth time and date
15. Enter “Mother’s Date of Birth”, “Infant K Number” and “Infant Birth Date” in the screening spreadsheet.
16. Repeat for each subject and diabetes screening day.

Linking Mother and Infant Charts:

17. Go back to search by ADMISSION DATE (inpatients)
18. Scroll up reach infant birth date and press Enter (the system codes the days from today’s date, so it will read a negative number). This will give you all admission for this date.
19. Search for the infant by sex, age, time born and last name. The infant’s age will be listed as “months and days” and there may be many who were born on this day. Rule out infants based on sex, and keep in mind the listings are generally in order by the hours that

day. Infants born in the morning will be closer to the top, while infants born later in the day will be listed closer to the bottom.

20. Select Infant and confirm their identity. Enter BIRTH RECORD and scroll to the bottom of the page. Confirm by checking sex, weight, birthdate and time.
21. Record Infant K Number in the screening spreadsheet.
22. Assign chart to RA

Appendix D: Data Collection Procedures

Data Collection

1. Log in to MEDITECH
2. Search by UNIT NUMBER and enter assigned Infant K Number
3. Enter SCANNED PERSONAL HEALTH RECORDS (this may or may not come up for some)
4. Enter OBSTETRICAL RECORDS
5. To obtain discharge date, Enter NEWBORN PLAN OF CARE. Scroll to the bottom of the first page and the discharge date should be listed.
6. To obtain other data, return to previous screen and select NEWBORN NUTRITION/ELIMINATION RECORD. All of the data you need will be listed here.
 - a. Each row represents a new feeding. Please record each feed as a new entry (or row) in the data collection spreadsheet.
 - b. Columns in the record:
 - i. 1st column: lists the date and time for each feed. Keep in mind the “Day #” is the days since the infant’s birth date and will be listed as 1, 2, 3, etc. (e.g. if an infant is born on May 23, 2017 at 23:21, Day 1 will be May 23, 2017 23:21 to May 24, 2017 23:21). This information will give you the “Day #” for the data spreadsheet.
 - ii. 2nd column: the LATCH score. If the LATCH score is filled out, this indicates the infant was breastfed. This will give you information for “type of infant feeding” and “method of infant feeding”.
 - iii. 3rd column: “Comments” are entered. Please review this column as it may provide further information for “type of infant feeding”, “source of breastmilk consumed in feeding” and “method of infant feeding”.
 - iv. 4th column: information for “feeding description” in the data collection spreadsheet (often this information is not provided). Also, feed type is listed in this column (e.g. formula type).
 - v. 5th column: oral feeds are listed. You may find information for “method of infant feeding” and “oral volume” listed here.
 - vi. 6th column: IV feeds are listed here. You find information for “method of infant feeding” and “intravenous volume” here.

7. If data is missing from NEWBORN NUTRITION/ELIMINATION RECORD, search the NEWBORN RECORDS – NEONATAL DISCHARGE SUMMARY (for NICU infants).
8. If the record is incomplete and data is still missing, the research coordinator will search maternal records for the NUSRING DISCHARGE SUMMARY PUBLIC HEALTH, providing a synopsis of feeding at discharge.
9. For infants admitted to the NICU, the search the NICU 24 HOUR SUMMARY INTAKE under NEONATAL INTENSIVE CARE. Total IV and oral feed volumes are listed for each day as a separate row. The type of oral feed (formula or breastmilk) is often provided beside the oral feed volume.

Appendix G: In-Hospital Type of Feeding: Example Calculation

Example in-hospital type of feeding calculation:

Feed 1: Breast milk

Feed 2: Breast milk

Feed 3: Formula

Feed 4: Breast milk

Feed 5: Breast milk

Feed 6: Breast milk

Feed 7: Breast milk/Formula

Feed 8: Formula

Feed 9: Formula

Feed 10: Breast milk

Total number of feeds: 10

Number of breast milk feeds: 6

Number of formula feeds: 3

Number of mixed feeds (breast milk and formula/IV fluid): 1 (0.5 breast milk + 0.5 formula)

$$\% \text{ of feeds breast milk} = \frac{\text{Number of feeds breastmilk}}{\text{Total number of feeds}} \times 100\% = \frac{6.5}{10} \times 100\% = 65\%$$

Based on the percentage of in-hospital feeds that were breast milk (65%), the in-hospital feeding type would be categorized as mixed feeding (25-75% of feeds breast milk).

Appendix H: Contingency Tables: Crosstabulations from SPSS

Table H.1. *Policy* group and maternal diabetes mellitus type (n=120)

			Maternal DM Type		Total
			GDM	T2DM	
Policy group	Pre-Policy	Count	48 _a	12 _a	60
		Expected Count	46.0	14.0	60.0
		% within <i>Policy</i> group	80.0%	20.0%	100.0%
	Post-Policy	Count	44 _a	16 _a	60
		Expected Count	46.0	14.0	60.0
		% within <i>Policy</i> group	73.3%	26.7%	100.0%
Total		Count	92	28	120
		Expected Count	92.0	28.0	120.0
		% of Total	76.7%	23.3%	100.0%

DM, diabetes mellitus; GDM, gestational diabetes mellitus; T2DM, type 2 diabetes mellitus

*Columns with different subscripts have significantly different column proportions.

Table H.2. *Policy* group and unit at discharge (n=120)

			Unit at Discharge		Total
			Family Newborn	NICU	
Policy group	Pre-Policy	Count	57 _a	3 _a	60
		Expected Count	57.0	3.0	60.0
		% within <i>Policy</i> group	95.0%	5.0%	100.0%
	Post-Policy	Count	57 _a	3 _a	60
		Expected Count	56.5	3.5	60.0
		% within <i>Policy</i> group	95.0%	5.0%	100.0%
Total		Count	114	6	120
		Expected Count	114.0	6.0	120.0
		% of Total	95.0%	5.0%	100.0%

NICU, neonatal intensive care unit

*Columns with different subscripts have significantly different column proportions.

Table H.3. *Policy* group and provision of breast milk at discharge for each participant (n=120)

			Breast milk at discharge		Total
			Yes	No	
Policy group	Pre-Policy	Count	35 _a	24 _a	59
		Expected Count	36.9	22.1	59.0
		% within <i>Policy</i> group	59.3%	40.7%	100.0%
	Post-Policy	Count	35 _a	18 _a	53
		Expected Count	33.1	19.9	53.0
		% within <i>Policy</i> group	66.0%	34.0%	100.0%
Total		Count	70	42	112
		Expected Count	70.0	42.0	112.0
		% of Total	62.5%	37.5%	100.0%

*Columns with different subscripts have significantly different column proportions.

Table H.4. *Policy* group and type of feeding at discharge for each participant (n=120)

			Type of feeding at discharge			Total
			Breast milk	Formula/IV Fluid	Mixed Feeding	
Policy group	Pre-Policy	Count	35 _a	11 _a	13 _a	59
		Expected Count	36.9	12.1	10.0	59.0
		% within <i>Policy</i> group	59.3%	18.6%	22.0%	100.0%
	Post-Policy	Count	35 _a	12 _a	6 _a	53
		Expected Count	33.1	10.9	9.0	53.0
		% within <i>Policy</i> group	66.0%	22.6%	11.3%	100.0%
Total		Count	70	23	19	112
		Expected Count	70.0	23.0	19.0	112.0
		% of Total	62.5%	20.5%	17.0%	100.0%

IV, intravenous

*Columns with different subscripts have significantly different column proportions.

Table H.5. *Policy* group and in-hospital type of feeding for each participant (n=120)

			In-hospital type of feeding				Total
			Exclusive Breast milk	Mostly Breast milk	Mixed Feeding	Mostly and Exclusive Formula/IV Fluid	
Policy group	Pre-Policy	Count	22 _a	12 _a	18 _a	8 _a	60
		Expected Count	24.0	11.0	19.5	5.5	60.0
		% within <i>Policy</i> group	36.7%	20.0%	30.0%	13.3%	100.0%
	Post-Policy	Count	26 _a	10 _a	21 _a	3 _a	60
		Expected Count	24.0	11.0	19.5	5.5	60.0
		% within <i>Policy</i> group	43.3%	16.7%	35.0%	5.0%	100.0%
Total		Count	48	22	39	11	120
		Expected Count	48.0	22.0	39.0	11.0	120.0
		% of Total	40.0%	18.3%	32.5%	9.2%	100.0%

IV, intravenous

*Columns with different subscripts have significantly different column proportions.

Table H.6. *Policy* group and total type of feeding for each feed (n=2,064)

			Type of feed				Total
			Breast milk	Mixed Feeding	Formula/IV Fluid	Not available	
Policy group	Pre-Policy	Count	596 _a	161 _a	175 _a	60 _a	992
		Expected Count	599.3	176.9	163.4	52.4	992.0
		% within <i>Policy</i> group	60.1%	16.2%	17.6%	6.0%	100.0%
	Post-Policy	Count	651 _a	207 _a	165 _a	49 _a	1072
		Expected Count	647.7	191.1	176.6	56.6	1072.0
		% within <i>Policy</i> group	60.7%	19.3%	15.4%	4.6%	100.0%
Total		Count	1247	368	340	109	2064
		Expected Count	1247.0	368.0	340.0	109.0	2064.0
		% of Total	60.4%	17.8%	16.5%	5.3%	100.0%

IV, intravenous

*Columns with different subscripts have significantly different column proportions

Table H.7. *Policy* group and source of breast milk for each feed (n=2,064)

		Source of Breast milk					Total	
		Mother's Milk	Donor Milk	Mother's Milk/Donor Milk	Not Applicable	Not Available		
Policy group	Pre-Policy	Count	756 _a	0 _{a, b}	0 _b	176 _a	60 _a	992
		Expected Count	758.9	1.0	15.4	162.9	53.8	992.0
		% within <i>Policy</i> group	76.2%	0.0%	0.0%	17.7%	6.0%	100.0%
	Post-Policy	Count	823 _a	2 _{a, b}	32 _b	163 _a	52 _a	1072
		Expected Count	820.1	1.0	16.6	176.1	58.2	1072.0
		% within <i>Policy</i> group	76.8%	0.2%	3.0%	15.2%	4.9%	100.0%
Total		Count	1579	2	32	339	112	2064
		Expected Count	1579.0	2.0	32.0	339.0	112.0	2064.0
		% of Total	76.5%	0.1%	1.6%	16.4%	5.4%	100.0%

*Columns with different subscripts have significantly different column proportions.

Table H.8. *Policy* group and method of feeding for each participant (n=120)

		Feeding Method			Total	
		Breast	Breast and Other	Other		
Policy group	Pre-Policy	Count	10 _a	42 _a	8 _a	60
		Expected Count	12.0	41.5	6.5	60.0
		% within <i>Policy</i> group	16.7%	70.0%	13.3%	100.0%
	Post-Policy	Count	14 _a	41 _a	5 _a	60
		Expected Count	12.0	41.5	6.5	60.0
		% within <i>Policy</i> group	23.3%	68.3%	8.3%	100.0%
Total		Count	24	83	13	120
		Expected Count	24.0	83.0	13.0	120.0
		% of Total	20.0%	69.2%	10.8%	100.0%

*Columns with different subscripts have significantly different column proportions.

Table H.9. *Policy* group and method of feeding for each feed (n=2,064)

			Feeding Method				Total
			Breast	Breast and Other	Other	Not Available	
Policy group	Pre-Policy	Count	420 _a	178 _b	43 _c	351 _a	992
		Expected Count	460.9	114.4	78.3	338.4	992.0
		% within <i>Policy</i> group	42.3%	17.9%	4.3%	35.4%	100.0%
	Post-Policy	Count	539 _a	60 _b	120 _c	353 _a	1072
		Expected Count	498.1	123.6	84.7	365.6	1072.0
		% within <i>Policy</i> group	50.3%	5.6%	11.2%	32.9%	100.0%
Total		Count	959	238	163	704	2064
		Expected Count	959.0	238.0	163.0	704.0	2064.0
		% of Total	46.5%	11.5%	7.9%	34.1%	100.0%

*Columns with different subscripts have significantly different column proportions.

Appendix I: Z-Scores (Standardized Residuals)

Table I.1. *Policy* group and z-scores for source of breast milk for each feed (n=2,064)

			Source of Breast milk					Total
			Mother's Milk	Donor Milk	Mother's Milk/Donor Milk	Not Applicable	Not Available	
Policy group	Pre-Policy	Count	756 _a	0 _{a, b}	0 _b	176 _a	60 _a	992
		Expected Count	758.9	1.0	15.4	162.9	53.8	992.0
		z-score ^a	-0.11	-1	-3.92	1.02	0.84	-
	Post-Policy	Count	823 _a	2 _{a, b}	32 _b	163 _a	52 _a	1072
		Expected Count	820.1	1.0	16.6	176.1	58.2	1072.0
		z-score ^a	0.10	1	3.78	-0.99	-0.81	-
Total		Count	1579	2	32	339	112	2064
		Expected Count	1579.0	2.0	32.0	339.0	112.0	2064.0

^az-score, standardized residual

Table I.2. *Policy* group and z-scores for method of feeding for each feed (n=2,064)

			Feeding Method				Total
			Breast	Breast and Other	Other	Not Available	
Policy group	Pre-Policy	Count	420 _a	178 _b	43 _c	351 _a	992
		Expected Count	460.9	114.4	78.3	338.4	992.0
		z-score ^a	-1.91	5.95	-3.99	0.68	-
	Post-Policy	Count	539 _a	60 _b	120 _c	353 _a	1072
		Expected Count	498.1	123.6	84.7	365.6	1072.0
		z-score	1.83	-5.70	3.84	0.66	-
Total		Count	959	238	163	704	2064
		Expected Count	959.0	238.0	163.0	704.0	2064.0

^az-score, standardized residual

Appendix J: Odds Ratio Calculations

1. *Policy* group and method of feeding:

Odds of feeding at the breast post-*Policy*, relative to pre-*Policy*:

$$\text{Odds ratio} = \frac{\# \text{ feeding method of interest post} - \text{Policy} / \# \text{ not method of interest post} - \text{Policy}}{\# \text{ feeding method of interest pre} - \text{Policy} / \# \text{ not method of interest pre} - \text{Policy}}$$

$$\text{Odds ratio} = \frac{539/533}{420/572}$$

$$\text{Odds ratio} = \frac{1.011}{0.734}$$

$$\text{Odds ratio} = 1.38$$

Odds of feeding by combination of breast and other method post-*Policy*, relative to pre-*Policy*:

$$\text{Odds ratio} = \frac{\# \text{ feeding method of interest post} - \text{Policy} / \# \text{ not method of interest post} - \text{Policy}}{\# \text{ feeding method of interest pre} - \text{Policy} / \# \text{ not method of interest pre} - \text{Policy}}$$

$$\text{Odds ratio} = \frac{60/1012}{178/814}$$

$$\text{Odds ratio} = \frac{0.059}{0.219}$$

$$\text{Odds ratio} = 0.27$$

Odds of feeding by other method post-*Policy*, relative to pre-*Policy*:

$$\text{Odds ratio} = \frac{\# \text{ feeding method of interest post} - \text{Policy} / \# \text{ not method of interest post} - \text{Policy}}{\# \text{ feeding method of interest pre} - \text{Policy} / \# \text{ not method of interest pre} - \text{Policy}}$$

$$\text{Odds ratio} = \frac{120/952}{43/949}$$

$$\text{Odds ratio} = \frac{0.126}{0.045}$$

$$\text{Odds ratio} = 2.78$$