

KTA Evidence Summary

What are the drivers of in-hospital formula supplementation in healthy term neonates and what is the effectiveness of hospital-based interventions designed to reduce formula supplementation?

Evidence Summary No. 8

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What are the drivers of in-hospital formula supplementation of term neonates and what is the effect of hospital-based interventions designed to reduce formula supplementation?

This report summarizes evidence around the main causes of in-hospital formula supplementation and the effectiveness of hospital-based interventions designed to reduce levels of formula supplementation in term neonates. Its intention is to support efforts that seek to reduce levels of unnecessary formula supplementation in Ontario.

Key Messages

- Formula supplementation among term neonates is harmful and often unnecessary practice; there are few infant or maternal conditions that justify complete and/or permanent discontinuation of breastfeeding. For conditions where supplementation is justified (e.g. severe maternal illness), the risks posed by the particular condition need to be weighed against the combined risks of formula supplementation and discontinuation and/or reduction of breastfeeding.
- Several observational studies involving diverse populations have sought to identify predictive factors associated with in-hospital supplementation. While various outcomes have emerged statistically within studies, it is difficult to determine a signal of particular outcomes across studies; in general though, maternal college education and prenatal education of the benefits of breastfeeding may be associated with reduced rates of in-hospital formula supplementation.
- Although many interventions have been put forward to improve in-hospital breastfeeding outcomes (and thereby reduce formula supplementation), high quality evidence from randomized controlled trials is limited. Nevertheless, various policies, programs and initiatives have been evaluated and have shown varying degrees of success in improving rates of breastfeeding initiation, duration, and exclusivity.
- Of note, no intervention study found in this summary was designed with the explicit intent of reducing formula supplementation; instead, the reduction of formula supplementation appeared to be considered as a positive corollary to improving breastfeeding outcomes. Because improved breastfeeding outcomes may not directly translate to the reduction formula supplementation, caution should be used in interpreting the findings of intervention studies.

Information about this evidence summary.

This report covers a broad collection of literature and evidence sources with a search emphasis on systematic reviews.

As such, evidence summarized from systematic reviews is highlighted in blue boxes, like this one. Systematic reviews are generally favoured over other study designs, because they incorporate evidence from multiple primary studies, instead of reporting evidence from just one study.

✓ This summary includes:

- **Key findings** from a broad collection of recent literature and evidence sources.

✗ This summary does not include:

- **Recommendations;**
- **Additional information** not presented in the literature;
- **Detailed descriptions of the interventions** presented in the studies.

All papers summarized in this document are available by request to kkonnyu@ohri.ca.

Many sections conclude with a **“Bottom line”** subsection that provides a statement summarizing the studies or aims to provide some context. These statements are not meant to address all of the evidence in existence on the subject, rather, only that which is featured in this document.

Background

Most mothers can breastfeed successfully.¹ This includes initiating breastfeeding at birth, breastfeeding exclusively for the first 6 months, and continuing complementary breastfeeding for up to 2 years or beyond, as recommended by the World Health Organization² and endorsed by Health Canada.³ The extensive short- and long-term benefits of breastfeeding are unequivocal.⁴ Formula supplementation in contrast, is detrimental to the health of both the child and the mother.⁵ While formula supplementation may be justifiably required in particular medical and social situations,¹ most newborns do not require, and should not receive supplementation.⁶

Despite the documented risks associated with formula supplementation, one-quarter of healthy full-term infants discharged from Ontario hospitals continue to receive supplementation⁷. Although the reasons underlying this knowledge-behavior gap are complex, and likely influenced by diverse socio-cultural norms,⁴ there is a universal appreciation for the role of hospital policies and practices in achieving successful breastfeeding outcomes, including reducing the number of infants receiving supplementation when not medically indicated.⁸

Accordingly, multiple approaches to promote breastfeeding/reduce formula supplementation have been undertaken in the hospital setting. The aim of this evidence summary is to summarize the evidence on the effect of hospital-based interventions to reduce formula supplementation in term babies, and where supplementation does occur, to explore the underlying causes.

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Notes on review methodology:

- Canadian studies are emphasized by the appearance of a Canadian flag (🇨🇦).
- Each piece of evidence presented in this summary is assigned a level (adapted from Cochrane MSK group)⁹:
 - 🌟 **Platinum**: Systematic reviews and meta-analyses
 - 🌟 **Gold**: Randomized controlled trials
 - 🌟 **Silver**: Observational studies (non-randomized trials, case-control, time-series, cohort studies, case series, literature reviews)
 - 🌟 **Bronze**: Expert committee guidelines, reports or opinions and/or clinical experience of respected authorities (e.g. commentary, editorial).
 - ⦿ Level of evidence cannot be determined

Summary of Findings

I. Causes of supplementation

a. Medical contraindications for breastfeeding/ recommendations for supplementation

Although the scope of this evidence summary pertains to the supplementation of the healthy newborn, proposed indications for supplementation have been provided for reference.

★ In 2009, the WHO published an update of acceptable medical reasons for temporary or long-term use of breast-milk substitutes.¹ The list was informed by recent evidence, expert opinion, and WHO oversight. The document emphasizes that the conditions that may justify a mother not breastfeeding either temporarily or permanently “concern very few mothers and their infants” and that in considering stopping breastfeeding, “the benefits of breastfeeding should be weighed against the risks posed by the presence of the specific condition”. A summary of the conditions reported for both infants is as follows:

Infants who should not receive breast milk or any other milk except specialized formula include:

- Infants with classic galactosemia;
- Infants with maple syrup urine disease;
- Infants with phenylketonuria

Infants for whom breast milk remains the best feeding option but who may need other food in addition to breast milk for a limited period:

- Infants born with very low birth weight;
- Infants born very pre-term;
- Infants at risk of hypoglycaemia by virtue of Impaired metabolic adaptation or increased glucose demand

Maternal conditions that may justify permanent avoidance of breastfeeding:

- HIV infection

Maternal conditions that may justify temporary avoidance of breastfeeding:

- Severe illness that prevents a mother from caring for her infant (e.g. sepsis)
- Herpes simplex virus type 1 on breasts
- Certain maternal medications

Maternal conditions during which breastfeeding can still continue, although health problems may be of concern:

- Breast abscess
- Hepatitis B or C
- Mastitis
- Tuberculosis
- Substance use

★ In their 2005 joint statement by the Canadian Paediatric Society, Dieticians of Canada, and Health Canada (🇨🇦)⁵⁹ it emphasized “breastfeeding is rarely contraindicated”. It further explains that “neither smoking nor environmental contaminants are necessarily contraindications to breastfeeding. Moderate, infrequent alcohol ingestion, the use of most prescription and over-the-counter drugs and maternal infections do not preclude breastfeeding”. Accordingly it recommends encouraging women to stop or reduce smoking and limit the intake of alcohol. With respect to the use of prescription drugs or possible infections, it recommends assessing each case on an individual basis. Finally, for women known to be HIV-positive, it states that alternatives to breastfeeding are recommended.

★ The 2000 Family-Centered Maternity and Newborn Care national guidelines released by Public Health Agency of Canada (🇨🇦)⁵⁸ endorses the indications for supplementation (which it emphasizes are “few in number”), as outlined in the 1992 BFHI manual:

- Infants with documented hypoglycemia that does not improve with increased effective breastfeeding;
- Infants whose mothers are severely ill (e.g. psychosis, eclampsia, shock);
- Infants with certain inborn errors of metabolism;
- Infants with dehydration that does not improve after breastfeeding; and
- Infants whose mothers are taking medication contraindicated with breastfeeding (e.g. cytotoxic drugs, radioactive drugs).

The guideline recommends that in situations where breastfeeding is temporarily delayed or interrupted and/or supplementation is medically indicated, fresh breast milk should be used, if available, and

alternatives to bottle feeding (e.g., finger feeding) should be employed where possible.

★ The US Academy of Breastfeeding Medicine Protocol Committee published a 2009 revision of their hospital guidelines (protocol #3) for the use of supplementary feedings in the healthy term, breastfed neonate.⁶ The guidelines lists specific infant and maternal clinical situations which may necessitate supplementation and others in which supplementation is not indicated. A brief summary of these indications is as follows:

Common clinical situation where evaluation and breastfeeding management may be necessary, but supplementation is not indicated:

- Sleepy healthy infant
- Nighttime fussy infant
- Constantly feeding infant
- Tired or sleeping mother

Indications for supplemental feeding:

- Separation of mother and infant
- Maternal illness
- Infant born with error of metabolism (e.g. galactosemia)
- Infant who is unable to feed at the breast (e.g. congenital malformation, illness)
- Contraindicated maternal medications

Possible indications for supplemental feedings:

Infant indications

- Asymptomatic hypoglycemia
- Severe dehydration
- Severe weight loss & delayed lactogenesis II
- Delayed bowel movements
- Insufficient intact despite adequate milk supply
- Hyperbilirubinemia
- “Neonatal” jaundice associated with starvation
- Breast milk jaundice

Maternal indications

- Delayed lactogenesis II
- Retained placenta
- Sheehan’s syndrome
- Primary glandular insufficiency
- Breast pathology or prior breast surgery resulting in poor milk

The guidelines recommend that hospitals should consider implementing an aggressive policy whereby a physician order is required when supplements are medically indicated, and informed

consent is sought from the mother when supplements are not medically indicated. Further they recommend that it is important to provide information to parents, and to document these efforts, as well as parents’ decisions. When supplementation is used, they recommend documenting the content, volume, method, and medical indication or reason. The protocol stresses that whenever supplementation is required, the goal is to both feed the infant while also optimizing the maternal milk supply until the necessitating issue is resolved.

Bottom Line: Various national and international groups have worked to outline acceptable medical and situational criteria that would justify the use of supplementation. Often these indications are rare and would not apply to the healthy newborn or mother.

b. Alternative strategies for feeding breast milk

☀ A 2007 Cochrane systematic review sought to determine the effects of cup feeding versus other forms of supplemental enteral feeding on breastfeeding success in newborn infants unable to breastfeed, or have initial difficulties with breastfeeding.¹⁰ A total of 4 RCTs were included in the review, and all compared cup feeding with bottle feeding. While cup feeding appeared to have a positive benefit on promoting breastfeeding in the hospital, the benefit was not sustained at 3 months and was associated with longer hospital stays. Consequently authors concluded that “cup feeding cannot be recommended over bottle feeding as a supplement to breastfeeding because it confers no significant benefit in maintaining breastfeeding beyond hospital discharge and carries the unacceptable consequence of a longer stay in hospital”.

c. Predictors of in-hospital supplementation (Table 1)

This table was produced with the aim of capturing the factors that drive supplementation. This knowledge can only be assessed through lower quality observational studies as opposed to controlled trials. While care was exercised in selecting higher quality and regional specific reports (e.g. sample size ≥ 100 ; regression analysis of predictors; Western and/or developed populations; report published after 1990), the lower quality design invariably invites potential biases, and findings should therefore be interpreted with caution.

Table 1. Review of observational studies (★) assessing factors predicting breastfeeding (bf) and/or supplementation outcomes*

Study	Country (n, demographic)	Primary methods	Question	Significant predictors
Asole et al. (2009) ¹¹	Italy (n=153 mothers from 17 hospitals in Lazio)	Longitudinal; review of medical records, in-hospital and multiple follow-up telephone interviews	What hospital practices predict complementary feeding in-hospital and at 1mos?	<i>Risk factors (in-hospital)</i> <ul style="list-style-type: none"> • Cesarean section • Lack of information about the advantages of bf • Absence or partial absence of rooming-in
Gagnon et al. (2005) ¹² 🇨🇦	Canada (n=564 mother-infant pairs in Montreal)	Cross sectional; in-hospital survey (unclear if self-administered), review of medical records	What factors predict in-hospital initial formula supplementation of healthy, breastfeeding newborns?	<i>Risk factors</i> <ul style="list-style-type: none"> • Overnight birth (between 7pm and 9am) • High maternal trait anxiety <i>Protective factors</i> <ul style="list-style-type: none"> • Maternal factors: Planning to exclusively bf; planning to bf for ≥ 3mos; born in Canada; completion of community college • Childbirth education • Male infant • Bf at delivery
Khoury et al. (2005) ¹³	United States (n=733 low-income mothers from Mississippi)	Cross sectional; mail survey	What factors predict bf vs formula supplementation at hospital discharge?	<i>Positive predictors</i> <ul style="list-style-type: none"> • Maternal factors: knowledge of bf benefits; married; college educated • Health care system counseling (supported bf) <i>Negative predictors</i> <ul style="list-style-type: none"> • Maternal factors: embarrassment about bf, black, WIC-certified, work full-time • Family support (supported formula supplementation)
Scott et al. (2001) ¹⁴	Australia (n=556 mothers in Perth)	Longitudinal; in-hospital self-administered survey, multiple follow-up telephone interviews	What factors predict abandonment of bf in-hospital?	<i>Positive predictors</i> <ul style="list-style-type: none"> • Infant feeding method chosen after becoming pregnant • Maternal perception that infant's father either preferred formula feeding or was ambivalent about how the infant was fed • Whether mother's own mother had ever breastfed
Tender et al. (2009) ¹⁵	United States (n=150 low-income mothers in Washington, DC clinic)	Retrospective; researcher-administered survey	What factors predict in-hospital formula supplementation?	<i>Risk factors</i> <ul style="list-style-type: none"> • Mothers not attending a prenatal bf class
Wojcicki et al. (2010) ¹⁶	United States (n=363 mothers in the WIC program in 2 San Francisco hospitals)	Cross sectional; face-to-face interview or self-administrated survey	What factors predict in-hospital supplementation? (mixed or formula feeding at 1-3 days)	<i>Risk factors</i> <ul style="list-style-type: none"> • Asian/Pacific Islander ethnicity • Thinking bf was physically painful or uncomfortable <i>Protective factors</i> <ul style="list-style-type: none"> • College graduate

Bottom Line: Based on evidence from observational studies, a variety of obstetric and maternal factors have emerged as being predictive of supplementation. While it is difficult to determine with certainty from this evidence the most important factors predicting in-hospital formula supplementation, poor maternal education (post secondary education and/or prenatal education), and non-white ethnicity, appear to be associated with increased rates of supplementation.

II. Interventions to reduce supplementation

a. Evidence on interventions aimed at improving breastfeeding outcomes

● A 2008 Cochrane systematic review evaluated the effectiveness of interventions aimed at improving the number of women who initiate breastfeeding.⁴ Included studies had to be randomized controlled trials (RCTs) and evaluate any population, with the exception of women and infants with special health problems. Interventions also had to have occurred prior to the first breastfeed. A total of 11 RCTs were included, 8 of which could be assessed via meta-analyses; only interventions potentially occurring during the in-hospital period are presented below.

Peer support (in the prenatal, perinatal, and postnatal periods) was assessed in 1 trial (n=165),¹⁷ and was also shown to be effective at improving rates of breastfeeding initiation. Breastfeeding duration up to 1 and 3 months postpartum was not improved.

Breastfeeding promotion packs were assessed in 1 trial (n=547).¹⁸ Results demonstrated that non-commercial breastfeeding promotion packs (compared with formula company produced packs), had no effect on increasing initiation rates.

Early mother-infant contact (followed by separation) was assessed in 1 trial (n=259)¹⁹ and had no effect on increasing initiation rates.

The authors conclude that "... peer support interventions can result in some improvements in the number of women beginning to breastfeed". In contrast, breastfeeding promotion packs and early mother-infant contact appeared to have no effect. Caution should be used in interpreting these findings however, given that each intervention was

evaluated in only one study, and that these studies were all conducted in a single country (United States), typically involving marginalized or ethnic minority populations.

● A 2000 UK Health Technology Assessment systematic review evaluated the effectiveness of interventions to promote the initiation of breastfeeding.²⁰ To be included, interventions had to have been implemented before the first breastfeed, and be evaluated through a RCT, non-RCT or before-and-after design. A total of 59 studies were included (14 RCTs, 16 non-RCTs and 29 before-after studies).

Health sector initiatives (HSIs) were the most commonly assessed intervention in this review (representing 25 of the 59 included studies). As defined by the authors, "these interventions aim to change the institutional or organizational nature of health services in favor of promoting breastfeeding. These interventions are mostly conducted within the hospital setting and may have several components implemented at the same time...[e.g.] introduction of breastfeeding policy, rooming-in facilities, removal of artificial milk from discharge packs, and training interventions for health professionals." Relevant to this summary, the review further defined 3 HSI categories:

- 1) **HSI – general** (interventions that did not have a particular framework or contextual setting) assessed by 1 RCT¹⁹, 3 non-RCTs^{21,22,23}, and 3 before-after studies^{24,25,26};
- 2) **HSI – Baby Friendly Hospital Initiative (BFHI)** (interventions that explicitly stated the BFHI as the framework for the development and implementation of the intervention; see Box 1) assessed by 1 RCT²⁷ and 1 before-after study²⁸;
- 3) **HSI – training of health professionals** (interventions that have provided professional training on breastfeeding to health sector staff as stand-alone interventions) assessed by 5 before-after studies^{29,30,31,32,33} (1 Canadian 🇨🇦³¹).

Summarizing the combined evidence for **general** and **BFHI** interventions, the authors found that "institutional changes in hospital practices to promote breastfeeding, either as part of, or independent to, the BFHI, can be effective at increasing both the initiation and duration of breastfeeding, particularly in developed

countries”. Assessing the evidence for *training of health professionals*, the authors found the “limited evidence available suggests that these programs may be useful in improving the knowledge of midwives and nurses” however attitudes of health professionals and breastfeeding rates remained unchanged.

Peer support was assessed by 2 non-RCTs^{34,35} and was found to be effective as a stand-alone intervention for women in low-income groups at increasing rates of breastfeeding initiation and duration – particularly among women expressing intent to breastfeed.

The authors conclude that while the findings “suggest that health promotion interventions aiming to increase initiation rates may be effective”, they emphasize caution in interpreting the results due to the methodological weaknesses and poor comparability of the included studies. Importantly, they note that it is difficult to gauge each interventions relative value in the absence of direct head-to-head comparisons.

Box 1 The Baby Friendly Hospital: Ten Steps to Successful Breastfeeding

- Step 1 Have a written breastfeeding policy that is routinely communicated to all healthcare staff
- Step 2 Train all healthcare staff in the skills necessary to implement this policy
- Step 3 Inform all women (face to face and leaflets) about the benefits and management of breastfeeding
- Step 4 Help mothers initiate breastfeeding soon after delivery
- Step 5 Show mothers how to breastfeed and how to maintain lactation (by expressing milk) even if they should be separated from their infants
- Step 6 Give newborn infants no food or drink other than breast milk, unless medically indicated
- Step 7 Practice rooming in. All mothers should have their infant cots next to them 24 hours a day
- Step 8 Encourage breastfeeding on demand
- Step 9 Give no artificial teats or pacifiers to breastfeeding infants
- Step 10 Foster the establishment of breastfeeding support groups and refer mothers to them

From Section 1: Background and implementation from the revised BFHI⁸

● A 1994 US ‘analytic overview’ and meta-analysis examined the effect of maternity ward practices on breastfeeding success.³⁶ Studies were restricted to those containing RCT or quasi-experimental designs. In total, 18 studies were included (16 RCTs and 2 quasi-experimental), 13 of which could be included via meta-analyses.

Commercial discharge packs were assessed in 6 studies (n=1,212^{37, 38, 39, 40, 41, 42}; 1 Canadian, n=406³⁷). Meta-analysis showed discharge packs to have a “detrimental effect on full breastfeeding at 1 month...on any breastfeeding at 4 months, and a marginal effect on any breastfeeding at 1 month”. Consequently, authors conclude that “commercial discharge packs are linked to poor lactation success”.

Rooming-in and breastfeeding guidance was assessed in 2 studies (n=540).^{43,44} Qualitative assessment of these studies findings led the authors to “suggest that both rooming-in and breastfeeding guidance in a rooming-in context can have a positive impact on lactation success”.

Early maternal-infant contact was assessed in 8 studies (n=599^{45,46,47,48,49,50,51,52,53}; 1 Canadian, n=40⁵²). Meta-analysis based on 7 studies “indicated that early contact had a beneficial effect on the likelihood of breastfeeding at 2-3 months”. However, the authors suggest caution in interpreting these results on account of the heterogeneous effect sizes across studies and the confounding of additional interventions (e.g. breastfeeding guidance) in several of the studies. While acknowledging the need for further evaluation, the authors conclude that “early maternal-infant contact might have a beneficial effect on lactation performance”.

Breast feeding on demand was assessed in 3 studies (n=427).^{54,55,56} Qualitative assessment of these studies revealed a positive relationship between women receiving advice to breastfeed on demand and lactation success. However, based on “serious methodological problems”, the authors do not make any definitive conclusions with respect to this practice.

In-hospital formula supplementation was assessed by 1 trial from Montreal, Canada (n=781⁵⁷). This study evaluated the impact of formula supplementation on the duration of breastfeeding and found no difference between the intervention

(supplementation restricted) and the control group (supplementation allowed).

The authors conclude that findings from their review present “strong evidence that several of the infant feeding policies recommended by WHO and UNICEF (i.e. discontinuation of commercial discharge packs, rooming-in, and breastfeeding guidance) can have a positive impact on lactation success.” Caution however should be used in interpreting the findings of this review due to their poor reporting of review methodology. Notably, it is unclear to what extent a systematic approach, determined *a priori*, was utilized for searching and excluding studies.

Bottom Line: This section included evidence from 3 systematic reviews published between 1994 and 2008 assessing various interventions (single- and multi-component) aimed at improving rates of breastfeeding initiation and/or duration. Evidence from a 2008 Cochrane review indicates that breastfeeding peer support can result in improved rates of breastfeeding initiation. Evidence from a 2000 Health Technology Assessment/systematic review indicates that various types of health sector initiatives (i.e. BFHI), as well as peer support, can result in improved rates of breastfeeding initiation and duration.

recommends that supplementation should not be given, unless medically indicated.

★ A 2005 joint statement by the Canadian Paediatric Society, Dietitians of Canada, and Health Canada (🇨🇦)⁵⁹ endorses the WHO recommendation and provides additional recommendations pertinent to in-hospital care. These include, among others, providing postnatal counseling on the principles and practice of breastfeeding and encouraging frequent feeds in the early postnatal period.

★ In 2007, the Registered Nurses of Ontario (🇨🇦) disseminated their revised breastfeeding best practice guidelines for nurses.⁶⁰ First among their 13 recommendations is that nurses endorse the BFHI and advocate for ‘Baby Friendly’ environments. Other examples of recommendations pertinent to in-hospital care include: endorsing the WHO recommendation; performing comprehensive breastfeeding assessment post-natally and prior to discharge in order to develop a breastfeeding plan; and providing information, emotional and physical support to breastfeeding mothers with an attitude that conveys support for breastfeeding.

b. Guidelines – breastfeeding promotion

★ In 2000, the Public Health Agency of Canada released the Family-Centered Maternity and Newborn Care national guidelines (🇨🇦).⁵⁸ The document states that “protecting, supporting, and promoting breastfeeding reflect the guiding principles of family-centered maternity and newborn care”. It endorses the WHO recommendation of exclusive breastfeeding for 6 months and complementary breastfeeding for up to 2 years or beyond (hereafter referred to as the WHO recommendation). To promote successful breastfeeding in the early days post birth, it recommends: starting early (within 1st half-hour after birth); encouraging frequent, unrestricted, baby-led feedings; waking a sleepy baby if necessary; allowing for maximum mother-baby contact; assisting with positioning and latch; and ensuring exclusive breastfeeding. Further, it

Additional Information

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Conflict of Interest

None declared

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