

BREASTFEEDING PROTOCOL #12:

Insufficient Breast Milk Supply



Background

In 2018, a partnership was formed with the Baby-Friendly Initiative (BFI) Strategy for Ontario and Toronto East Health Network (TEHN) to update and revise the Breastfeeding (BF) Protocols for Health Care Providers to create a current and evidence informed resource. With the support of partner organizations and service providers, five BF Protocols were revised and released in 2019 and early 2020. This project was then paused due to the COVID-19 Pandemic.

In 2024, TPH resumed work on the protocols independently with acknowledgement from TEHN. TPH has reviewed and updated protocol content and references based on current breastfeeding resource information. Resources used in this review include Government references, breastfeeding texts, medication use during lactation guides and websites, and recognized organizations such as Academy of Breastfeeding Medicine and La Leche League.

Use of this Protocol

This Protocol is intended to support evidence-informed clinical practice. This Protocol may be copied or printed for the purpose of educating health care professionals, provided the authors are acknowledged and content is not altered, nor used or reproduced for commercial gains.

Disclaimer

This Protocol is a guideline. Every breastfeeding dyad and their circumstances must be assessed on an individual basis. In doing so, health care providers use their own professional judgement along with the evidence in assessing the care and support that the family needs. At times, consultation with another breastfeeding expert or advice from a medical practitioner, e.g., physician, midwife, or nurse practitioner, will be required.

Acknowledgements

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Protocol #12: Insufficient Breast Milk Supply

“Not enough milk” is one of the most common worries of new breastfeeding parents and reasons given for early discontinuation of breastfeeding. It is rarely related to a maternal physical condition but is more frequently related to inadequate removal of breast milk from the breastfeeding parent’s breast. There may be a low breast milk supply or a misunderstanding of the baby’s feeding behaviour; it may be actual or perceived. Ultimately, the question becomes “Is the baby getting enough breast milk?”

Observation and Assessment

1. The baby may have one or more signs that may indicate a problem of inadequate breast milk intake.

Assess the baby for:

- Absence of effective sucking and swallowing at the breastfeeding parent’s breast (e.g., few or no deep and slow sucks).
- Inadequate urine and stool output (*Protocol #3: Signs of Effective Breastfeeding*).
- A loss of more than 7-8% of birth weight in the first 3-4 days of life.
- Inadequate weight gain. A weight gain of less than 25-35 g (0.9-1.2 oz.) per day for the first 3 – 4 months of age (after the initial weight loss in the first 3-4 days of life and showing a pattern of gaining by 4-6 days of life). Breastfed infants will double their birth weight between 3-6 months and triple between 9-18 months. (*Protocol #3: Signs of Effective Breastfeeding*).
- Birth weight that is not regained by 10 -14 days of age.
- Possible lethargy, irritability, and/or breast refusal. However, some infants with inadequate weight gain may mistakenly appear to have a personality that is content and placid.
- Signs of dehydration, e.g., sunken fontanelle, sunken eyes, dry mucus membranes, poor skin turgor, ketonic odour, uric acid crystals (*Protocol #3: Signs of Effective Breastfeeding*).

2. The breastfeeding parent may have one or more signs that may indicate a problem with actual low breast milk supply or lactation failure.

Assess the breastfeeding parent for:

- No signs of the breast milk ejection or letdown reflex. Breastfeeding parents may not always feel a letdown reflex but may recognize the letdown when the baby’s sucks changes from shallow and quick to deep and slow (*Protocol #3: Signs of Effective Breastfeeding*).
- No breast changes after birth (e.g., no breast engorgement or breast milk coming in).
- No breast changes during pregnancy (e.g., no tenderness, darkening of the areola, enlargement, or leaking) or no breast growth but presence of stretch marks on breasts.

- No or minimal breast changes during puberty.
- One breast that is markedly different in size and/or shape from the other.
- Unusually shaped breasts e.g., tubular or cone shaped breasts or widely spaced breasts with spacing greater than 1.5 inches, bulbous areola. (Spencer, Campbell & Chamberlain, 2022; Wilson-Clay & Hoover, 2022).
- Breast injury, surgery, or biopsy in which major nerves and ducts in the breastfeeding parent's breasts are damaged, e.g., burns to the breastfeeding parent's breast, breast reduction with incisions to the areola and/or nipple. Breast implants usually do not affect breast milk supply.
- History of fertility concerns or metabolic conditions, e.g., diabetes, thyroid, polycystic ovary syndrome (PCOS).
- Loss of sensation in the breastfeeding parent's breast.

Possible Contributing Factors or Causes

Assess the baby for:

- Delay in the initiation of breastfeeding after birth (*Protocol #1: The Initiation of Breastfeeding*).
- Ineffective positioning and latching (*Protocol #2: Positioning and Latching*).
- Medical conditions that may compromise the baby's suck (e.g., jaundice, dehydration, hypertonia/hypotonia, cleft lip/palate, abnormal tongue, birth trauma, small or large for gestational age, prematurity, hospitalization) (*Protocol #10: Ineffective Suck and Protocol #14: Jaundice in a Breastfed baby*). The baby needs to be assessed by a primary health care provider to rule out any medical condition.
- Ineffective or weak suck, clicking sound when sucking, tongue retracting or thrusting. Restrictive tongue movement/tongue tie (*Protocol #10: Ineffective Suck*). (Spencer, Campbell & Chamberlain, 2022).
- Self-limited feeding or refusing the breast due to negative or painful experiences at breast (e.g. high breast milk flow, reflux, allergies) (Spencer, Campbell & Chamberlain, 2022).
- Inadequate frequency and duration of breastfeedings (*Protocol #3: Signs of Effective Breastfeeding*).
- Supplementation (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).
- Use of bottles and pacifiers.

Assess the breastfeeding parent for:

- Knowledge of normal lactogenesis (breast milk production) and infant feeding and sleep behaviours.
- Ineffective breastfeeding management, e.g., infrequent breastfeeding, inadequate breast milk removal, and improper use of breast pumps.
- Lack of confidence in the ability to breastfeed.
- Supplementation for inadequate breast milk supply or perceived inadequate breast milk supply (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).
- Engorgement lasting for more than 48 hours (*Protocol #5: Engorgement*).
- Uncontrolled pain.
- Significant stress.

- Maternal medical conditions that may delay or decrease breast milk supply, e.g., diabetes, obesity, anemia, hypertension, untreated hypothyroidism, pituitary disorders, autoimmune conditions, history of fertility concerns.
- Use of herbs and medications that decrease breast milk supply (e.g., sage, contraceptives containing estrogen, ergot alkaloids, thiazide diuretics, cold preparations such as decongestants e.g. pseudoephedrine) (Hale, 2023).
- Cigarette smoking.
- Excessive alcohol consumption.
- Acute dehydration or excess fluid intake.
- Use of a pacifier to delay breastfeedings.
- Pregnancy.
- Improper use of nipple shields.
- Breastfeeding parent/baby separation (e.g. returning to work, school).
- Lack of nutrients and restrictive diets (Spencer, Campbell & Chamberlain, 2022).
- History of exposure to endocrine disruptors (e.g. bisphenol A) or chemicals that could interfere with hormones. (Spencer, Campbell & Chamberlain, 2022).
- Nipple size or shape that may affect positioning and effective latching.
- Congenital insufficient glandular tissue or hypoplasia (underdeveloped breast tissue) e.g., Poland syndrome which is a congenital chest wall condition that affects one side of the body and presents as mild to severe hypoplasia on one breast (Walker, 2023). (See *General Principles*).
- Breast injury, surgery, or biopsy in which major nerves and ducts in the breastfeeding parent's breasts are damaged (e.g., burns to the breastfeeding parent's breast, breast reduction with incisions to the areola and/or nipple, previous history of mastitis and/or abscess). Breast implants usually do not affect breast milk supply. The reason for breast surgery may stem from physical or medical conditions that delay or decrease breast milk supply (e.g., Poland Syndrome).

Suggestions

1. Assess whether the breastfeeding parent has a perceived or an actual insufficient breast milk supply.

If the exclusively breastfed baby has adequate urine and stool output and is gaining weight well, offer reassurance to the breastfeeding parent that they do have sufficient breast milk supply.

2. Reassure the breastfeeding parent that the following signs do not indicate an insufficient breast milk supply:

- Fussiness with adequate weight gain (*Protocol #11: Crying and Colic in the Breastfed Baby*).
- Frequent breastfeedings (at least 8 times within 24 hours).

- Increased breastfeedings during a growth spurt. Growth spurts may occur at any time. These are commonly described as occurring at, but are not limited to, 10 days to 2 weeks, 6–8 weeks, 3 months, and later (Lauwers & Swisher, 2021; Spencer, Campbell & Chamberlain, 2022).
- Cluster breastfeedings. These are periods when the baby breastfeeds frequently, followed by periods when the baby sleeps longer between breastfeedings. These are most common in the late afternoon and evening.
- Baby takes a bottle after breastfeeding (many babies will suck on anything even if they are full because they find sucking pleasurable).
- Breasts that normally soften 10–14 days after birth due to the breastfeeding parent’s breasts adjusting to the baby’s needs.
- Lack of sensation when the letdown reflex occurs, or a decreased letdown reflex sensation. The breastfeeding parent should also look for other signs of the letdown reflex such as when the baby’s sucks change from shallow and quick to deep and slow.
- Breasts that have little or no leaking.
- Breastfeeding parent reports expressing no breast milk or only a small amount of breast milk.
- Shorter breastfeeding sessions, with adequate weight gain. Older babies (over 6 weeks old) breastfeed more efficiently, and the length of feedings can vary. Some infants may obtain a full feed in 5-10 minutes.

3. If the breastfeeding parent is assessed to have an actual insufficient breast milk supply.

Assess for possible cause(s) (see the previous section on *Possible Contributing Factors or Causes*).

1. If the baby is showing signs of inadequate weight gain, the baby needs to be assessed by a primary health care provider to rule out any possible medical condition such as jaundice, dehydration, urinary tract infection, hypertonia/hypotonia, cleft lip/palate, abnormal tongue, or birth trauma.
 2. If the baby has an ineffective suck, refer to *Protocol #10: Ineffective Suck*.
 3. If the breastfeeding parent’s breasts are engorged, refer to *Protocol #5: Engorgement*.
 4. If breastfeeding management is assessed to be ineffective or not optimal, offer suggestions to optimize breastfeeding management (*Protocol #3: Signs of Effective Breastfeeding*). It is always appropriate for the breastfeeding to be assessed and optimized.
 5. If the baby is showing signs of failure to thrive, the baby needs to be referred to a primary health care provider for further assessment and monitoring. Immediate supplementation may be medically indicated if the baby is truly failing to thrive (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).
- Low intake of breast milk means low caloric intake, which compromises infant weight gain, height, and most significantly head circumference. In turn slow weight gain/failure to thrive/inadequate breast milk intake of the infant has been associated with compromised development and cognition.

- Offer information to the breastfeeding parent so that they can recognize and observe signs of slow weight gain as differing from failure to thrive (*see chart below*).

Slow weight gain Gains weight slowly and consistently	Failure to thrive Very low, erratic, or no weight gain
<ul style="list-style-type: none"> • alert, responsive, healthy appearance • normal muscle tone • good skin turgor • pale, diluted urine, 6 or more times/day • frequent seedy stool, or infrequent large stool • breastfeeding well • 8 or more breastfeedings/day • good suck • good letdown reflex • weight gain consistent but slow 	<ul style="list-style-type: none"> • apathetic, lethargic, or weak cry • poor muscle tone • poor skin turgor • concentrated “strong” urine, few times/day • infrequent scant stools • difficult or ineffective breastfeeding, often from birth • fewer than 8 breastfeedings/day, usually brief • may have poor suck • no signs of functioning letdown reflex • poor or erratic weight gain (\leq 3rd percentile or crosses down two percentile lines); may lose weight

(Adapted from Spencer, Campbell, Chamberlain 2022, and Lawrence, 2022)

Provide the breastfeeding parent with suggestions to increase their breast milk supply.

Before breastfeeding, encourage the breastfeeding parent to:

- Follow early feeding cues to breastfeed frequently (*Protocol #3: Signs of Effective Breastfeeding*).
- Reduce or eliminate the use of pacifiers (if using) to help identify feeding cues.
- Ensure that the letdown reflex is initiated. The baby’s rooting, sucking and hands on the breastfeeding parent’s breasts are the natural stimuli for letdown when breastfeeding is initiated early before the baby is overly hungry and begins crying (see early feeding cues in *Protocol #3: Signs of Effective Breastfeeding*).

The breastfeeding parent can try the following ideas to initiate letdown:

- Breastfeed in a quiet, relaxed place.
- Use relaxation strategies, such as a warm shower, heat applied to the breastfeeding parent’s back and shoulders, relaxation breathing, a warm drink, supportive positions.
- Manage pain to support, comfort, and relax to facilitate breast milk letdown.
- Initiate breastfeeding early, before the baby is stressed and crying.
- Clothe the baby in only a diaper to promote skin-to-skin contact.
- Support the baby in a vertical chest-to-chest position, with the nose approaching the breastfeeding parent’s nipple, to facilitate the baby’s reflexes and self-attachment behaviours.

- To help stimulate the milk ejection reflex, gently massage the breasts. Apply moist or dry heat to their breasts for a few minutes before or during massage until letdown occurs. Heat may be applied with a warm, wet towel or disposable diaper, a warm bath or shower, a bowl of warm water, a heating pad on low, or a hot water bottle wrapped in a cloth. Then gently express some breast milk (*Protocol #19: Expressing and Storing Breast Milk*).
- Stimulate the nipples. Have the parent gently roll their nipples between the index finger and thumb for several minutes or until the letdown reflex occurs. Then gently express some breast milk (*Protocol #19: Expressing and Storing Breast Milk*).

During breastfeeding, encourage the breastfeeding parent to:

- Breastfeed frequently – at least 8 times a day, including at least once overnight, if the baby is younger than 6 months old.
- Dress the baby in a diaper only when breastfeeding to promote skin-to-skin contact.
- Use effective positioning and latching practices (*Protocol #2: Positioning and Latching*).
- Ensure that the baby is sucking and swallowing effectively at each breastfeeding.
- Offer both breasts at each feeding to increase stimulation to the breastfeeding parent's breasts.
- Try “switch nursing” if the baby is sleepy or loses interest quickly. Offering each breast 2–3 times during a feeding to keep the baby interested as the baby's sucking slows down, can help to optimize the amount of time the baby actively sucks and swallows. The term “switch nursing” has been used by La Leche League leaders (LLL, 2011). Switching between breasts triggers the milk ejection reflex more often, which increases breast milk flow (La Leche League Canada, 2022). When switch nursing, continue to ensure that the breasts are drained and baby is satisfied after the feeding (Lawrence & Lawrence, 2022; Wambach & Spencer, 2021).
- If the baby breastfeeds on only one side, encourage the breastfeeding parent to express some breast milk from the other breast. This will ensure that both breasts are stimulated at each feeding.
- Use gentle breast compressions to help stimulate sucking and swallowing and to increase breastmilk fat content given to the baby. See *Protocol #3 Signs of Effective Breastfeeding* for a description of breast compressions.
- Feed the baby only breast milk for the first 6 months of life unless supplementation is medically indicated (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).
- Breastfeed the baby first, then offer solid foods once the baby has begun taking solid foods. As solids are introduced, breast milk remains the primary source of nutrition.

Note: Breastfeeding parents are advised to exclusively breastfeed their babies to 6 months of age and to introduce nutrient-rich solid foods, with particular attention to iron, at 6 months, with continued breastfeeding for up to 2 years and beyond (Health Canada, 2014).

After breastfeeding, encourage the breastfeeding parent to:

- Eat and drink according to *Eating Well with Canada's Food Guide* (Health Canada, 2019).
- Avoid using bottles and pacifiers.
- Avoid smoking, alcohol, and caffeine.

- Express both breasts after breastfeeding to increase stimulation to the breastfeeding parent's breasts (*Protocol #19: Expressing and Storing Breast Milk*).
- Get help from family and friends with cleaning, cooking, caring for the baby, caring for other children.

If the baby is unable to breastfeed effectively, encourage the breastfeeding parent to:

- Express each breast after each time that the baby is unable to breastfeed effectively. If breastfeeding is stopped for any length of time, encourage the breastfeeding parent to express each breast regularly in order to maintain their breast milk supply. Generally, this should be at least 8 times in 24 hours, with a minimum of 1 expression overnight, to mimic the normal pattern of feeding. The breastfeeding parent may need to express more often if their breasts become uncomfortable or overly full (*Protocol #19: Expressing and Storing Breast Milk*).
- Hands-on pumping can increase the amount of breast milk expressed (*Protocol #19: Expressing, Collecting, and Storing Human Breast Milk*).
- Power pumping is another method that can be considered. It involves expressing milk frequently for short periods of time. Variations may include pumping every 10 mins and resting every 10 mins for 1 hour; or pumping for 5-10 mins whenever possible (Mohrbacher, 2020; Spencer, Campbell & Chamberlain, 2022). Although there is insufficient research on power pumping itself, the strategy mimics baby's cluster feeding patterns to increase milk production.
- Parallel pumping is a strategy to express breast milk from one breast while breastfeeding from the other breast. It can be an option for families that have difficulty managing with triple feeding (combination of breastfeeding, hand expression or pumping, and supplementing afterwards).
- Feed the baby with expressed breast milk using an alternative feeding method, e.g., cup, spoon, syringe, finger feeding, lactation aid on the breast.
 - Using a lactation aid on the breastfeeding parent's breast is recommended over the other alternative feeding methods if the baby is able to latch onto the breastfeeding parent's breast. This method allows the baby to remain at the breast and provides the breasts with stimulation (*Protocol #18: Alternative Feeding Methods*).
 - If expressed breast milk is not available and it is assessed that supplementation is medically indicated, then an appropriate supplement should be offered (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).
- Consult a health care provider or breastfeeding expert for further assessment as soon as possible.

If the breastfeeding parent and baby are unresponsive to non-pharmacological strategies to optimize breast milk supply and the breastfeeding parent has inquiries about the use of a galactagogue, encourage them to:

- Understand the possible benefits and risks associated with the use of galactagogues if they inquire about using such medications or herbs for managing an insufficient breast milk supply. It is important that information is shared to assist the breastfeeding parent in making a fully informed decision about the use of galactagogues. Offer further assessment and refer for further support as needed (see Galactagogues in *General Principles*).
- Breastfeeding parents should consult a health care provider or breastfeeding expert before the use of galactagogues is considered.

- It is essential to optimize all non-pharmacological measures to optimize breastfeeding management, including a thorough breastfeeding assessment. If the breastfeeding parent inquires about using a galactagogue to increase breast milk supply, it is important to first explore with them any possible underlying causes of insufficient breast milk supply. Inquire about their current breastfeeding management practices and attempts to manage their breast milk supply and offer suggestions to optimize basic breastfeeding management.

4. If the breastfeeding parent has had surgery such as augmentation or reduction mammoplasty, breast injury, or is suspected of having congenital insufficient glandular tissue, they should be referred to a breastfeeding expert or breastfeeding clinic for a thorough breastfeeding assessment. The breastfeeding parent should be supported and encouraged to attempt breastfeeding, as full or partial lactation is often possible.

General Principles

A common concern that breastfeeding parents have in the early postpartum period is that they do not have enough breast milk for their baby. This is one of the most common reasons given by a breastfeeding parent for discontinuing breastfeeding or for supplementing with human milk substitute (infant formula).

It is often the case that insufficient breast milk supply is a perceived and not an actual problem. This may be due in part to a lack of knowledge regarding normal infant behaviours and feeding cues, and the normal process of breastfeeding, e.g., growth spurts, cluster, and frequent breastfeeding.

Wambach & Spencer define insufficient breast milk as “insufficient breast milk production to sustain normal infant weight gain despite appropriate breastfeeding routines, maternal motivation to continue breastfeeding, and skilled assistance with breastfeeding problems” (Wambach & Spencer, 2021).

Very few breastfeeding parents experience actual insufficient breast milk supply if breastfeeding is appropriately managed from birth (*Protocol #1: The Initiation of Breastfeeding*).

Insufficient breast milk supply that is permanent and irreversible can be caused by congenital insufficient glandular tissue, or breast injury, surgery, or biopsy in which the major nerves and ducts of the breastfeeding parent’s breasts are damaged, e.g., burns to the breastfeeding parent’s breast or breast reduction with incisions to the areola and/or nipple. Breast implants usually do not affect breast milk supply.

Breastfeeding parents with a history of breast injury or surgery may be able to breastfeed exclusively, whereas women with true congenital insufficient glandular tissue often require supplementation with breastfeeding (*Protocol #17: Indications for Supplementation or Cessation of Breastfeeding*).

According to Spencer et. al, glandular hypoplasia, a condition of insufficient or abnormal glandular tissue, can result in suboptimal milk production ranging from mild to severe (Spencer, Campbell, Chamberlain, 2022). A breastfeeding parent with this condition will often report that they experienced no changes to their breasts during pregnancy or after birth, e.g., no enlargement, tenderness, or breast milk coming in. Each breast may also be markedly different in size and/or shape, with one breast being much larger than the other. One or both breasts may also be unusually shaped, e.g., cone shaped.

Galactagogues

If the breastfeeding parent inquires about the use of medications or herbs to increase breast milk supply, it is important to first explore with them any contributing factors related to insufficient breast milk supply, as well as their breastfeeding self-efficacy. It is also important to inquire about their previous breastfeeding history, current breastfeeding management and attempts to manage their insufficient breast milk supply, and then offer suggestions to optimize basic breastfeeding before introducing further interventions.

A thorough assessment of breastfeeding, including breast milk supply and breast milk transfer, is essential. If they are unresponsive to non-pharmacological measures to enhance breast milk supply, refer them to an appropriate health care provider for further assessment, screening, and/or treatment.

Although commonly used to increase low milk production there continues to be limited data in the form of controlled trials regarding the use of medications and herbs as galactagogues to establish standardized dosages, determine the mechanism of action, efficacy, and potential risks for the baby, or possible interactions with other medications. A Cochrane review found that there is not yet enough high-quality research to statistically validate the effectiveness of any particular galactagogue or natural galactagogues as a group (Spencer, Campbell, Chamberlain, 2022).

The updated Protocol of the Academy of Breastfeeding Medicine reports that emerging data suggest more caution be exercised in recommending galactagogues than in its previous edition (ABM, 2018). Both the Academy of Breastfeeding Medicine *Protocol #9* (2018) and Lawrence (2022) include appendices that present the current “minimal specific data” known for common galactagogues.

Galactagogues should not be the first strategy recommended to manage an insufficient breast milk supply and they should only be initiated by a health care provider who has the breastfeeding expertise to thoroughly assess the potential effectiveness and risks of use for the breastfeeding pair. The practitioner is responsible for establishing a plan with the breastfeeding parent for the ongoing management and evaluation of the intervention. Practitioners who do not have the capacity, i.e., lactation expertise or time, to continue to support the dyad appropriately should refer the breastfeeding parent to other health care providers as appropriate and work collaboratively.

It is important that breastfeeding parents be aware of this information in order to make an informed decision as well as how to monitor themselves and the baby for possible side effects. For more information see the Academy of Breastfeeding Medicine’s *Protocol #9: Use of Galactagogues in Initiating or Augmenting Maternal Milk Secretion* (ABM, 2018) (*Protocol #16: Drugs and Breastfeeding*).

Medications that may increase breast milk supply (pharmacologic galactagogues): Refer breastfeeding parents to a health care provider for further consultation.

Domperidone (Motilium) is a medication that may increase breast milk supply by stimulating the production of prolactin. It is traditionally used to treat disorders of the gastrointestinal tract. There is evidence for use of domperidone as a galactagogue, although limited, with a few small sample size-controlled trials. Most studies demonstrated that domperidone modestly increased breast milk production and provided some guidance on the recommended dose (Hale, 2023). A prescription is required.

Hale (2023) rates domperidone as L3 or moderately safe and acknowledges that it is known to produce significant increases in prolactin levels (a side effect of the medication) and has proven useful as a galactagogue. It does not enter the brain compartment and has fewer CNS effects. Hale's (2023) recommended domperidone dose is 10-20 mg three times a day. There is no evidence that higher doses are more effective but may dramatically increase the risk of QT prolongation and severe withdrawal symptoms in the mother.

It is essential that breastfeeding parents be aware of the risks associated with high dosages as well as other side effects, along with the benefits of domperidone, when making a decision to use it. Side effects of domperidone may include headache, drowsiness, dizziness, changes in mood, seizures (rare), arrhythmias (QT prolongation), dry mouth, abdominal cramps, diarrhea, withdrawal symptoms following high doses (Hale, 2023).

The recommendation of Domperidone as a galactagogue is considered "off label" use in Canada. Health Canada (2023) advises limiting domperidone to the lowest possible effective dose, with a maximum dose of 30mg per day due to risks of cardiac events. If prescribed high doses of domperidone (more than 30mg/day), withdrawal symptoms may occur if abruptly discontinued and/or quickly tapered. Withdrawal symptoms include psychiatric events such as depression, anxiety, and insomnia. Parents should be aware of the risks and consult with their healthcare provider prior to discontinuation.

Domperidone is not an approved drug by the American Food and Drug Administration (FDA). The FDA also warns against the use of domperidone by lactating women based on associations with serious cardiac adverse events, including prolonged QT intervals, cardiac arrest, and sudden death.

Metoclopramide (Maxeran) also known as Raglan, is another gastrointestinal medication that is also used to stimulate prolactin release and increase breast milk supply. Not all women respond to it and the effects are dose dependent. Metoclopramide passes the blood-brain barrier of the parent (Hale, 2023), which may lead to significant CNS side effects such as sedation, anxiety, depression, and extrapyramidal symptoms (e.g. spasms, jerky movements, muscle contractions). Health Canada warnings include rare cases of irreversible tardive dyskinesia if used for more than three months. A prescription is required. Health Canada has not authorized this medication for increasing low milk supply.

According to the ABM (2018), the following important issues should be considered when thinking of introducing pharmaceutical galactagogues.

- Pharmaceutical galactagogues can increase serum prolactin, however not all women with low milk supply have low levels of prolactin.
- Potential side effects should be weighed carefully against the benefits of use.
- Prescription medications used as galactagogues is considered off label in most countries.

Oxytocin nasal spray is another medication that has mixed research on the effectiveness of using it to increase breastmilk supply (Walker, 2023). Although there may be minimal effectiveness for parents with functioning milk ejection reflexes, it could be helpful to stimulate the reflex for individuals that have nerve damage, breast surgeries, chest injuries and/or spinal cord injuries (Lauwers & Swisher, 2021). Hale (2023) recommends intranasal oxytocin sprays of 40 IU/mL (1 spray per nostril prior to breastfeeding or pumping). Chronic use can lead to dependence, and it is advised to limit use to the first week of the postpartum period (Hale, 2023) or for two days (Spencer, Campbell & Chamberlain, 2022).

Herbs that may increase breast milk supply (plant based galactagogues):

Refer breastfeeding parents to someone formally trained in herbals, a breastfeeding expert, pharmacist, or health care provider.

Herbal products are available without prescription in Canada and are regulated under the Natural and Non-prescription Health Products Directorate (NNHPD). For more information about regulations, and using natural health products visit the Health Canada website: www.hc-sc.gc.ca/

Health Canada has regulations to ensure the quality, effectiveness, and safety of natural health products (herbs). Natural health products approved under these regulations will have a Natural Product Number (NPN) or Drug Information Number – Homeopathic Medicine (DIN-HM) on the label. Few products have been tested for safety in pregnancy and breastfeeding and are thereby not recommended by Health Canada for use in breastfeeding.

Many herbal remedies have been used throughout history to enhance breast milk supply. Most have not been scientifically evaluated but traditional use suggests safety and possible efficacy (ABM, 2018).

Currently there is not enough scientific information about the safety of various herbs and natural health products to recommend their general use during breastfeeding. Breastfeeding women should use natural products with caution and consult with someone formally trained in herbals, a breastfeeding expert, pharmacist, or their health care provider regarding the safety of use with breastfeeding.

Fenugreek and blessed thistle are two herbs that have been recommended by some breastfeeding experts for increasing breast milk supply with no apparent adverse effects.

Hale rates both fenugreek and blessed thistle as L3 or moderately safe (Hale, 2023). This expert opinion however is based on clinical observation, including anecdotal evidence. There were no clinical trials to establish efficacy or dosage, identify benefits/risks to the breastfeeding parent or infant, or possible interactions with other medications.

Other herbs that have been used traditionally include borage, goat's rue, milk thistle (*Silybum marianum*), dandelion, millet, oats, anise, basil, marshmallow, seaweed, fennel, barley, moringa or malunggay, papaya, ginger, and others (Brodribb & ABM, 2018; Lawrence & Lawrence, 2022). Herbs are available in different forms including pills, teas, or tinctures. They may also be included in traditional foods for breastfeeding parents.

The following guidance has been provided by various practitioners regarding fenugreek:

- Hale suggests a dosage of 6 grams of fenugreek per day (2023).
- Lawrence & Lawrence (2022) suggests 2-3 capsules four times a day with no standard dose listed.
- Brodribb & ABM (2018) suggests fenugreek herbal teas with 570-600mg to be taken 3 times a day.

Although there is inconclusive evidence on fenugreek increasing milk supply, there is likely a placebo effect (ABM, 2018). When using fenugreek, infants may develop colic and increased fussiness. Individuals allergic to peanuts and chickpeas may have a cross-allergy to fenugreek. High doses of fenugreek may also lower blood sugar.

Regarding blessed thistle, Hale states it lacks justification as a galactagogue, although they do state that it is virtually nontoxic if breastfeeding (2023). Lawrence says it is not a galactagogue and is often confused with milk thistle (2022). Hale suggests an adult dose of 1.5 to 3 grams in tea up to 3 times a day.

With limited research to support the use of plant based galactagogues for breastfeeding, caution is required regarding the use of herbal products because of the lack of standardized dosing, possible allergic reactions, and potential for interactions with other medications.

Breastfeeding parents may find information about the use of galactagogues available on the internet and should be encouraged to speak with their health care provider to assess safety for their individual use. Galactagogues, herbs and natural health products should be used with caution and in consultation with a healthcare provider. Parents should be provided with available evidence-based information regarding the impact of the product on milk production and any potential side effects and drug interactions for the parent or infant (Spencer, Campbell, Chamberlain, 2021).

Healthcare professionals can refer to other databases on the risk and safety of medications and herbal products during breastfeeding to support breastfeeding families:

- Thomas Hale’s Infant Risk Center (U.S.: Texas Tech University Health Sciences Center): <https://infantrisk.com/>
- LactMed Drugs and Lactation Database (U.S.: National Institute of Child Health and Human Development): <https://www.ncbi.nlm.nih.gov/books/NBK501922/>
- E-lactancia (U.S.: Association for Promotion of and cultural and scientific Research into Breastfeeding): <https://e-lactancia.org/>
- First Exposure (Canada: University of Toronto): <https://firstexposure.ca/>
- MothertoBaby (U.S.: The Organization of Teratology Information Specialists): <https://mothertobaby.org/>

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