Abstract

The short term and long term benefits to mother and baby with breastfeeding are well-documented, however, the actual rates of exclusive breastfeeding to 6 months of age are less than 17% in Canada. The most often cited reason for discontinuation of breastfeeding is not enough breastmilk, which has increased the use of galactagogues - substances used to induce or augment lactation in breastfeeding women. There is a lack of guidance regarding the appropriate use of galactagogues because at present there is only one clinical practice guideline from the American Academy of Breastfeeding Medicine (ABM) which does not describe actual use in practice and has not been updated since 2004. This has resulted in practice based on anecdotal evidence, with a wide variation in indications, dosages, and duration of treatment among primary care practitioners. A literature review of galactagogue use and research from 2000 to 2010 was performed, grey literature such as presentations, theses and dissertations were included, and practitioners were interviewed regarding their own use of galactagogues in practice. In Canada the most widely used galactagogues are the herb fenugreek, and the medication domperidone. Fenugreek has not had any randomized controlled trials (RCT) to support its safety or efficacy in practice, which makes its recommendation more difficult, particularly because it has been reported to have significant side effects such as hypoglycemia. Conversely, domperidone has been shown to be safe and effective, with low incidence of side effects. Domperidone is used widely in Canadian practice for this off-label purpose by physicians and nurse practitioners (NP). When accompanied by assessment and treatment of underlying physiological causes of breast milk insufficiency and or milk transfer issues such as poor infant latch, domperidone 10 mg three times daily with thorough assessment and follow up is a reasonable and safe galactagogue choice.
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# Table of Contents

Abstract ......................................................................................................................... 2  
Acknowledgements .......................................................................................................... 3  
Table of Contents ........................................................................................................... 4  
Introduction ..................................................................................................................... 5  
Literature Review ............................................................................................................ 7  
  Clarification of Terms .................................................................................................... 8  
Background .................................................................................................................... 9  
  Benefits of Breastfeeding ............................................................................................ 9  
  Physiology of Breast Milk Production ....................................................................... 11  
Causes of Insufficient Nutritional Status in Newborns ............................................... 13  
Perceived Versus Actual Breast Milk Insufficiency ....................................................... 15  
Herbal Galactagogues .................................................................................................... 19  
  Fenugreek .................................................................................................................. 19  
  Blessed Thistle .......................................................................................................... 21  
  Other Herbal Galactagogues .................................................................................... 22  
Alternative Non-Pharmaceutical Galactagogues ......................................................... 23  
  Alcohol ...................................................................................................................... 23  
  Acupuncture .............................................................................................................. 24  
Pharmaceutical Galactagogues ..................................................................................... 24  
  Metoclopramide ....................................................................................................... 24  
  Domperidone ........................................................................................................... 25  
Less Commonly-Used Medications ............................................................................. 30
Research that clearly demonstrates the benefits and superiority of breastfeeding over breast milk substitutes has led in recent years to an increase in the number of women who choose to breastfeed their babies, and has increased societal pressure on all women to do the same. Breastfeeding has become more of an infants’ rights issue than a choice for women, an almost complete reversal of the women’s rights movements only five decades ago that viewed breastfeeding as tying women down, and glamorized the modern household in which babies were bottle-fed (Thulier, 2009). “Baby-Friendly” initiatives now encourage hospitals to ban all breast milk substitutes and artificial nipples from their premises, and the slogan “Breast is Best” are seen on posters everywhere mothers and babies are likely to be found. While there is no denying the benefits of breastfeeding for both mother and baby, this increased pressure to succeed at breastfeeding has created a niche market of herbal, alternative, and pharmaceutical treatments that claim to increase maternal breast milk production through a variety of mechanisms. Despite the increasing demand for these products from breastfeeding mothers, the development of evidence-based guidance regarding how to safely prescribe galactagogues has not kept pace with this demand, and anecdotal evidence is often used as the only resource for practitioners. Galactagogues are not a new concept, and cultures around the world have a variety of methods to increase maternal breast milk production. However, based on my own experience, and from speaking with primary care providers, nurse practitioners (NP) frequently find themselves in the position of being asked for their advice regarding herbal or alternative galactagogues, and responsible for prescribing pharmaceutical galactagogues.

NPs have only been legislated to practice in British Columbia (BC) since 2005 (Canadian Institute For Health Information, 2006), and as relatively new primary care providers, often access guidelines to ensure that they provide the best possible care using the latest evidence.
NPs working in primary care certainly may have patients who request treatment for insufficient milk supply. The lack of up-to-date information and direction regarding appropriate assessments and treatment for this condition, including the use of such commonly prescribed treatments as galactagogues, is a concern. This paper will include a review and critique of the latest research findings on galactagogues that are commonly used in Canada, as well as the guidelines that are currently available. Recommendations for practice will be presented based on these findings in an attempt to provide that missing guidance for appropriate and safe prescribing of galactagogues by NPs.

**Literature Review**

Information for this project was found using the search engines Medline, CINAHL, and Google Scholar. The key words used to search for information were galactagogues, galactogogues, breast feeding, lactation, augmentation, and galact*. Terms of exclusion were adoption, as the focus of this project was on the augmentation rather than the induction of breastfeeding and maternal milk supply. Only papers published from 2000 to 2010 were included in the literature search, and only those that were available in English whether translated or not, with the intent of including only the most current information and research. The reference lists of all accepted articles were used to find additional evidence. This process was continued until the results became repetitive, with several key articles becoming apparent.

Personal communications in the form of email and personal interviews were used when no published information was available, and dissertations and theses were accepted. The wide range of acceptable literature for this project was a result of the difficulty in finding current research on this topic. The idea for this project arose from previous paper written in which the clinical practice guideline for galactagogue use were analyzed and critiqued. This critique
brought to light the lack of consensus regarding galactagogue use, and the fact that anecdotal rather than research-based evidence was being used to guide clinicians in their decisions regarding when and how to prescribe galactagogues.

The supporting literature for breastfeeding self-efficacy, which is defined as maternal confidence in the ability to breastfeed (Dennis, 1999), was found during research for a previous paper, and the physiology of breastfeeding information was gleaned from the galactagogue literature, as well as current textbooks that were frequently cited in this same literature. Resources were not exhausted with regard to supporting literature, but stopped searching stopped when information became repetitive. Canadian sources were used preferentially over American or international references whenever possible, and the breastfeeding recommendations are from current Health Canada literature.

**Clarification of Terms**

To avoid potential misunderstandings, the following terms require a brief explanation of how they are defined for this particular paper. The terms primary care and primary health care are often used interchangeably. For the purposes of this paper, the definition of primary health care will be that of the World Health Organization’s (WHO) Declaration of Alma-Ata:

“Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self reliance and self-determination. It forms an integral part both of the country’s health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.” (WHO, 1978, p. 2)
The definition of primary care for this paper therefore is that it is an integral part of primary health care, the main entry point or primary level of contact of individuals and or families to the national health care system (Thomas-Maclean, Tarlier, Ackroyd-Stolarz, Fortin, & Stewart, 2008). In other words, primary care settings are where primary health care takes place, and primary care providers offer primary health care.

The term successful breastfeeding will refer to exclusive breastfeeding of infants to 6 months of age, which means no supplemental feeds with breast milk substitute, but may include expressed breast milk given by bottle. After 6 months of age, solids are recommended to be introduced and exclusive breastfeeding is no longer the recommendation (Health Canada, 2004). Galactagogues are defined as medications, substances, or treatments that are used to initiate, stimulate, increase, enhance, or maintain maternal milk supply for the purposes of breastfeeding (The Academy Of Breastfeeding Medicine (ABM) Protocol Committee, 2004; Anderson & Valdes, 2007; Betzold, 2004; Brodribb, 2000; Gabay, 2002; Henderson, 2003; Low Dog, 2009).

**Background**

**Benefits of Breastfeeding**

The benefits to newborns of exclusive breastfeeding have been reported and include, but are not limited to decreased incidence of gastrointestinal, upper respiratory, and otitis media infections; decreased incidence of sudden infant death syndrome, prevention of allergies, improved cognitive development demonstrated by higher scores on IQ tests as well as academic performance in school, and increased contact between mother and newborn (Public Health Agency of Canada (PHAC), 2009; Health Canada, 2005; Health Canada, 2007; Kramer & Kakuma, 2001).
Maternal benefits include decreased incidence of breast and ovarian cancer and osteoporosis, delayed onset of menses, and increased and more rapid weight loss in the postpartum period (Health Canada, 2009a; Kramer & Kakuma, 2001). Bartick and Reinhold (2010) performed a pediatric cost analysis and determined that if 90% of American families could exclusively breastfeed their infants for 6 months, the United States (US) would save 13 billion dollars in health care costs and prevent 911 deaths, most of them infant deaths.

Environmental benefits include no processing, no packaging, and no waste, as well as the cost-benefits, which are considerable (PHAC, 2009). The Infant Feeding Action Coalition (INFACT) Canada (1997) surveyed formula costs across the country based on income assistance for a single mother, and determined that there was great variation in formula prices, 5%-34% of the monthly income, depending on the geographical location and demand for formula in that area. The most expensive locales were remote areas with associated decreased rates of breastfeeding. This led INFACT to the realization that “[the formula] industry varies its prices according to the degree of competition presented by breastmilk.” (INFACT Canada, 1997). Breastfeeding for socioeconomically disadvantaged families, particularly those in rural and remote areas, may mean the difference between food security or insecurity for the entire family.

Adults who were breastfed as infants, when compared with control groups who were not breastfed, had lower systolic and diastolic blood pressure (Martin, Gunnell, & Smith, 2005), lower mean total cholesterol levels, were less likely to be overweight or obese, less likely to be diagnosed with Type 2 diabetes mellitus, score higher on intelligence tests, and obtain better grades in school (Horta, Bahl, Martines, & Victora, 2007). While the direct costs to the health care system have not been specifically measured, the decrease in chronic disease cannot help but to lessen the burden on the system.
In 2004, Health Canada changed the recommended duration of exclusive breastfeeding from 4-6 months to 6 months of age, in line with the WHO 2001 recommendation (Health Canada, 2004). Despite the recommendations and acknowledged benefits to both mother and baby, while 85% of Canadian women in 2003 initiated breastfeeding, only 17% breastfed exclusively for at least six months. British Columbia (BC) had the best initiation and duration rates, with 93% of women initiating breastfeeding, and 28% exclusively breastfeeding for at least six months (Millar & Maclean, 2005). Interior Health Authority in BC notes an 89% initiation rate with 53% of women doing some breastfeeding at six months postpartum (Bryan, 2005), unfortunately there is no indication of whether or not this is exclusive breastfeeding. For those women who did not breastfeed exclusively for the recommended six months, the most commonly cited reason for stopping breastfeeding was “not enough milk” (Millar & Maclean, 2005, p. 27), at 31%. Similar statistics are noted in Australia, the US, and the United Kingdom (UK) with fewer than 23% of women maintaining any breastfeeding to six months postpartum, and only 50% of women exclusively breastfeeding to six months in developing countries (Blyth et al., 2002).

**Physiology of Breast Milk Production**

Lactogenesis takes place in two stages. Lactogenesis I occurs during the second trimester of pregnancy, whereby the formation and expansion of ducts and lobules occurs, and epithelial cells of the alveoli differentiate into secretory cells (Biancuzzo, 2003; Riordan, 2005). Prolactin is released from the anterior pituitary gland and stimulates the production of colostrum (Eglash, Montgomery, & Wood, 2008; Riordan, 2005). The amount of colostrum produced is small, and it is hypothesized that high levels of estrogen and progesterone during pregnancy inhibit the action of prolactin on milk production prior to delivery of the placenta (Berens, 2004; Gabay,
Lactogenesis II is the onset of copious milk production, occurs after delivery of the infant (and perhaps more importantly the placenta), and may take up to eight days postpartum to be fully achieved (Riordan, 2005).

The delivery of the placenta causes a sharp drop in progesterone levels and thereby removes that antagonism from the effect of prolactin, which increases milk supply (Berens, 2004; Eglash et al., 2008; Hurst, 2007). This occurs simultaneously with a change in the composition of the breastmilk to one high in lactose and milk lipids, and lower in sodium, chloride and protein. This is a result of junction complex closure between alveolar cells, which allows for passage of substances between these alveoli (Riordan, 2005).

Full realization of lactogenesis II and continuation of milk production during the first three to five days postpartum are dependent on the feedback mechanism of milk removal from the breast. This occurs with supply and demand infant suckling and feeding, or mechanical pumping of the breast if infant feeding is not possible (Eglash et al., 2008). When the nipple is stimulated by infant suckling or mechanical pumping, and milk is removed from the breast, the hypothalamus inhibits dopamine, which allows for increased release of prolactin from the anterior pituitary, and therefore increased milk production (Riordan, 2005). Nipple stimulation also causes release of oxytocin from the posterior pituitary, which helps with milk secretion or “let down” by causing contraction of myoepithelial cells in the breast (Gabay, 2002). The culmination of these processes is a switch from the initial process of endocrine-controlled lactation, which all women experience immediately postpartum whether they breast feed or not, to the secondary and long-term process of autocrine-controlled lactation, which can only be maintained through continued breast milk removal (Mohrbacher & Stock, 2003). While this provides a rather simplified explanation of maternal milk production, a more detailed account of
the process is outside the scope of this project. Rather, this brief explanation can suffice to
demonstrate how NPs might explore possible causes of insufficient milk supply in women and
consider the various causes.

Causes of Insufficient Nutritional Status in Newborns

There are three possible physiological mechanisms for insufficient nutritional status of a
breastfed newborn. The first is primary failed or delayed lactogenesis II, and while the actual
rates are unknown, it is estimated that between 5% and 15% of women will experience one of
these circumstances (Hurst, 2007). Recall that lactogenesis II is the transition from hormonally-
induced production of colostrum during pregnancy to milk production following delivery. Hurst
differentiates between delayed and failed lactogenesis II, with the implication that delayed
lactogenesis, defined as later than 72 hours after delivery (Riordan, 2005), can still progress to
full and successful lactation, while failed lactogenesis II is further broken down into either a
“primary inability to produce adequate milk volume, or a secondary condition as a result of
improper breastfeeding management and/or infant-related problems”(Hurst, 2007, p. 589).

There are numerous conditions that may impact on the ability to attain lactogenesis II.
The intricate interplay of hormones required to produce breast milk can be interrupted by any
condition that is hormonal in nature such as obesity, thyroid abnormalities, and diabetes (Hurst,
2007). Women with Type I diabetes mellitus have lower levels of prolactin in their breast milk
and this can cause a delay in lactogenesis II. Women with polycystic ovarian syndrome or theca
lutein cysts have higher levels of testosterone, which may interfere with the hormones required
for lactogenesis II and lead to a delay. Postpartum hemorrhage can lead to Sheehan syndrome,
which affects pituitary gland function and therefore prolactin and oxytocin secretion (Hurst,
2007). Retained placental fragments may secrete sufficient progesterone to impair prolactin
release and thereby interfere with lactogenesis II. Cesarean birth, prolonged second stage of labour, and maternal stress may increase cortisol levels, which is thought to be associated with delayed lactogenesis II (Riordan, 2005). Women with anatomical breast abnormalities such as insufficient mammary glandular tissue, or those who have experienced invasive breast surgery such as augmentation or reduction, may have physical disruptions in normal lactation. Finally, cigarette-smoking and administration of hormonal contraceptives during the first week postpartum also decrease prolactin secretion and therefore breast milk production (Hurst, 2007).

The second cause of insufficient nutritional status of a breastfed newborn is secondary delayed lactogenesis related to breastfeeding management or breast milk transfer issues. This can comprise delayed breastfeeding initiation due to maternal-infant separation secondary to any number of causes, including cesarean section, prolonged second stage of labour, preterm delivery, maternal or newborn ill health, which can delay onset of lactogenesis II, and feeding infrequently or supplementing with breast milk substitutes, which leads to decreased prolactin release and therefore delayed lactogenesis II. Poor infant latch secondary to tongue tie, congenital malformations such as cleft palate/lip, prematurity, ill health, jaundice, congenital heart defects, or poor overall breastfeeding technique can lead to decreased milk transfer, or removal of breast milk from breast, decreasing prolactin secretion and thereby delaying lactogenesis II (Hurst, 2007).

The third cause of insufficient nutritional status of a breastfed newborn is organic failure to thrive, which means that there is a pathophysiological reason that the newborn is not gaining weight. This category encompasses a variety of congenital conditions such as: gastroesophageal reflux; pyloric stenosis; lactose intolerance; Hirschsprung disease; milk protein intolerance; liver disease; pancreatic disease; kidney disease; cardiopulmonary disease; thyroid disorders; cerebral
hemorrhage; mental retardation; bacterial or parasitic infections of the gastrointestinal tract; inborn errors of metabolism; chromosomal abnormalities; as well as a variety of congenital syndromes (Evers, 2006; Petersen-Smith & McKenzie, 2009). It is beyond the scope of this paper to discuss the myriad of factors that may affect a newborn’s ability to breastfeed and or to metabolize breastmilk successfully, however it is extremely important that any pathophysiological cause be ruled out during the initial breastfeeding assessment of a mother-baby dyad.

**Perceived Versus Actual Breast Milk Insufficiency**

Perceived or actual insufficient milk supply is described in numerous studies as a common, if not the most common, reason for breastfeeding discontinuation (Dyson, McCormick, & Renfrew, 2009; Flidel-Rimon & Shinwell, 2006; Lewallen et al., 2006; McCarter-Spaulding & Kearney, 2001; Sakha & Behbahan, 2008). Perceived breast milk insufficiency is defined as “the mother’s belief that her breast milk is inadequate in amount or nutritional quality to meet her infant’s needs” (McCarter-Spaulding & Kearney, 2001, p. 517), and is closely linked to confidence, support, and self-efficacy (Chung, Raman, Trikalinos, Lau, & Ip, 2008; McCarter-Spaulding & Kearney, 2001); while poor latch at the breast, maternal medical conditions, some medications, and disruptive health care practices are associated with actual breast milk insufficiency as discussed previously (Berens, 2004; Hurst, 2007; Meier, Furman, & Degenhardt, 2007).

The perception of insufficient maternal milk supply is intertwined with the western cultural ideals placed on objective measurements for data. Women and families are uncomfortable with not knowing exactly how much breastmilk the infant is receiving (Lewallen et al., 2006). When mothers perceive that their milk supply is insufficient, they often respond by
supplementing unnecessarily with formula, which interferes with the intricate feedback mechanism that influences maternal milk production as discussed previously, creating a situation of actual milk insufficiency (McCarter-Spaulding & Kearney, 2001). If the baby does not show any signs of dehydration, is gaining weight, and has adequate output, then there is no problem with milk insufficiency, no matter what the duration or frequency of feeds are. In this case, logic would suggest that the mother requires reassurance and education only. For this reason it is extraordinarily important to educate women regarding variety of feeding patterns among babies, and the reassuring signs of adequate intake and growth.

Another consideration is the cultural, societal, public health pressure to breastfeed that is experienced by women. In her summary of the history of breastfeeding in America, Thulier (2009) observes that research regarding the benefits of breastfeeding to both mother and baby, the increasing awareness of child health issues, and the need to contain costs to the health care system have led to the current wave of breastfeeding promotion and awareness campaigns from all sectors of health care. “Breast is Best” is arguably one of the best known health care slogans in our society. Perhaps the movement toward more natural, organic foods, and the sense of distrust and disillusionment with mega-corporations such as Nestle have also contributed to the increasing trend to breastfeed (Baby Milk Action, n.d.; Breastfeeding.com, n.d.; International Baby Food Action Network (IBFAN), n.d.).

Women who are unable to breastfeed for any number of reasons may find themselves dealing not only with an internal sense of failure, but with a societal burden wherein their sense of worthiness as a mother is challenged because they are not doing what they may strongly believe is “best” for their baby. Saisto, Salmela-Aro, Nurmi, and Halmesmaki (2008) found that women who experienced breastfeeding as pleasant suffered less parental stress when their
children were toddlers compared to parents who had difficulty breastfeeding, and Health Canada (2005) has listed “added self-esteem for mother” as a benefit of breastfeeding, and boldly claim that “mothers often like it more than bottle feeding”. This leaves women who are unable or unwilling to breastfeed at risk for feelings of inadequacy and being abnormal. Women may find themselves going to extraordinary lengths to succeed at breastfeeding as a way to prove that they are good mothers (Ryan, Bissell, & Alexander, 2010). The other side of this coin is women who choose to bottle feed against health care provider advice, and are forced to justify this decision in the face of societal pressure to breastfeed (Ryan et al., 2010). It could be argued that this is another reason for perception of breast milk insufficiency, as inadequate breast milk supply might be viewed as an acceptable reason to not breastfeed, giving women a way out of the moral dilemma.

Ryan et al. highlight the moral work that women undergo when making decisions around how to feed their infant with the statement, “They are social and moral actors in both private and public realms, disciplining their bodies and minds to meet social expectations and preserve their social identity and moral integrity while balancing past, present and future self-concepts.” (Ryan et al., 2010, p. 955). In other words, the decision to breastfeed is not simply a private, family matter, but also one made in the public arena and open to public scrutiny and judgement. Mothers of preterm infants and multiples are even more vulnerable to this public and medical pressure as they begin their role as a mother with no privacy, but instead under the “institutional authority” and constant observation (Flacking, Ewald, & Starrin, 2007, p. 2405) of health care providers in the neonatal intensive care unit, where staff are advised to “actively encourage” mothers of preterm and multiples to breastfeed (British Columbia Perinatal Health Program (BCPHP), 2007).
The pressure to successfully breastfeed, from almost all facets of society and
government on both local and global scales has ensured that medications and herbs that induce or
augment lactation have an excellent marketing niche, as well as buy in from both prescribers and
patients. The prescribing of galactagogues has become commonplace, particularly in situations
known to be challenging for breastfeeding, with much of the literature regarding galactagogue
use discussing its use in mothers of preterm infants and multiples (Albright, 2004; Campbell-Yeo
et al., 2010; da Silva, Knoppert, Angelini, and Forret, 2001; Henderson, 2003; Leonard, 2002;
Newman, 2003; Wan et al., 2008), but also in low risk mother baby dyads that have developed
breast milk insufficiency secondary to poor breastfeeding management, poor breastfeeding
support, or medications.

There are a number of reasons for the increasing use of galactagogues, despite the fact
that they really should only be used as a last resort. We live in a society that is accustomed to
medical treatment in all facets of our health, and so readily accept medications as a solution. A
societal discomfort with not knowing how much breast milk a baby is receiving with each feed,
and our perception of babies as chubby and cherubic so that when they are more slender and do
not fit that stereotype, leads to unwarranted concern and a desire to fix a problem that does not
exist. Finally primary care providers may not ascribe the same importance to knowledge of the
normal physiology of breastfeeding as they do to the pathophysiology of disease because of the
perception that this is a natural process. Unfortunately this rather laissez-faire viewpoint, much
the same as that toward herbal and alternative remedies, leads to anecdotal and personal
experience guiding practice rather than evidence, and the subsequently wide variation in practice
with regard to galactagogues that presently exists.
Herbal Galactagogues

There are numerous herbal remedies and recipes used all over the world to increase milk supply. For the purposes of this paper, I have chosen to focus on fenugreek and blessed thistle, the two most commonly recommended herbal galactagogues in Canada (ABM, 2004; Mallory, 2008; Newman, 2003b).

Fenugreek

Fenugreek, or Trigonella foenum-graecum, is native to southern France, Turkey, northern Africa, India, and China (D’ltri, 2006). It is eaten as a vegetable in India and Egypt, and is used extensively in Indian and Chinese medicine for many reasons including induction of labour, help with digestion, to improve overall health and metabolism, as a poultice to treat skin inflammations, to treat abdominal pain, impotence, hernias, fever, vomiting, anorexia, weight loss, coughs, bronchitis, colitis, to decrease serum cholesterol and glucose levels, reduce vasomotor symptoms in perimenopausal women, treat hair loss in both men and women, and as a lactation aid (Abascal & Yarnell, 2008; D’ltri, 2006; Low Dog, 2009; Ulbricht et al., 2007).

While the mechanism of action is not known, it is speculated that the galactagogue effect is related to the herb’s ability to increase sweat production, with the breast being a modified sweat gland (Curtis, n.d.; Gabay, 2002; Huggins, n.d.; Mallory, 2008).

Fenugreek is usually recommended to be taken two to three times per day when used as a galactagogue, however there is little agreement on how much should be taken at each dose, with a range of 400-2400 mg, and acknowledgement that because these are herbal preparations that are not standardized, it is difficult to know for certain what dose the patient is taking at any time (Abascal & Yarnell, 2008; ABM, 2004; Curtis, n.d.; D’ltri, 2006; Gabay, 2002; Huggins, n.d.; Low Dog, 2009; Mallory, 2008; Mohrbacher & Stock, 2003; Newman, 2003b). Most sources
claim that fenugreek may be discontinued once adequate breast milk supply has been established, but there is disagreement in the literature regarding whether fenugreek can be stopped abruptly or should be weaned off over one week (Curtis, n.d.; Gabay, 2002; Huggins, n.d.; Newman, 2003b).

The side effects of fenugreek are described as a maple syrup odour to urine, sweat, and breast milk; diarrhea; aggravation of asthma; and hypoglycemia (ABM, 2004; Curtis, n.d.; D’Itri, 2006; Gabay, 2002; Huggins, n.d.; Mallory, 2008; Tiran, 2003; Ulbricht et al., 2007). The babies of women taking fenugreek can also have urine that smells like maple syrup, and there is some theoretical risk that these babies could be mistakenly diagnosed with maple syrup urine disease (Abascal & Yarnell, 2008; Laurence, n.d.; Low Dog, 2009). Other potential concerns with fenugreek use are allergic reactions, uterine contractions, and an interaction with warfarin that increases its anticoagulation effect. For these reasons it is not recommended in women who are pregnant, diabetic, asthmatic, who have cardiovascular disease, or previous gastrointestinal disease (ABM, 2004; D’Itri, 2006; Gabay, 2002; Tiran, 2003; Ulbricht et al., 2007).

There are two citations referred to often in the literature as preliminary reports that reportedly demonstrate the effectiveness of fenugreek (Co, Hernandez, & Co, 2002; Swafford & Berens, 2000). Unfortunately it was not possible to locate the report by Co, Hernandez, and Co, but Dr. Berens was kind enough to e-mail a copy of the unpublished presentation delivered by herself and Dr. Swafford. Swafford and Berens measured breast milk production in ten women who were at least 14 days postpartum, with infants born 28-38 weeks gestation. The study took place over two weeks. The first week the women pumped and measured the volume of breast milk as a baseline, the second week they took three fenugreek capsules three times daily and measured their breast milk using the same pumps. The average volume of breast milk pumped
daily increased from 207 ml in the first week to 464 ml in the second week. There is no mention of whether this was exclusive pumping, or following a feed, and it is difficult to know how much of this increase can be attributed to fenugreek versus a natural increase based on supply and demand without a control group against which to compare these results.

Another frequently cited study on the use of fenugreek is Huggins (n.d.), who discusses anecdotally that among approximately 1200 women with whom she has worked and who have taken fenugreek, “Nearly all of the mothers…report an increase in milk production, generally within 24-72 hours” (Huggins, n.d.). It is impossible at this point to know if this increase is actual or perceived. Newman (2003b) states, “If they [fenugreek and blessed thistle] do work, you will usually notice a difference within 3 to 4 days…If not, they probably won’t work.” (Handout #24). Laurence notes (n.d.), again anecdotally, that her results with fenugreek have been mixed, with some mothers reporting no change in milk supply and others reporting significant increases.

Fenugreek is listed as Generally Recognized As Safe by the US Food and Drug Administration (US FDA, 2010), and Health Canada (2009c) also has minimal concerns regarding its use although they do not have a list of safe herbs per se and they do not require any safety trials or standardization for fenugreek to be sold in Canada.

**Blessed Thistle**

Blessed thistle, or *Cnicus benedictus*, is an herb that has no listed uses other than as a galactagogue, and it is often recommended to be taken along with fenugreek, with Newman (2003) claiming that the two herbs work better together. Abascal and Yarnell (2008) include a recipe for “More Milk Plus” tincture that contains fenugreek, blessed thistle, stinging nettle, and fennel. The mechanism of action is not listed in the literature so is presumed to be unknown.
The recommended dosage is three capsules three times daily or 20 drops of tincture three times daily. The outcome is suggested to be similar to fenugreek, with increased maternal milk supply noted, albeit subjectively, within 3-4 days (Mallory, 2008; Newman, 2003b). Reported side effects include vomiting and diarrhea when taken in amounts greater than 5 grams per dose. (Mallory, 2008; Newman, 2003b). There were not any studies on blessed thistle found in the literature.

Health Canada (2008a) has a warning on the product monograph for blessed thistle, stating: “Consult a health care practitioner prior to use if you are breastfeeding”, and that it should not be used during pregnancy. This monograph does not list lactation as an indication for use of blessed thistle.

**Other Herbal Galactagogues**

Additional herbs that are mentioned briefly in the literature include: Goat’s rue (*Galega officinalis*); Fennel seed (*Foeniculum vulgare*); Chaste tree seed (*Vitex agnus-castus*); wild asparagus roots (*Asparagus racemosus*); aniseed (*Pimpinella anisum*); fireweed (*Epilobium*); stinging nettle (*Urtica dioica*); caraway seed; cinnamon; dill; raspberry leaf; brewer’s yeast; alfalfa (*Medicago sativa*); cotton root (*gossypium*); borage leaves (*Borago officinalis*); hops (*Humulus lupulus*); basil; marshmallow (Abascal & Yarnell, 2008; ABM, 2004; Low Dog, 2009; Mallory, 2008; Newman, 2003b). These herbs have only anecdotal evidence describing their use as galactagogues.

There is a small study in Peru that examined the effect on human milk production of micronized Silymarin, an extract of milk thistle, that has demonstrated success in increasing milk production in cows. Di Pierro, Callegari, Carotenuto, and Mollo Tapia (2008) noted an increase in breast milk production of 85.95% in the women taking silymarin compared with 32.09% in
the placebo group from day of delivery to day 63 post partum, with no difference in milk composition. The mechanism of action is unknown, although it is hypothesized that there is an effect on estrogen that may increase milk production. There are no known side effects (Di Pierro et al., 2008).

**Alternative Non-Pharmaceutical Galactagogues**

There are two other complementary or alternative methods of augmenting breast milk production that were mentioned frequently in the literature, therefore a brief discussion of the use of alcohol and acupuncture to increase breast milk production is included.

**Alcohol**

Alcohol is considered a galactagogue in many cultures, including North America, and many women report that they were told by their primary care provider that alcohol, particularly barley-based alcohol such as beer, will increase milk production and assist with milk let-down (Giglia & Binns, 2007; Mennella, 2001; Mennella, Pepino, & Teff, 2005). This is despite the fact that there is no evidence to support this theory, and in fact, current research suggests just the opposite.

Mennella (2001) notes that studies have demonstrated that infants consume, on average, 20% less breastmilk in the 3 to 4 hours after maternal alcohol consumption, compared with regular feedings. This is not related to the feeding time, or refusal to nurse, but rather to maternal breast milk production. Alcohol seems to inhibit suckling-induced prolactin production, oxytocin release, and subsequently milk production and infant intake, although it has no effect on baseline prolactin levels (Mennella et al., 2005).
Acupuncture

It was difficult to find English-language studies examining the effect of acupuncture on lactation, however there are Chinese-to-English translated abstracts available that claim to increase milk production using acupuncture (Wang & Li, 2004; Wei, Wang & Han, 2007), although it is difficult to determine how increased milk supply was measured. As well, there have been two recorded case studies of inadvertent induction of lactation following acupuncture treatments in women who were not lactating at the time of treatment (Campbell & Macglashan, 2005; Jenner & Filshie, 2002).

Li’s (n.d.) dissertation on the effect of acupuncture on increasing the milk supply of lactating women claims that traditional Chinese acupuncture increased infant weight gain and decreased need for supplementation with formula. Her assumption is that this weight gain is related to maternal milk production. This was a pilot study consisting of 27 women in a single blind controlled trial. It is unfortunate that maternal milk production was not measured in a more objective manner such as pumping.

Pharmaceutical Galactagogues

The two most frequently discussed pharmaceutical galactagogues in the literature are metoclopramide and domperidone. In Canada domperidone has become the more widely used of the two, because it does not cross the blood-brain barrier and so has fewer central nervous system side effects when compared to metoclopramide.

Metoclopramide

Metoclopramide is a central nervous system dopamine-antagonist that was originally promoted and sold as an antipsychotic in Europe; however it has been most recently used in North America as a gastric motility agent for treatment of nausea, vomiting, and
gastroesophageal reflux (ABM, 2004; Anderson & Valdes, 2007; Betzold, 2004; Brodribb, 2000; Gabay, 2002). The off-label use of metoclopramide as a galactagogue has been reported and studied since 1975 (Anderson & Valdes, 2007). It is frequently described as the most commonly used medication to induce or augment lactation in the US (ABM, 2004; Henderson, 2003). The mechanism of action for metoclopramide with regard to inducing or augmenting lactation is the antagonism of dopamine – known to inhibit the release of prolactin from the anterior pituitary. This dopamine antagonism therefore increases prolactin levels, and subsequently increases breast milk production (Henderson, 2003; da Silva, 2004).

The most commonly prescribed dosage of metoclopramide as a galactagogue is 10 mg orally three times daily (ABM, 2004; Anderson & Valdes, 2007; Henderson, 2003; Hsi & Leeman, n.d.). Possible side effects of metoclopramide include restlessness, anxiety, drowsiness, insomnia, fatigue, lassitude, dizziness, and GI effects such as cramping and diarrhea (ABM, 2004; Betzold, 2004; Brodribb, 2000; Henderson, 2003; Hsi & Leeman, n.d.). Metoclopramide may also increase maternal depression and risk for seizures, and so is not recommended for women with a known history of depression, psychosis, pheochromocytoma, or seizures (Betzold, 2004; Henderson, 2003). This drug can have extrapyramidal side effects, including dystonic reactions (ABM, 2004; Gabay, 2002; Betzold, 2004; Hsi & Leeman, N.D.) and the US FDA has issued a black box warning stating metoclopramide should not be used for longer than 12 weeks at any dosage due to an increased incidence of extrapyramidal side effects with prolonged treatment (US FDA, 2009).

**Domperidone**

Domperidone is approved for use in Canada as a gastrokinetic medication with indications including treatment of motility disorders, nausea and vomiting, headache disorders
associated with nausea and vomiting, gastroparesis, dyspepsia, gastritis, esophageal reflux, and in anorexia and bulimia to relieve bloating and constipation (ABM, 2004; Albright, 2004; Brodribb, 2000; Compendium of Pharmaceuticals and Specialties (CPS), 2010; da Silva et al., 2001; Gabay, 2002; Henderson, 2003; Newman, 2003a). The CPS (2010) does discuss the use of domperidone as a galactagogue, despite no official approval from Health Canada, stating, “[d]omperidone has been used in nursing mothers to improve lactation.” (p. 775).

Domperidone is a dopamine antagonist that does not cross the blood/brain barrier. The mechanism of action with regard to inducing or augmenting lactation is similar to metoclopramide in that it is the antagonism of dopamine – which inhibits the release of prolactin from the anterior pituitary. This dopamine antagonism therefore increases prolactin levels, and subsequently increases breast milk production (Albright, 2004; Betzold, 2004; da Silva, 2004; Gabay, 2002; Henderson, 2003; Hsi & Leeman, n.d.; Newman, 2003a; Ruddock, 2005; Wan et al., 2008).

There are discrepancies in the literature regarding the dosage for domperidone when used as a galactagogue. Recommended dosages range from 10 mg to 30 mg anywhere from two to four times daily (ABM, 2004; Albright, 2004; Anderson & Valdes, 2007; Brodribb, 2000.; da Silva, 2004; Gabay, 2002; Henderson, 2003; Newman, 2003a; Ruddock, 2005; Wan et al., 2008). Wan et al. (2008) tested both 30mg daily and 60mg daily dosing in their study, and found that the 60 mg dose only slightly increased prolactin levels compared to the 30 mg dose, while increasing the incidence and severity of side effects. The CPS (2010) simply notes that “As a galactagogue, domperidone is usually given at an oral dose of 60 to 80 mg daily though 30 mg daily has been used”. (p. 775).
Potential side effects of domperidone include: edema and palpitations (0.5%); headache (1.2%); insomnia, dizziness, thirst, lethargy, irritability, nervousness (< 1%); acute dystonic reactions (rare in adults); skin rash, itching, urticaria (< 1%); breast enlargement, galactorrhea, menstrual irregularities, hot flushes, mastalgia, elevated serum prolactin (1.3%); dry mouth (1.9%); abdominal cramps, diarrhea, regurgitation, appetite changes, nausea, heartburn, constipation (< 1%); stomatitis, conjunctivitis, urinary frequency, dysuria, leg cramps, asthenia, drug intolerance, elevation of AST, ALT, cholesterol (< 1%) (CPS, 2010, p. 775).

The effect of domperidone on prolactin levels and breast milk volume has been studied in two double-blind RCTs with placebo by da Silva et al. (2001), and Campbell-Yeo et al. (2010). da Silva et al.'s study, while small with only 21 women, demonstrated significantly higher prolactin levels and breast milk production in women in the domperidone group compared with women in the placebo group. Campbell-Yeo et al.’s study was slightly larger with 46 participants, and examined mean breast milk volume pumped by mothers of preterm infants randomly assigned to receive either domperidone 10 mg three times daily for two weeks or placebo. “Breast milk volumes increased by 267% in the domperidone-treated group and by 18.5% in the placebo group” (Campbell-Yeo et al., 2010, p. e107). There was no significant difference in breast milk composition when energy, fat, carbohydrate, sodium, and phosphate content were compared in breast milk from the two groups. (Campbell-Yeo et al., 2010). The participants in these studies had all delivered prematurely at 30-31 weeks gestation, and were entered in the study after demonstrating insufficient milk supply at three to five weeks postpartum. Both studies observed steady increases in breast milk volume in participants taking domperidone within 48 hours of initiation of the drug (da Silva et al., 2001; Campbell-Yeo et al., 2010).
Wan et al. (2008) performed a double-blind, randomized crossover trial to examine the effect of dosage of domperidone on milk supply in six women. Breast milk volumes were measured on day 0 and day 7 of the study and were found to be statistically similar between the two groups, however the authors concede that this is likely due to the low power of their study with so few participants. It is interesting to note the authors’ observation of a higher prevalence of side effects such as dry mouth, headache, and abdominal cramping in the group receiving 20 mg three times daily compared with the group receiving 10 mg three times daily.

Finally, Brown et al. (2000) examined the effect of parity on the response of ten non-pregnant women to a single dose of one of the following: metoclopramide 5 mg, or 10 mg, or domperidone 10 mg. The authors found that among nulliparous women metoclopramide 10 mg had a more rapid onset of action and overall higher peak prolactin levels compared with the 5 mg dose or the domperidone. However, among multiparous women there was no difference in onset of action timing or peak prolactin levels between either the two doses of metoclopramide or the domperidone. The authors suggest that parity should be considered when determining which drug/dose to prescribe as a galactagogue. This information may be useful if prescribing galactagogues for nulliparous women who are adopting and wish to breastfeed, however this topic is outside the scope of this paper. The pertinent point for the purposes of this paper is that all 10 women responded with increased prolactin levels to both of these drugs.

In the past decade, domperidone has become widely used in practice in Canada for its off-label use as a galactagogue. While there are no statistics on actual number of prescriptions written for domperidone as a galactagogue, interviews were done with numerous practitioners regarding their own practice. Each of these practitioners, who were either NPs or physicians, had prescribed domperidone as a galactagogue, and had found it to increase milk supply,
however there was acknowledgement that simply increasing milk supply did not always solve the problem of insufficient nutrition in the newborn. It was recognized that other factors often contributed to breast milk insufficiency such as poor breastfeeding technique, and previous maternal breast surgery. Clinicians prescribed domperidone most frequently using the CPS as a resource for determining dosage, with no consensus as to the length of time women should be taking it, and all used infant weight gain as an indicator of efficacy. Domperidone is anecdotally considered a safe drug with an excellent side effect profile and therefore is more likely to be prescribed by practitioners, although most admitted to not having examined any research regarding domperidone as a galactagogue (A. Carter, personal communication, July 20, 2010; C. Lapadat, personal communication, March 12, 2010; C. Evanson, personal communication, June 3, 2010; R. Klepsch, personal communication, March 10, 2010; I. Scrooby, personal communication, July 14, 2010; V. Stafford, personal communication, March 22, 2010).

Domperidone is not approved by the US FDA for any use at all; however women are able to obtain domperidone from other countries such as Canada, or through compounding pharmacies (Wlock, 2006). This prompted the US FDA to issue a warning to women who are using or are considering using domperidone to augment or induce lactation. The warning is based on reported deaths following the administration of domperidone intravenously in patients who were receiving chemotherapy (US FDA, 2004). There have been no reported incidents with the oral route. The drug plasma levels in oral administration are approximately 80 to 150-fold lower than similar doses administered via the intravenous route. Domperidone's bioavailability is only 13% to 18% when administered orally, which is reported to be a marked difference from intravenous administration (Betzold, 2004; Ruddock, 2005). Campbell-Yeo et al. had begun enrollment in their study on domperidone in Canada when the US FDA warning was issued.
While the study was placed on hold briefly, a No Objection Letter was issued by Health Canada October 1, 2004, and ethics approval was reinstated for the study October 5, 2004 (Campbell-Yeo et al., 2007).

Less Commonly-Used Medications

Growth hormone, thyrotropin-releasing hormone, sulpiride, chlorpromazine, recombinant human prolactin, and oxytocin nasal-spray are also briefly mentioned in the literature (ABM, 2004; Gabay, 2002; Sauberan & Wight, 2006), however these are not commonly used as galactagogues, and research is limited, therefore they will not be discussed in this paper.

Summary of Present Research

There is a considerable scarcity of evidence regarding the use of herbal preparations such as fenugreek, however there is a lot of unreferenced, personal anecdotal-based discussion of their use available from a large variety of sources. There have not been any RCTs done with any herbal preparations and the literature review for the use of fenugreek as a galactagogue is a conflicting one with many gaps. Many of the sources did not provide references, evidence, or sometimes even explain the claims that were made. There was not a single study to support the safety or efficacy of blessed thistle as a galactagogue. This may be a result of the mentality that natural products are by their very nature safe and therefore do not require the same rigorous examination that pharmaceuticals are subjected to, which may lead to anecdotal evidence being viewed as satisfactory.

To date the most compelling evidence for an herbal galactagogue comes from the RCT with placebo trial of silymarin, or milk thistle, in Peru (Di Pierro et al., 2008), that enrolled 50 women (higher than many of the pharmaceutical galactagogue studies) and demonstrated increase in milk supply through test-weighing of the infants as well as measured volumes of
breastmilk pumped following feeds. It would be compelling to see these results repeated in further trials.

Current research would suggest that alcohol should not be touted as a galactagogue, that it actually decreases maternal milk production and breast milk intake by infants rather than improving it as is commonly suggested. In fact, more research needs to be done to determine possible effects on the breastfeeding infant who is exposed to alcohol through breast milk, as this may prove to actually be a harmful intervention.

From the limited information currently available, acupuncture may improve maternal breastmilk production and therefore may be a potentially useful galactagogue. The safety profile of acupuncture is also reasonable, provided single-use disposable needles are used (Li, n.d.), with the only identified concern being that it simply may not work. More research with more objective means of determining milk production needs to be done. However, there does not appear to be any reason to actively discourage women from attempting this approach at this time with the proviso that there is limited evidence for the effectiveness of acupuncture in increasing milk supply.

Metoclopramide remains prominent in the US literature, with the abundance of studies done in the 1970’s and 1980’s cited as confirmation of its effectiveness as a galactagogue. However, there have been few recent studies performed and it is not widely used in Canada due to its higher incidence of side effects when compared to domperidone.

The four most recent studies on domperidone use as a galactagogue all demonstrated that domperidone is effective in increasing prolactin levels and breast milk production compared with placebo or with no intervention (Brown et al., 2000; Campbell-Yeo et al., 2010; Da Silva et al., 2001; Wan et al., 2008). These studies were all randomized, which places them in the “good”
level in the hierarchy of evidence (Evans, 2003), and means that the studies focused clearly on the effectiveness of domperidone in increasing maternal milk production, rather than examining its use in clinical practice, or using anecdotal evidence. RCTs are currently considered to be the least biased type of study and to yield the strongest evidence of effectiveness of an intervention (Johnston, 2005). All four studies were single centre studies, and all were relatively small, with participant numbers ranging from six to 46 women. This places them at a level 3 out of 5 on the hierarchy of evidence scale (Ciliska, Thomas, & Buffet, 2008), and suggests that further research with larger numbers of participants with a multi-centre approach would be valuable in confirming efficacy as well as determining risks and side effects.

There has not been any research done regarding the use of domperidone with mothers of older infants. Perhaps this is not a common use of domperidone: certainly the practitioners that were interviewed for this paper only spoke of use during the newborn period. This is not to say that this use does not occur, simply that I was not able to find any information, anecdotal or otherwise, regarding the use of domperidone with older infants.

Analysis of Clinical Practice Guidelines

The guideline from the Academy of Breastfeeding Medicine (ABM) is “Protocol #9: Use of galactagogues initiating or augmenting maternal milk supply”, and is the only clinical practice guideline currently available for clinicians regarding prescribing of galactagogues. Until recently, this guideline was available for viewing on the both the National Guideline Clearinghouse (NGC) and ABM websites, however the NGC has recently removed the guideline from their website. The NGC states that:

Guideline summaries are removed from the NGC Web site because they no longer meet the NGC Inclusion Criteria with respect to date, or because the guideline developer has
indicated that the clinical practice guideline upon which the summary is based is obsolete, should no longer be used, or has not yet been replaced with a new/revised guideline. (NGC, 2010)

A critical analysis of this guideline using the Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument (The AGREE Collaboration, 2001), reveals many flaws and gaps, which I will outline below.

The first issue that I uncovered with this critique of the guideline was the lack of multidisciplinary input, despite the wide range of health care providers who would be accessing these guidelines. There is no input from health care professions such as pharmacists, nurses, or lactation consultants despite their obvious role in breastfeeding success. In fact, there were only four people on the committee for these guidelines, and all are fellows with the ABM.

A second concern is the lack of any type of decision-making tool for clinicians, and no patient information handouts. Essentially the guideline consists of a brief summary of research, or expert consensus when no research is available, with no clarification as to how this information should be used in practice. There is a lack of information regarding appropriate follow up for treatment recommendations, expected outcomes, or possible barriers to treatment such as cost and availability.

Finally, several herbal preparations are discussed in the guideline, despite the lack of evidence of their safety or efficacy. The references for the herbal recommendations are the anecdotal references discussed earlier in this paper (Co, Hernandez, and Co, 2002; Huggins; n.d.; Low Dog, 2001; Swafford & Berens, 2000), and the Huggins reference is the only one easily accessible online. The presentation by Low Dog is no longer available (T. Low Dog, personal communication, June 7, 2010), and there is no contact information for Co et al.: however, I was able to obtain the Swafford and Berens paper via personal communication. The inability to
actually find the references used does not seem appropriate for a clinical practice guideline, and the use of these references could lead the undiscerning practitioner to assume that there is evidence to support the use of these herbal preparations, when in fact this is not the case.

Despite these flaws, the ABM guideline is cited in the Fraser Health Breastfeeding Guidelines (Fraser Health Authority, 2008), and in much of the literature (Hsi & Leeman, N.D.; Mallory, 2008; Marasco, 2007; Shealy, Li, Benton-Davis, and Grummer-Strawn, 2005). There are no Canadian CPGs, but much of the recent research on galactagogues has come from Canada (Brown, et al., 2000; Campbell-Yeo et al., 2010; Da Silva et al., 2001).

**Implications for Practice**

Galactagogues should not be a first line treatment for possible breast milk insufficiency. The practitioner must first determine whether the insufficient maternal milk supply is a perceived problem or an actual problem. If it is an actual problem then it must be determined which of the three categories of causes is the basis of the problem: primary failed or delayed lactogenesis II; secondary delayed lactogenesis related to breastfeeding management or breast milk transfer issues; or organic failure to thrive, with newborn pathology. There are no guidelines currently available to aid with this determination, nor with what assessments and interventions should take place prior to prescribing galactagogues.

The recommendations that follow reflect the available evidence, and focus on the first several weeks following delivery rather than older infants. There is perhaps an assumption that breast milk insufficiency is more urgent in the initial weeks following birth, when all of the infant’s nutritional needs are expected to be met by breast milk, rather than in older infants who may be consuming solid foods in addition to breast milk. However, it is reasonable to assume that an NP faced with the possibility of decreased breast milk supply in the mother of an older
infant could perform the same assessments and interventions recommended below, with the understanding that congenital newborn conditions are unlikely to appear at this point. Rather, issues of maternal hormonal conditions, the introduction of new maternal medications, or changes in feeding patterns are much more likely.

Assessment of Maternal Milk Supply

So what assessments should be performed by the NP when a woman presents with the chief complaint of “I don’t have enough milk to feed my baby”? The initial issue is whether or not the milk insufficiency is a perceived or actual problem. This is quite easily determined with the following assessments. The infant’s weight should be assessed and weight should be plotted serially on a growth chart to track patterns of weight change. A weight loss of 5-10% can be normal in the first three to four days after birth, however breastfeeding should be assessed when infant has lost more than 7% (BCPHP, 1997; Health Canada, 2007; Mohrbacher & Stock, 2003). The baby should regain birth weight by two to three weeks after birth (BCPHP, 1997; Health Canada, 2007; HealthLink BC, 2009; Mohrbacher & Stock, 2003). Weight gain thereafter should be approximately 120 to 180 grams per week, or 17 to 26 grams per day for the first three to four months of life (BCPHP, 1997; Health Canada, 2007; La Leche League International (LLLl), 2007; Mohrbacher & Stock, 2003).

Second, the output of the baby should be assessed. By day 5, baby should be having at least six wet diapers every day and the urine should be clear or light yellow in colour, not dark or odorous. There should also be two to five quarter-sized bowel movements daily. The baby must also be assessed for signs of dehydration such as lethargy, poor skin turgor, sunken fontanelles, jaundice, dry mucous membranes and eyes, or fever (BCPHP, 1997; Health Canada, 2007; HealthLink BC, 2009; LLLl, 2007; Mohrbacher & Stock, 2003).
Should it be determined that the baby is not gaining weight adequately, does not have sufficient output, and or shows signs of dehydration, it must be determined whether this is an issue of insufficient milk supply or poor milk transfer. The LATCH breastfeeding assessment tool has been found to be a valid tool for assessing breastfeeding latch both in the hospital and community settings, and is recommended to flag women and baby dyads who are at increased risk for early weaning due to nipple discomfort (Riordan, Bibb, Miller, & Rawlins, 2001).

Improper latch can lead to inadequate emptying of the breast, in turn leading to decreased milk production as well as inadequate infant intake (Hurst, 2007). Therefore, a tool to assess latch is an important aspect of primary care breastfeeding management, and should be used to determine adequacy of breastfeeding sessions.

The LATCH tool is a relatively quick measurement of latch that primary health care providers may find helpful in assessing latch and determining if this is the cause of poor infant breast milk intake. Should the nurse practitioner find that the latch score identifies concerns with the latch such as poor infant suck, a tongue-tie, or flat to inverted nipples then this can be further assessed and dealt with by the practitioner. If he or she is not competent or comfortable in this area, then referral to another resource such as a lactation consultant, breastfeeding counselor, or a La Leche League representative should be considered, subject to availability. Discussion of how to correct problems with latch is beyond the scope of this project.

If breast milk transfer is found to be adequate using a latch assessment tool, but the infant is not gaining weight appropriately, or is losing weight, then the issue is more likely to be related to breast milk production, which is estimated to affect 5-15% of breastfeeding women (Hurst, 2007). Hurst notes that primary lactation failure can be related to conditions such as “anatomic breast abnormalities or hormonal aberrations. Insufficient mammary glandular tissue,
postpartum hemorrhage with Sheehan syndrome, theca-lutein cyst, polycystic ovarian syndrome, and some breast surgeries” (Hurst, 2007, p. 590). The process of diagnosing any of these conditions requires a thorough history and physical examination, which should include the details of the pregnancy, labour and delivery. Laboratory tests should be ordered to check for any hormonal irregularities, and the specific tests and assessments will vary depending on what diagnoses are being ruled in or out.

Secondary lactation failure in the first six weeks postpartum can be related to poor latch as mentioned above, as well as the over-use of pacifiers, restrictive feeding schedules rather than baby-led feeding, supplementary feeds, and some maternal medications such as oral contraceptives (Hurst, 2007). Once again, a thorough history that includes a review of all medications and herbs is required to assess for this, along with detailed recall of feeds and use of pacifiers and supplements. Secondary lactation failure can and should be managed with education regarding the use of pacifiers, supplementary feeds, and restrictive feeding schedules and how these can interfere with breast milk production. Maternal medications that are found to be interfering with milk supply should be discontinued if possible, and alternative treatments found.

Primary lactation failure requires treatment of the underlying cause. Treatment of both primary and secondary lactation failure should be accompanied by increased breast stimulation, i.e. infant suckling at the breast and or pumping the breasts, and increased breast emptying to stimulate milk production (Hurst, 2007). Only after these measures have been implemented should the use of pharmaceutical galactagogues be considered, and only with close follow up and re-assessment within two to three days.
**NP Scope of Practice**

The prescribing of domperidone is within the scope of practice for NPs in BC (The College of Registered Nurses of British Columbia (CRNBC), 2010), however the assumption in the scope of practice document is that the domperidone is being prescribed for its approved use as a gastrokinetic medication. So what does the legislation say regarding NP prescribing of medications for off-label purposes, which is to say, prescribing a medication for its side effects rather than its approved purpose?

The CRNBC does not directly address the subject of NPs prescribing medications for off-label uses, however there are examples in grey literature (Keith, 2007) as well as in family NP practice in BC (C. Evanson, personal communication, June 3, 2010; C. Lapadat, personal communication, March 12, 2010; V. Stafford, personal communication, March 23, 2010).

Consulting with the CRNBC NP practice consultant regarding this issue revealed that as long as the standards of practice are met, in this case the standards under section B of the scope of practice document “Prescribing and Dispensing Drugs”, then off-label prescribing is an acceptable practice (CRNBC, 2010; A. Komaryk, personal communication, May 11, 2010). In the UK, NPs may prescribe medications for off-label uses where this is common practice (Drug and Therapeutics Bulletin, 2006). There is no official Health Canada or Canadian Medical Association policy on off-label medication prescribing (Silversides, 2006): however, it is acknowledged that this is common practice. This is mainly due to the logistics of obtaining approval to market a drug for a second purpose, which can take years (Canadian Broadcasting Corporation News, 2008). The US FDA also acknowledges this as common practice among prescribers and recommends that the prescriber must have excellent knowledge of the medication, and that the off-label use of any medication should be evidence-based (2009).
Despite the absence of any actual policies regarding off-label prescribing, there does not appear to be any official reason for nurse practitioners not to prescribe medications for off-label use. This is provided that there are no known contraindications in the patient’s history, that they are practicing within their scope of practice, have an excellent understanding of the pharmacodynamics, pharmacokinetics, expected therapeutic effect, and possible adverse effects of that drug, as well as compelling evidence of the drug’s safety and efficacy when used for this purpose.

Recommendations

There is an abundance of evidence that suggests that well-informed primary care providers with education and training regarding lactation is one of the most important and influential factors in increasing breastfeeding initiation, success, and duration rates (ABM, 2006; Chung et al., 2008; Couto De Oliveira, Bastos Camacho, & Tedstone, 2001; Dennis, 2002; Dyson et al., 2009; Eglash et al., 2008; Gill, Reifsnider, & Lucke, 2007; Hurst, 2007; Porteous, Kaufman, & Rush, 2000; Shealy et al., 2005; Sikorski, Renfrew, Pindoria, & Wade, 2003).

All primary health care providers, including nurse practitioners, should ensure that they have an adequate knowledge base to discuss benefits to mother and baby of breastfeeding, the risks associated with formula feeding, and the current cost of formula in their community. They should have sufficient knowledge to assess breastfeeding technique, in other words, latch and milk transfer, and they should be confident with methods to intervene when there are problems with latch or milk transfer (PHAC, 2002).

I believe that this should be incorporated into the curriculum of all primary health care providers, including nurse practitioners. WHO/Unicef has developed a 20 hour breastfeeding course that teaches health care providers lactation management and The Infant Feeding Action
Coalition (INFACT) Canada offers this course frequently (INFACT Canada, 2010; Unicef, 2009). This course should be included as part of the basic curriculum for nurse practitioners, particularly those in the family and pediatric streams of practice. The importance of breastfeeding as primary health care promotion cannot be overemphasized, and it should be given more time in health care provider education than it currently receives. In my nurse practitioner program, management of breastfeeding problems was simply one of twenty learning objectives in one week of class. This cannot be considered adequate in light of the frequency with which breastfeeding issues such as perceived or actual insufficient milk supply lead to discontinuation of breastfeeding (Millar & Maclean, 2005). There was no information available regarding number of hours spent learning about breastfeeding in other primary care provider courses.

Research should be actively pursued with regard to the most commonly-prescribed galactagogues, domperidone and fenugreek. For the women who demonstrate actual insufficient milk supply, with infants showing nutritional insufficiency when all other causative factors have been ruled out, domperidone may mean the difference between being successful at breastfeeding, or having to supplement with formula. This is of huge importance to these women and families on a personal level, and to Canadians overall as a public health issue. As discussed earlier, the short and long term benefits to mother and baby are significant, and for this reason the use of a safe and effective galactagogue is relevant and important.

What is missing from the recommendations regarding herbal treatments as galactagogues is evidence. There are a number of reasons for this. The first is that companies that market herbal over-the-counter remedies are not required to follow the same rigorous process as manufactured pharmaceuticals. It does not make much sense to spend money on expensive trials
if it is not required in order to sell your product. The second is the perpetual myth that somehow herbal remedies are safer and less toxic than pharmaceuticals. Those who market herbal preparations point out that these herbs have been used for generations, with plenty of anecdotal evidence to back them up. A third is the current organic and natural trend discussed earlier, which favours herbs and supplements, vilifying mega-corporations such as pharmaceutical companies, and encouraging a more natural approach to all aspects of life. What is not considered is the stringent guidelines and safety testing that is required for pharmaceuticals and is not required for herbal remedies. I would suggest that requiring the same standardization and testing for safety and efficacy with herbal products would help NPs to make informed decisions regarding their use, and to offer education and guidance to their patients. NPs, as holistic health care providers, may have a special interest in pushing for these types of regulations at a policy level in Canada.

The lack of research regarding safety of herbal preparations simply means that there is no record of adverse events, not that those event do not occur. People are living longer, and with a better quality of life thanks to pharmaceuticals and the research that they inspire, and this is what many proponents of the natural/organic movement forget. The medications produced must be efficacious, tolerable, and safe, or the pharmaceutical companies do not make any money from them, because health care providers do not continue to prescribe questionable or poorly tolerated medications to their patients.

The promotion of herbs by high profile figures such as Jack Newman help to perpetuate the myth that somehow herbal remedies are safer and less toxic than pharmaceuticals. Jack Newman is a well-respected physician and crusader for breastfeeding, which is admirable, but the complete lack of references or research on his websites and handouts, which are easily
accessible by the public, cannot be overlooked (Newman, 2003a; Newman, 2003b). Herbal preparations such as fenugreek and blessed thistle have not been subjected to the same rigorous testing as pharmaceutical galactagogues and therefore their efficacy, safety, and even recommended dosage have not been agreed upon in the literature (Abascal & Yarnell, 2008; Curtis, n.d.; Health Canada, 2009; Huggins, n.d.; Lagrave, n.d.; Laurence, n.d.; Low Dog, 2009; Marasco, 2007; Mills, Duguo, Perri, & Koren, 2006; Newman, 2003a; Tiran, 2003; Ulbricht et al., 2007)

Alcohol has not shown any efficacy as a galactagogue, and due to potential for side effects for the infant as well as the potential for abuse, using alcohol as a galactagogue should be actively discouraged. Patients should be educated regarding the demonstrated decrease in breast milk consumption by infants whose mothers drink even moderate amounts of alcohol prior to breastfeeding, which suggests alcohol is actually counter-productive as a galactagogue (Mennella et al., 2005).

There is limited evidence regarding acupuncture, but what is available is compelling, and the safety profile is excellent. Further research should be done with regard to efficacy, but as a complementary alternative therapy there is no reason to actively discourage its use.

Metoclopramide does seem to demonstrate effectiveness with increasing prolactin levels, but the increased incidence of side effects, and in particular the ability of metoclopramide to cross the blood-brain barrier and cause extrapyramidal side effects makes it a less-attractive choice. The continued use of metoclopramide as a galactagogue in the US likely has more to do with the difficulty obtaining domperidone and with the FDA warning, than with any practitioner preference for this drug.
The research on domperidone is ongoing, and the drug also appears to have efficacy with regard to increasing prolactin levels and thereby milk supply, however, prolactin levels are only one factor in breast milk production, which is why an adequate knowledge base in lactogenesis and management of common breastfeeding problems as well as how to intervene with them must accompany any pharmaceutical intervention. Larger scale studies would be beneficial, particularly with regard to the safety profile of domperidone in light of the US FDA warning against its use in any capacity. In the meantime, domperidone is commonly used in Canada as a galactagogue, with no reported safety concerns. There is no apparent reason to not use domperidone as the research currently available is compelling, provided that other possible causes of insufficient nutritional status of the newborn have been ruled out or identified and addressed. Cost is not prohibitive at less than two dollars per day for a dosage of 10 mg four times daily (Maclean, 2007). The cost of formula is approximately $2.50 to $3.50 per day depending on the brand (Skelton, 2009), so when one considers the health benefits of breastfeeding compared with formula feeding, using domperidone to increase breastfeeding success is a very feasible intervention, and in fact is a better and less-expensive option than supplementing with formula.

If domperidone is appropriate, then the research to date suggests that a dosage of 10 mg orally three times daily for two weeks is likely to be effective, while minimizing possible side effects (Campbell-Yeo et al., 2010; Da Silva et al., 2001; Wan et al., 2008). Follow up with the mother and baby should involve infant weights, serial plotting on a growth chart, and 24 hour surveillance of the newborn’s output. The frequency of follow up is at the discretion of the NP with consideration to the specific circumstances of each case. The mother must be educated
regarding the feedback mechanism involved in autocrine control of breast milk production, and ensure that her breasts are adequately emptied on a frequent basis to facilitate this.

**Conclusion**

The benefits of breastfeeding in newborns include decreased incidence of infections, allergies, SIDS, and potential improvement in cognitive development (PHAC, 2009; Health Canada, 2005; Health Canada, 2007; Kramer & Kakuma, 2001). Long term benefits for adults breastfed as infants include lower blood pressure, lower cholesterol, lower incidence of obesity and type 2 diabetes mellitus (Horta et al., 2007; Martin et al., 2005). Maternal benefits include decreased incidence of some cancers and osteoporosis, increased weight loss in the postpartum period, and decreased cost. Environmental benefits include no packaging, waste or processing.

These benefits are well-known, and the societal pressure to breastfeed is enormous. This has led to an increase in the request for galactagogues by breastfeeding women and their families, and the NP as primary health care provider should be prepared to prescribe galactagogues appropriately and safely. This requires adequate knowledge of the physiology of breastfeeding, of the causes of lactation failure, and adequate assessment of breastfeeding latch and milk transfer using validated tools. It also requires vigilance with regard to current literature, and critical analysis of all recommendations to ensure that they are up to date, and that the evidence presented is based on adequate and well-done research.

There are no herbal remedies that have been studied adequately enough to recommend their use in primary health care. The two drugs that have been studied and thus far demonstrate efficacy in increasing maternal milk supply are domperidone and metoclopramide. Domperidone is the more commonly used in Canada, due to its decreased incidence of side effects when compared to metoclopramide. The prescribing of domperidone must be
accompanied by counseling regarding breastfeeding technique and the need for baby-led feeding versus scheduled feeding, and avoidance of the use of supplementary feeds or pacifiers. As well, women who are prescribed domperidone should be followed closely, within two to three days, and infants must be watched closely for signs of improving intake, with closely supervised supplementation as required.

Insufficient milk supply is a complicated, multifactorial issue that women should not be expected to cope with alone. This requires intensive follow up with a health care provider that is well-educated and confident regarding breastfeeding assessment and intervention. The perception that breastfeeding is a natural process is possibly one that has led to the extraordinarily poor numbers of women who are able to meet the Health Canada (2004) recommendations for exclusive breastfeeding duration (Millar & McLean, 2005). Domperidone is currently the only galactagogue that demonstrates efficacy along with an acceptable side effect profile, but this drug should not be prescribed haphazardly or without close supervision.

Domperidone should be used when deemed appropriate, with excellent assessment and follow up by an experienced, educated clinician. The best armament the primary health care NP has with regard to perceived or actual breast milk insufficiency is knowledge to ensure that this drug is used appropriately and only when absolutely required. The NP must be able to provide reassurance when no intervention is required, to provide excellent counseling regarding breastfeeding technique, and to confidently prescribe domperidone once the need is determined through thorough assessment. It must also be noted that NPs must support mothers who choose to bottle feed their infants, particularly in the face of societal, cultural, and government pressure to breastfeed.
There is plenty of evidence that support and education from primary health care providers is often all that is required to help women succeed with breastfeeding. Systematic assessment and therapeutic intervention using the algorithm in appendix A when the NP is faced with perceived or actual breast milk insufficiency will help to decrease the unnecessary use of galactagogues in practice, ensure that when they are used the dosage and monitoring of effectiveness is methodical and safe, and help to increase the rate of successful breastfeeding as per the Health Canada recommendations.
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Appendix A: Algorithm for Assessment of Breast Milk Insufficiency in Newborn Period

Clinical Presentation:
Breast Milk Insufficiency

1. Infant Wt gain appropriate?
   - Yes: Reassure mother and follow as per usual.
   - No: Determine Cause

2. Number of voids and stools adequate?
   - Yes: Consider Domperidone.
   - No: Supplement with breast milk substitute.

3. Maternal Milk Production Issue
   - Maternal Endocrine Disorder
     - Diabetes Mellitus
     - PCOS
     - OCP
   - Maternal Stressors:
     - CIS, Prolonged 2nd stage of labour
     - Personal stress
     - Smoking
   - Anatomical Breast Abnormalities

4. Milk Transfer Issue
   - Feeding or supplementation
     - Ensure at least 8 feeds per 24 hrs and gradually remove any supplementing feeds, replace with BF
     - Consult Domperidone.
     - Consider Domperidone.

5. Feeding/Latching Issue
   - Correct poor Latching
     - Feeding: Ensure at least 8 feeds per 24 hrs
     - Consider Domperidone.

6. Inborn Errors of Metabolism
   - May require breast milk substitute.
   - Consider Domperidone.
### Appendix B: Herbal Galactagogues

<table>
<thead>
<tr>
<th>Name</th>
<th>Other Uses</th>
<th>Recommended Dosage</th>
<th>Evidence to Support Use</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenugreek (Trigonella foenum-graecum)</td>
<td>- Labour induction&lt;br&gt;- Improvement of digestion, overall health and metabolism&lt;br&gt;- Treatment of inflammation, abdominal pain, impotence, hernias, fever, vomiting, anorexia, weight loss, coughs, bronchitis, colitis</td>
<td>- Daily dosage recommendations range from 400-2400mg, divided into two or three doses daily&lt;br&gt;- No consensus, and no standardization of dosage in packaging</td>
<td>- No RCTs&lt;br&gt;- One large anecdotal report re: use with over 1200 women&lt;br&gt;- 2 &quot;preliminary reports&quot; given at conferences that are not obtainable</td>
<td>- Maple syrup&lt;br&gt;- Odour to urine, sweat, and breastmilk&lt;br&gt;- Diarrhea&lt;br&gt;- Asthma&lt;br&gt;- Hypoglycemia&lt;br&gt;- Uterine contractions&lt;br&gt;- Increases effect of warfarin</td>
</tr>
<tr>
<td>Blessed Thistle (Cnicus benedictus)</td>
<td>- None, other than as galactagogue</td>
<td>- 3 capsules 3 times daily OR - 20 drops of tincture 3 times daily</td>
<td>- Anecdotal only, no studies</td>
<td>- Vomiting and diarrhea</td>
</tr>
<tr>
<td>Goat’s Rue (Galega officinalis)</td>
<td>- Platelet aggregation inhibition, antibacterial properties, and weight loss</td>
<td>- Taken in tea form: 1 tsp dried leaves in 8 ounces water steeped for 10 min 2-3 times daily OR 1-2 mls of tincture 3 times daily</td>
<td>- Reports of increased milk supply when used in cows&lt;br&gt;- No human studies</td>
<td>- Hypoglycemia&lt;br&gt;- Decreased calcium, albumin, hematocrit, white blood cells, and platelets</td>
</tr>
<tr>
<td>Milk Thistle (Silybum marianum)</td>
<td>- None, other than as a galactagogue</td>
<td>- Taken in tea form: 1 tsp crushed seeds in 8 ounces water steeped for 10 minutes 1-3 times daily.</td>
<td>- Small RCT in Peru demonstrated significant increase in breastmilk production</td>
<td>- No known side effects</td>
</tr>
<tr>
<td>Fennel Seed (Foeniculum vulgare)</td>
<td>- Treatment of: colic in infants, acute and chronic glaucoma, dementia, and dysmenorrhea</td>
<td>- In tea form: 5-7 gms of seeds daily</td>
<td>- No studies on galactagogue effects</td>
<td>- No known side effects</td>
</tr>
<tr>
<td>Chaste Tree Seed (Vitex agnus-castus)</td>
<td>- Treatment of premenstrual syndrome (PMS) and premenstrual</td>
<td>- As a tea, 1 teaspoon of chaste berries in one cup of water 3 times</td>
<td>- No studies that demonstrate effectiveness</td>
<td>- GI upset, dizziness, headache, fatigue, and dry</td>
</tr>
</tbody>
</table>
dysphoric disorder (PMDD)
- treatment for menstrual cycle irregularities, and cyclical breast discomfort

<table>
<thead>
<tr>
<th>Common Recommendation</th>
<th>Evidence to Support Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>daily OR - 2.5 milliliters of tincture three times daily OR -20 to 40 mg per day</td>
<td>mouth - contraindicated during pregnancy</td>
</tr>
</tbody>
</table>

### Appendix C: Alternative Galactagogues

<table>
<thead>
<tr>
<th>Name of Treatment</th>
<th>Common Recommendation</th>
<th>Evidence to Support Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>Barley-based alcohol such as beer will increase milk supply and aid milk let-down reflex</td>
<td>None. Studies show that alcohol decreases suckling-induced prolactin production (not baseline prolactin) and oxytocin release, thereby inhibiting both milk production and milk let-down</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>Acupuncture administered 3 times per week for 2 weeks performed by qualified acupuncture therapist using disposable needles</td>
<td>A single blind RCT showed increased infant weight gain and decreased need for supplementation with formula when acupuncture used to increase maternal milk supply</td>
</tr>
</tbody>
</table>

### Appendix D: Pharmaceutical Galactagogues

<table>
<thead>
<tr>
<th>Drug</th>
<th>Usual Indications</th>
<th>Recommended Galactagogue Dosage</th>
<th>Adverse Effects</th>
<th>Evidence to Support Use</th>
</tr>
</thead>
</table>
| Metoclopramide | - Treatment of delayed gastric emptying  
- Treatment of nausea and vomiting postoperatively | 10 mg orally 3 times daily | - restlessness, anxiety, drowsiness, insomnia, fatigue, lassitude, dizziness, and GI effects such as cramping and diarrhea 
- may also increase maternal depression and risk for seizures 
- Rarely can have extrapyramidal side effects, including dystonic reactions | - Conflicting evidence, with much of the cited research being done before 2000 
- 2 recent studies did not show increase in breastmilk production or infant weight gain with metoclopramide use |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Treatment of nausea and vomiting, gastro paresis, dyspepsia, and esophageal reflux</th>
<th>- wide disparities in dosage, literature notes range of 30-90mg per day in 2-4 divided doses</th>
<th>- dry mouth, abdominal cramping, headache, and diarrhea</th>
<th>-2 double-blind RCTs since 2000 demonstrate significantly increased prolactin levels and breastmilk volume (measured by pumping) in women given domperidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domperidone</td>
<td>- Latest evidence suggests 30mg/day adequate, with larger doses increasing side effects but not therapeutic effect</td>
<td>- Does not cross the blood/brain barrier and breastmilk dose - Latest evidence suggests 30mg/day adequate, with larger doses increasing side effects but not therapeutic effect</td>
<td>- Common local practice is 10-20mg 2-4 times daily</td>
<td></td>
</tr>
<tr>
<td>recombinant human prolactin (r-hPRL)</td>
<td>- None, other than as potential galactagogue (experimental)</td>
<td>- Test subjects were injected subcutaneously once daily for 7 days</td>
<td>- No significant adverse effects observed</td>
<td>- Double-blind, placebo-controlled RCT done in 2007 on non-lactating women demonstrated expressible galactorrhea in test subjects given r-hPRL</td>
</tr>
<tr>
<td>Sulpiride</td>
<td>- Antipsychotic - Not available in Canada</td>
<td>- 50 mg orally 2-3 times daily</td>
<td>- Sedation, weight gain, depression, restlessness, impaired concentration, and extrapyramidal effects</td>
<td>- No studies since 2000, and studies done prior to this found to have methodology-issues</td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>- Antipsychotic</td>
<td>- 25 mg orally 3 times daily for 1 week</td>
<td>- See sulpiride</td>
<td>- No studies available for use as a galactagogue</td>
</tr>
</tbody>
</table>
Appendix E: The LATCH Breastfeeding Assessment Tool

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<th>2</th>
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</table>
| **L:** Latch | Too sleepy or reluctant  
No latch achieved                  | Repeated attempts                        | Grasps breast  
Hold nipple in mouth  
Stimulate suck          |
| **A:** Audible swallowing | None                      | A few with stimulation                               | Spontaneous and intermittent at <24 hours  
Spontaneous and frequent at >24 hours |
| **T:** Type of nipple | Inverted                  | Flat                                         | Everted (after stimulation)                                      |
| **C:** Comfort (breast/nipple) | Engorged  
Cracked/bleeding/large blisters or bruises  
Severe discomfort | Filling                                    | Soft  
Non-tender                 |
| **H:** Hold (positioning) | Full assist (staff holds infant at breast) | Minimal assist  
Teach one side, mother does other  
Staff holds and then mother takes over | No assist from staff  
Mother able to position/hold infant |

(Jensen et al., 1994)