Academy of Breastfeeding Medicine
Annotated Bibliography:
Use of Galactogogues in Initiating or Augmenting Maternal Milk Supply

Abbreviations:

CI: Confidence Interval
ECG: Electrocardiogram
FDA: Food and Drug Administration (of the United States government)
hGH: human Growth Hormone
HOP: Hands-on Pumping
MDV: Mean daily volume (of milk expression)
OR: Odds Ratio
PCA: Post-conceptional age
RCT: Randomized Controlled Trial
SQ: subcutaneously
TRH: Thyrotropin Releasing Hormone
TSH: Thyroid Stimulating Hormone
U.S.: United States of America

Citation	Comment	**Level of Evidence
Background Information		
Anderson P, Valdés V. A critical review of pharmaceutical galactagogues. *Breastfeeding Medicine.* 2007;2(4):229-242.	Systematic review of studies regarding various galactagogues. Selection criteria included study design as well as inclusion of information regarding the type of lactation support provided. Overall, few studies were of sufficient quality to provide meaningful results; the few studies with acceptable quality of design did not provide convincing evidence of effectiveness of galactagogues when skilled lactation support was provided. Considering potential adverse effects of galactagogues, the authors urged caution in the use of these drugs until larger, better quality studies are available.	I
Dennis C-L, Hodnett E, Gallop R, Chalmers B. The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial. *CMAJ*. 2002;166(1):21-28.	Randomized controlled trial to assess effectiveness of peer telephone support upon rates of breastfeeding beyond 2 months postpartum in 256 women. In addition to analyzing data regarding peer support, the study gathered information about reasons for supplementation and cessation of breastfeeding. Over 50% of participants were supplementing at 12 weeks postpartum; the most common reason given was because of insufficient .milk supply. More mothers continued breastfeeding in the peer support group at every time point measured up to 12 weeks.	I
Sjolin S, Hofvander Y, Hillervik C. Factors related to early termination of breastfeeding: a retrospective study in sweden. *Acta Paediatr Scand.* 1977; 66:505-11	Retrospective random sample of all deliveries in 1971 in Upsala Sweden. 298 mothers interviewed between 6-13 months post-partum. The most common reason for terminating breastfeeding among women who terminated breastfeeding before six months (sooner they wished) was that the “milk dried up” (66%).	II-2
Hauck YL, Fenwick J, Dhaliwal SS, Butt J. A Western Australian survey of breastfeeding initiation, prevalence and early cessation patterns. *Matern Child Health J*. 2010. Available at: http://www.ncbi.nlm.nih.gov/pubmed/20077131. Accessed August 12, 2010.	A cross sectional survey of 2,669 women in the hospital and again at 9 weeks postpartum. Of women who had ceased breastfeeding at 9 weeks, the most frequent reason given for stopping was insufficient milk supply.	II-3
Huang Y-Y, Lee J-T, Huang C-M, Gau M-L. Factors	A cross sectional study of 205 women during the birth hospitalization. A low score for “perceived infant	II-3

related to maternal perception of milk supply while in the hospital. *J Nurs Res*. 2009;17(3):179-188.	satiety" was the main factor correlated with mothers' perception of insufficient milk supply.	
Li R, Fein SB, Chen J, Grummer-Strawn LM. Why Mothers Stop Breastfeeding: Mothers' Self-reported Reasons for Stopping During the First Year. *Pediatrics.* 2008;122(Supplement_2):S69-76.	Prospective identification of ~2,500 breastfeeding women who participated in a longitudinal survey of infant feeding practices at 9 time points during the first year. Among 1,323 women who remained in the study until complete cessation of breastfeeding, "perception that their infant was not satisfied by breast milk alone was cited consistently as 1 of the top 3 reasons in the mothers' decision to stop breastfeeding regardless of weaning age (43.5%–55.6%) . . . ."	II-3
Otsuka K, Dennis C-L, Tatsuoka H, Jimba M. The relationship between breastfeeding self-efficacy and perceived insufficient milk among Japanese mothers. *J Obstet Gynecol Neonatal Nurs*. 2008;37(5):546-555.	A cross sectional study of 262 breastfeeding Japanese women in the hospital and at 4 weeks postpartum. Sixty percent of women were using formula at 4 weeks, and 73% of those cited perceived insufficient milk as the reason for supplementation or complete cessation of breastfeeding. Self efficacy explained 21% of the variance in perceptions of insufficient milk.	II-3
McCann MF, Bender DE. Perceived insufficient milk as a barrier to optimal infant feeding: examples from Bolivia. *J Biosoc Sci*. 2006;38(3):341-364.	A cross sectional survey of 836 women in two periurban areas in Bolivia. All women had children under 18 months of age and 98.8% were breastfeeding. Insufficient milk was the main reason given by the few women who never start ed breastfeeding. Throughout the study and in both locations, insufficient milk was in the top three reasons for cessation of breastfeeding and for giving other foods or liquids prior to 4 months. Perceptions of insufficient milk were a significant barrier to breastfeeding in these areas of Bolivia.	II-3
Segura-Millan S, Dewey D, Perez-Escamilla R. Factors associated with perceived insufficient milk in a low-income urban population from Mexico. *J Nutr*. 1994;124:202-212.	Interviews of 165 women recruited during the hospital stay and contacted at 1 week, 2 months and 4 months. Ninety percent of infants received water, herbal teas or both during the first several days after delivery. The most common reason for providing introducing artificial milks or for discontinuing breastfeeding was "maternal report of insufficient milk." Across all time points (1 week to 4 months). Altogether, 80% of women reported perceived insufficient milk during the first 4 months. The authors investigated and discussed multiple variables associated with perceived insufficient milk.	II-3
Murray L (ed): *Physicians' Desk Reference*, 63rd ed. Montvale, NJ: Thomsen Reuters; 2009.	Compendium of U.S. pharmaceutical manufacturers' informational "inserts" that provide drug data regarding pharmacology of the drug, indicated and approved uses, spectrum of activity, dosages, potential adverse effects and contraindications.	III
Hale T, Hartmann P (eds.). *Textbook of human lactation*. Amarillo, TX: Hale Publishing; 2007.	Review of anatomy and physiology of human milk production and maintenance with multiple primary references.	III
Lawrence RA, Lawrence RM. *Breastfeeding: A Guide for the Medical Profession,* 6th Ed, Mosby, St. Louis, 2005.	Review of the normal anatomy and physiology of human milk production and maintenance with multiple primary references.	III
Academy of Breastfeeding Medicine. Use of galactogogues in initiating or augmenting maternal milk supply, 2004. Available at http://www.bfmed.org/Resources/Protocols.aspx (accessed on February 17, 2010).	Review of evidence and expert opinion regarding the use of medications/foods/herbs to stimulate increased milk synthesis. The references contained 6 RCT's for oral metoclopramide, 3 RCT's for oral domperidone, one RCT for oral thyrotropin releasing hormone, 3 RCT's for sulpiride, 2 RCT's for human growth hormone and one RCT for an herbal preparation. Additional references were provided with lesser levels of evidence. Recommendations were given regarding the use of metoclopramide and domperidone as galactogogues among women who had already been evaluated and advised regarding non-pharmacologic methods of increasing milk synthesis.	III
Uvnäs-Moberg K. *The Oxytocin Factor*. Cambridge, MA: Perseus Books; 2003.	A summary of research findings related to the physiology of oxytocin, citing large number of both animal and human studies	III
Gabay, MP. Galactogogues: Medications that induce lactation. *JHL* 2002; 18:274 – 279.	Review article of selected galactagogues. Method is not specified, but this is not a systematic review of the topic.	III

Neville MC, Morton J, Unemura S. Lactogenesis: Transition from pregnancy to lactation. Ped Clin NA 2001; 48(1):35-52.	Review of the normal physiology of lactogenesis with multiple primary references.	III
Emery, MM. Galactogogues: Drugs to Induce Lactation. *JHL* 1996;12:55-57.	Review article of selected galactagogues. Method is not specified, but this is not a systematic review of the topic.	III

Articles Addressing General Information about Milk Expression and Rate of Synthesis		
Becker GE, McCormick FM, Renfrew MJ. Methods of milk expression for lactating women. *Cochrane Database Syst Rev*. 2008;(4):CD006170.	A systematic review of the literature revealed 12 randomized or quasi-randomized related to methods of milk expression. Method of pumping was not associated with contamination, breastfeeding at discharge, fat content of milk or serum prolactin. Maternal satisfaction, adverse outcomes, and economic effects of methods were poorly reported. In terms of milk volume produced, the review cites the above citation by Slusher in saying "mothers appear to obtain greater totoal volumes of milk in six days after birth using the electric or foot powered pump tested compared to hand expression. There was one study with evidence of increased milk volume associated with use of a relaxation tape at one expression during week two postpartum. Conclusions: further research with larger numbers and more comprehensive reporting is needed.	I
Slusher T, Slusher IL, Biomdo M, Bode-Thomas F, Curtis BA, Meier P. Electric breast pump use increases maternal milk volume in African nurseries. *J Trop Pediatr* 2007;53:125-30.	A randomized trial of 65 mothers of preterm infants in Kenya and Nigeria; women were randomized to one of three groups depending upon type of milk expression. Group I utilized a professional type double electric pump, Group II used a non-electric pedal pump and Group III used hand expression. There was a large dropout rate: 25% of recruited participants had babies who died and another 12% either breastfed prior to one week of age or withdrew from the study, for a total of 37% dropout rate. The three methods were introduced at 2 days postpartum in 98% of subjects and the mean length of pumping with recorded values was 8.7 days. The results showed a significantly higher mean maternal milk volume (MMV) with the electric pump method (Group I) than with hand expression (Group III). The pedal pump method (Group II) was associated with an intermediate amount of milk, but it was not statistically different from Group I or Group III. Some areas of potential bias or methodological flaws exist: there was a 27% dropout rate; the sample sizes of each group were small and may not have had sufficient power to determine statistical significance; there is a sentence in the report that indicates that Group I were instructed in a particular method of milk expression that may have biased results upward; and the study received in-kind donations from a breast pump company.	I
Jones E, Dimmock PW, Spencer SA. A randomised controlled trial to compare methods of milk expression after preterm delivery. *Arch. Dis. Child. Fetal Neonatal Ed.* 2001;85(2):F91-95.	A randomized, controlled, sequential trial with crossover, comparing simultaneous (double) pumping with sequential (single) pumping, each with or without massage; outcomes measured were volume of milk pumped and fat content of the milk. 36 mothers of preterm infants completed the study, Simultaneous pumping with massage was associated with the highest mean volume of milk expression, followed by simultaneous pumping with no massage, then sequential pumping with massage and finally, sequential pumping without massage. There was no difference in percentage of fat (fat concentration) within the four groups.	I

Green D, Moye L, Schreiner R, Lemons J. The relative efficacy of four methods of human milk expression. *Early human development*. 1982;6:153.	A quasi-experimental study design of 6 mothers of 2 week old term infants who were exclusively breastfed. Four methods of milk expression were studied with a crossover design and none of the women had previous experience with any of the methods. The pumping sessions were arranged for 5 days during one month; each day there were 4 pumping sessions using various combinations of pump order. Pumping sessions were limited to 10 minutes on each breast. Milk volume and milk creamatocrit were recorded. Results were adjusted for analysis of variance (for factors other than type of pump). The professional type electric pump was associated with the highest volume of milk expressed per 10-minute session than the other methods. The other methods were 2 different hand pumps and hand (manual) expression; there were no differences in milk volume among these three methods. There were no differences in fat content among all 4 methods. Authors conclude that the electric pump may be preferable for women who need to pump for a long period of time, but that the results may not translate to a woman who will initiate lactation by pumping (eg, for a critically ill infant). The sample size of this study is extremely small.	II-2
Bose CL, D'Ercole J, Lester AG et al. Relactation by mothers of sick or premature infants. *Pediatr* 1981; 67:565.	Clinical intervention (lactation support, supplemental nursing system) and clinical research unit administration of TRH (thyrotropin-releasing hormone) with basal and 15/30 min measurements of serum prolactin concentrations, in 7 women attempting relactation (1 adoptive mother). Shorter postpartum interval and less postpartum breast involution correlated with the likelihood of successful relactation and the rapidity of the onset of lactation. Basal prolactin levels and stimulation tests were of no additional predictive value.	II-2
Ohyama M, Watabe H, Hayasaka Y. Manual expression and electric breast pumping in the first 48 h after delivery. *Pediatrics International*. 2010;52(1):39-43.	Eleven mothers of preterm infants underwent a sequential cross-over study between electric breastpump expression versus manual expression. The participants were sequentially allocated to begin with either electric breastpump or manual expression for the first session at 6 hours postpartum. They expressed milk every three hours and alternated the method of expression for seven sessions utilizing each method during the first 48 hours after delivery. Main outcome measures were milk volume and pain assessment scale at each expression. Manual expression resulted in a mean of 2 ml per session, statistically significantly greater than 0.6 obtained by electric pump. However, the electric pump was more comfortable than hand expression.	II-3
Morton J, Hall JY, Wong RJ, et al. Combining hand techniques with electric pumping increases milk production in mothers of preterm infants. *Journal of Perinatol*. 2009;29(11):757-64.	Observational study enrolled 67 mothers of preterm infants less than 31 weeks PCA who were expressing milk. Mothers were instructed in hand expression techniques for obtaining colostrum and as an adjunct to mechanical pumping (hands-on pumping, HOP) during the first eight weeks postpartum. Maternal records of volumes expressed were examined for 2 weeks and 8 weeks postpartum.There were 48 participants with complete records for both 2 weeks and 8 weeks. Maternal age was inversely associated with mean daily volume (MDV) at 2 weeks and and infant PCA was inversely associated with MDV at 8 weeks. Frequency of hand expression of colostrum during the first 3 days was associated with MDV at weeks 2 through 7. Pumping 7 or more times per day was significantly associated with MDV at 2 weeks but not at 8 weeks. MDV at 8 weeks was associated with frequency of electric pumping, pumping session duration, and longest interval between pumping sessions. Study participants, on average, showed a steady increase in MDV over the 8 weeks following birth. The authors concluded that pumping 7 or more times per day was associated with improved establishment of lactation than with maintenance of lactation. Increased frequency of expression of colostrum in the first 3 days was important to the maintenance of lactation.	II-3
Kent JC, Mitoulas LR, Cregan MD, et al. Importance of vacuum for breastmilk expression. *Breastfeed Med.* 2008;3(1):11-19.	23 fully breastfeedijng/breastmilk feeding women underwent an observational trial using various vacuum pressures during milk expression with a professional electric pump. Maximum comfortable vacuum was associated with a greater yield in milk expression than higher or lower values.	II-3
Breastfeeding.com. Expressing breastmilk. www.breastfeeding.com/helpme/helpme_images_expression.html (accessed on February 17, 2010).	A publicly available instructional video regarding hand expression. A number of different women are shown and different techniques are illustrated.	III

Morton J. Internet Video available at Hand expression of breastmilk. http://newborns.stanford.edu/Breastfeeding/HandExpression.html (accessed on February 17, 2010).	A publicly available instructional video regarding hand expression of breastmilk. This video footage illustrates the method of milk expression used in the research project published in Morton's citation, above.	III
Brown RE. Relactation: An overview. *Pediatr* 1977; 60:116.	Review of international situations and techniques for relactation with limited references.	iii

Metoclopromide		
Sakha K, Behbahan A. Training for perfect breastfeeding or metoclopramide: which one can promote lactation in nursing mothers. *Breastfeeding Medicine*. 2008;3(2):120-123.	RCT of 20 mothers with their TERM newborns who were not gaining weight adequately (gained less than 500 g in a month) around one month of age and whose mothers complained of insufficient milk. All dyads were evaluated for breastfeeding techniques and mothers were given a short training course to standardize their techniques and optimize physiologic parameters. The mothers were randomized to placebo or metaclopramide 10 mg orally three times a day for 15 days. 18/20 (90%) of infants gained a mean of 400 g during the two week trial. The training of mothers in breastfeeding technique had a significant impact upon infant weight gain, but there was no statistical difference between the placebo and metoclopramide groups. The authors conclude that counseling women regarding optimal feeding techniques is critical to weight gain and that metoclopramide does not provide any advantage for term infants.	I
Hansen WF, McAndrew S, Harris K, et al. Metoclopramide effect on breastfeeding the preterm infant: A randomized trial. *Obstet Gynecol* 2005; 105:383-399.	Sixty-nine women who planned to breastfeed and who delivered premature infants (24 to 34 weeks post-conceptional age) were recruited. They were randomized to metoclopramide, 10 mg three times a day, or placebo. They started in the first 96 hours postpartum (no selection for volume of colostrum/milk expressed) and continued for 10 days. All subjects received breastfeeding education and support in addition to free provision of a self-cycling double pump. Data was analyzed for intent to treat. At day 17 of the study, there was no significant difference in milk volume between groups. There was no significant difference in median duration of breastfeeding between the groups. There was a 17% dropout rate, Relatively high dropout rate and intent to treat analysis may attenuate differences if they exist.	I
Seema, Patwari AK, Satyanarayana L. An effective intervention to promote exclusive breastfeeding. *J Trop Pediatr* 1997; 43:213-216.	A RCT of 50 women with partial or complete lactation failure (LF) were supported in the process of relactation. The study infants had a mean age of 63 days and mean weight of 2.5kg, indicating that most of the infants had inadequate weight gain after birth. All mothers received peer support and professional assistance with frequent suckling and supplementation at the breast as needed. All bottles and pacifiers were discontinued. The intervention group received metoclopramide in addition to the standard care given to the control group. Complete relactation was achieved in 92% of women, partial relactation in 6% and only 2% failed to relactate whatsoever. There was no difference in measures of relactation between those women who received metoclopramide and those who did not. Authors conclude that relactation is universally achievable with consistent assistance and support of both lay people and professionals; the support team needs to be strongly motivated, patient and persistent in order to provide such support.	I
Ertl T, Sulyok E, Ezer E et al. The influence of Metoclopramide on the composition of human breast milk. *Acta Paediatr Hung* 1991; 31(4):415-422.	RCT of maternal metoclopramide (10 mg tid for 5 days) in 11 treated and 11 control healthy mothers of full-term infants started on the first day postpartum. Maternal metoclopramide treatment augmented milk production without an effect on the prolactin or sodium concentrations of the milk, or infant plasma prolactin concentration on the 5th postnatal day.	I
Kauppila A, Anunti P, Kivinen S, Koivisto M, Ruokonen A. Metoclopramide and breast feeding: efficacy and anterior pituitary responses of the mother and the child. *Eur. J. Obstet. Gynecol. Reprod. Biol.* 1985;19(1):19-22.	RCT (placebo, double-blind) of metoclopramide (10 mg po tid for 3 wks) in 11 treated women and 14 placebo treated women starting 4 to 20 wks after delivery. Metoclopramide significantly increased serum prolactin and milk yield without changing maternal TSH or free thyroxine. Serum concentrations of prolactin, TSH and free thyroxine were similar in both groups and remained unchanged throughout the study.	I

deGezelle H, Ooghe W, Thiery M et al. Metoclopramide and breast milk. *Eur J Obstet Gynecol Reprod Biol* 1983; 15(1):31-36.	Placebo-controlled, double blind RCT of metoclopramide started on first postpartum day at a dose of 10 mg tid for 8 days. Total milk yield was approximately 50% greater in the treated group. Breastmilk composition was similar for both groups except for the amino acid content which indicated a faster rate of transition from colostrum to mature milk in the metoclopramide treated group. HOWEVER, the method of measurement of milk volume was probably not valid: measurement was only one time per day for days 3 – 8.	I
Lewis P, Devenish C, Kahn C. Controlled trial of metoclopramide in the initiation of breast feeding. *British Journal of Clinical Pharmacology*. 1980:217-219.	2 studies: 1- Sub-therapeutic amount of metoclopramide passed into breastmilk in 10 patients given single oral dose of 10 mg on day 7-10 post-partum. 2: RCT (placebo) of metoclopramide (10 mg po tid) from first post-operative day for 7 days in 10 women (10 controls) intending to breastfeed at least 3 months, who underwent elective or emergency cesarean section. No objective or subjective side effects noted. Extensive lactation support for both groups. All 20 mothers successfully established breastfeeding at discharge. Equal discontinuation of breastfeeding at 6 weeks and 3 months in both groups. "Most important conclusion is, therefore, that interest, advice and encouragement are of paramount importance in enabling a woman to establish successful breastfeeding."	I
Guzmán V, Toscano G, Canales ES, Zárate A. Improvement of defective lactation by using oral metoclopramide. *Acta Obstet Gynecol Scand.* 1979;58(1):53-55.	RCT comparing placebo with 20 mg daily metoclopramide, started within 48 hrs postpartum, for 4 weeks in 21 women with a past history of defective lactation. Patients treated with metoclopramide (11) had a persistent elevation of prolactin levels and maintained a good milk supply. Placebo treated women (10) showed an abrupt fall in prolactin and failure of lactation.	I
Kauppila A, Kivinen S, Ylikorkala O. A dose response relation between improved lactation and metoclopramide. Lancet. 1981;1(8231):1175-7.	Placebo-controlled, crossover study of 37 women starting Metoclopramide (5, 10, 15 mg po tid) or placebo 13-110 days post-partum for inadequate milk supply (at least 30% less than normal infant intake). 30 and 45 mg of metoclopramide daily increased both serum prolactin and daily milk yield, whereas 15 mg per day did not. No adverse effects were observed with the infants, but 7 of the women on metoclopramide and 3 women on placebo complained of side effects.	II-1
Toppare MF, Laleli Y, Senses DA, et al. Metoclopramide for breast milk production. *Nutr Res* 1994; 14:1019-1029.	Thirty-two women with preterm or term infants were recruited because of "inadequate daily milk production" (estimated by one-time milk expression). Babies ranged in age from 10 to 120 days of age and 72% received formula supplementation. The women were provided lactation instruction and support for one week prior to treatment with metoclopramide 10 mg every 8 hours for 15 days. A matched control group of exclusively breastfeeding women was selected with similar demographic and perinatal characteristics. The treatment group demonstrated a significant increase in volume of milk expression compared to their baseline values. The control group showed no change over the same period of time. There was no correlation of milk volume with peak prolactin levels.	II-3
Ehrenkrantz RA, Ackerman BA: Metoclopramide effect on faltering milk production by mothers of premature infants, *Pediatrics* 78: 614, 1986.	Evaluation of milk yield and prolactin levels in 23 women delivered of preterm infants started on metoclopramide (10 mg po tid for 7 days, then tapered over 2 days) for low milk supply at a mean of 32 days post-partum, after increasing pumping failed to increase milk supply. Daily milk production significantly increased, as did basal prolactin levels. No major side effects were reported in the women, and no untoward effects were noted in the infants.	II-3
Gupta AP & Gupta PK: Metoclopramide as a lactogogue. *Clin Pediatr* 24(5): 269-272, 1985.	Metoclopramide treatment (10 mg po tid for 10 days) of 12 cases of complete lactation failure (absence of milk flow for at least 7 days) and 20 mothers with partial lactation failure (inadequate milk output with infants requiring supplement), with response (milk output) evaluated 5 and 10 days after starting therapy and, if a positive response, every 2 weeks for 8 weeks. Lactation improved in 67% of mothers with no breastmilk and all of those with inadequate milk output. Improvement persisted after discontinuing treatment. Average time to effect was 3.375 days in mothers with lactation failure and 3.35 days in mothers with partial lactation. No untoward effects in mothers or infants.	II-3

Kauppila A, Arvel P, Koivisto M et al. Metoclopramide and breast feeding: transfer into milk and the newborn. *Eur J Clin Pharm* 1983; 25(6):819-823.	Pharmacokinetics of metoclopramide in 5 mothers/infants with deficient lactation starting 3-9 days after delivery and in 18 mothers 8-12 weeks after delivery at 10 mg po tid for 2 weeks. Milk yield increased. Metoclopramide detected in all milk samples, generally at higher concentration than maternal plasma, but only in the plasma of 1 of 5 neonates studied. Exposure calculated as significantly less than therapeutic dose in children. Plasma prolactin levels in 4 of 7 neonates higher than control children. Plasma thyrotropin normal for all infants.	II-3
Kauppila A, Kivinen S, Ylikorkala O. Metoclopramide increases prolactin release and milk secretion in puerperium without stimulating the secretion of thyrotropin and thyroid hormones. *J Clin Endocrinol Metab* 1981;52(3): 436-439.	17 mothers with poor lactation treated with oral metoclopramide (10 mg tid) for 3 weeks starting 18-141 days post-partum, 1-week pause, then a further 2 weeks. Stimulation tests with IV metoclopramide (10 mg) and TRH (200 μg) done before and at the end of the oral metoclopramide therapy. Oral metoclopramide increased mean plasma prolactin levels and daily milk volumes significantly and caused no significant side effects. Plasma TSH, T_3, and T_4 did not change.	II-3
Tolino A, Tedeschi A, Farace R et al: The relationship between metoclopramide and milk secretion in puerperium. *Clin Exp Obstet Gynecol* 1981;8(3): 93-95.	40 women with insufficient lactation administered metoclopramide (10 mg po tid) for 3 weeks starting 2 weeks post-partum. Significant increase in both serum prolactin levels and milk supply, although the two did not necessarily correlate. No changes in maternal or infant serum T3, T4 and TSH. No side effects noted.	II-3
Sousa PLR, Barros FC, Pinheiro GNM et al: Reestablishment of lactation with metoclopramide. *J Trop Pediatr Environ Child Health* 1975;21: 214.	Short-term clinical trial (6-10 days) of metoclopramide (10 mg every 8 hrs) in 5 healthy primiparous mothers with decreased milk supply for at least 72 hours. None of the infants needed to be weaned and no side effects were observed.	II-3
U.S. Food and Drug Administration. FDA requires boxed warning and risk mitigation strategy for metoclopramide-containing drugs, FDA News Release, February 26, 2009. www.fda.gov/bbs/topics/NEWS/2009/NEW01963.html	The U.S. FDA placed a serious "black box" warning on the informational insert regarding the potential for chronic use of metoclopramide to cause tardive dyskinesia that can persist after cessation of the drug and may be permanent. The longer the drug is used, the greater the risk for tardive dyskenesia.	III
Budd SS, Erdman SH, Long DM et al: Improved Lactation with metoclopramide. A case report. *Clin Pediatr* 1993;32: 53.	Case report of 11 day old readmitted for dehydration and hyperbilirubinemia because of insufficient maternal milk supply. Little response to pumping, Metoclopramide (10 mg po tid) started on postpartum day 18 with increased milk supply noted within 48 hrs. Metoclopramide stopped after 10 days but continued improvement with full exclusive breastfeeding by 34 days post-partum.	III

Domperidone		
Campbell-Yeo ML, Allen AC, Joseph KS, et. Al. Effect of Domeperidone on the Composition of Human Breast Milk. *Pediatrics* 2010;125:e107–e114.	Blinded RCT with placebo control. 46 mothers of preterm infants of less than 31 weeks post-conceptional age who were expressing breastmilk and who met the study's definition of "lactation failure." Over 75% of women were less than 4 weeks postpartum. After 14 days of dompieridone, 10 mg orally, three times per day, the domperidone group had a statistically significant increase in within-subject milk expression compared to placebo group. The domperidone group also had a significantly higher within-subject rise in serum prolactin levels. Two women in the domperidone group did not respond with increased milk volume. Protein, fat, sodium and phosphate values of milk were not altered in the domperidone group, though calcium was increased within subjects in the domperidone group. One woman had mild abdominal cramping. Domperidone is useful in many mothers of preterm infants less than 31 weeks post-conceptional age who are expressing milk and experiencing lactation failure.	I

Wan EWX, Davey K, Page-Sharp M, et al. Dose-effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply, and its transfer into milk. *Br J Clin Pharmacol* 2008; 66(2): 283-289.	Double blind RCT with placebo control. 6 mothers of preterm infants between 24 to 29.4 weeks post-conceptional age and two to three weeks postpartum were expressing insufficient milk volumes of less than 300 g/day. They were studied without medication, followed by a randomized crossover exposure to either 30 mg per day or 60 mg per day of domperidone. Prolactin measurements and drug levels in milk were also studied.One subject withdrew because of severe abdominal cramping. Other side effects included dry mouth, constipation, headache and depressed mood. All side effects were more marked at the 60 mg per day dosage. Two women had no response to domperidone at either dose. Prolactin levels PRE-pumping increased on domperidone, but POST-pumping prolactin levels did not increase. The amount of domperidone in milk was very low, with the relative infant dose less than 0.012% at both 30 mg and 60 mg per day doses. With this very small sample size, the authors concluded that there are "responders" and "nonresponders" in terms of milk volume increase by oral domperidone. They also conclude that if women do not respond to the 30 mg daily dose, they 60 mg daily dose is also unlikely to be effective.The authors expressed an opinion that adverse effects of domperidone on QTc were "grossly overstated."	I
daSilva OP, Knoppert DC, Angelini MM, Forret PA. Effect of domperidone on milk production in mothers of premature newborns: a randomized, double-blind, placebo-controlled trial. *Can Med Assoc J*. 2001; 164:17-21.	16 patients (mothers of preterm infants who were pumping) randomly assigned to receive either domperidone (10 mg po tid) or placebo for 7 days (starting mean day 32-33) with milk volume and serum prolactin levels measured. Mean increase in milk production of 44.5% in domperidone group and 16.6% in the placebo group with significant increase in serum prolactin in domperidone group by study day 5 and fall to baseline level 3 days after the last dose. Domperidone was detected at very low levels in breastmilk.	I
Hofmeyr GJ, Van Iddekinge B, Blott JA. Domperidone: secretion in breast milk and effect on puerperal prolactin levels. *Br J Obstet Gynecol* 1985 Feb; 92:141-144	Double blind RCT of prolactin levels in maternal serum and domperidone levels in breastmilk of 10 mothers whose infants were temporarily unable to take breastmilk, starting from 2-8 days post-partum. There was a significant elevation of serum prolactin 2 hrs after treatment with 20 mg of domperidone. The mean domperidone level in all breastmilk samples during treatment with 10 mg po tid was significantly higher than after a single dose, but also considerably lower than values available for metoclopramide and sulpiride, relative to the therapeutic dosage.	I
Petraglia F, DeLeo V, Sardelli S et al. Domperidone in defective and insufficient lactation. *Europ J Obstet Gynec Reprod Biol* 1985; 19:281-287	Double blind RCT of prolactin levels and daily milk yield in 15 women with a history of prior lactation failure (Group A) and 17 primiparous women with inadequate lactation (milk yields at least 30% lower than normal) at 2 weeks. In both groups, domperidone-treated women always showed baseline prolactin levels and daily milk yield significantly higher than the placebo group. No side effects were noted.	I
Hofmeyer GJ, Van Iddekinge B. Domperidone and lactation. *Lancet* 1983; 1:647	Pilot study to assess safety by measuring levels of domperidone in breastmilk of 2 mothers and comparing serum and milk levels with prior studies levels of sulpiride and metoclopramide. They concluded that domperidone was secreted in considerably lower amounts in breastmilk relative to therapeutic dosage than either metoclopramide or sulpiride and recommend further investigation of domperidone as a lactogogue.	II-1
Straus SM, Sturkenboom MC, Bleumink GS, et al. Non-cardiac QTc-prolonging drugs and the risk of sudden cardiac death. *Eur Heart J.* 2005;26:2007-2012.	Population-based case control study from a longitudinal observational database of over 500,000 people in the Netherlands from 1995 – 2003. The use of any non-cardiac QTc-prolonging drug (eg domperidone) had an increased risk of sudden cardiac death of adjusted OR 2.7 (95% CI of 1.6 – 4.7). The risk of death was highest in women and "recent starters."	II-2
Rossi M, Giorgi G. Domperidone and long qt syndrome. *Curr Drug Saf* 2010. Available at: http://www.ncbi.nlm.nih.gov/pubmed/20394569. Accessed June 16, 2010.	A systematic review from 1966-2010 regarding arrhythmias associated with domperidone administration. Two cases were reported of cardiotoxicity from oral medication. A case - control study from a general practice observational database reported an OR: 3.8 (95% CI: 1.5-9.7) for sudden cardiac death after domperidone exposure. Prescribers should take into account the risk of QT syndrome in domperidone users, particularly in patients concomitantly taking other QT prolonging drugs.	II-3

Djeddi D, Kongolo G, Lefaix C, Mounard J, Leke A. Effect of domperidone on QT interval in neonates. *J Pediatr*. 2008;153(5):663-6.	31 neonates and infants received ECG before and after oral administration of domperidone. QTc prolongation occurred in subjects 32 weeks PCA and olde. The mean increase in QTc was 14 msec, though all QTc intervals remained less than the upper limit of normal of 440 msec. No arrhythmias were detected, Domperidone results in prolongation of QTc in infants over 32 weeks PCA. Though authors recommend pre- and post- dose ECGs, they do not suggest what action be taken with the results.	II-3
Collins KK, Sondheimer JM. Domperidone-induced QT prolongation: add another drug to the list. *J Pediatr* 2008;153(5):596-8.	A review and commentary regarding the arrhythmia-inducing potential of prokinetic agent domperidone. Prolongation of QTc interval is unpredictable but potentially fatal. Authors suggest that clinicians err on the side of caution when prescribing this drug for children or infants.	III
Domperidone and sudden death. Cardiac rhythm disorders: QT interval prolongation. *Prescrire Int* 2008;17(94):67. [Translated from *Rev Prescrire* May 2007;27(283):351	A brief report of 9 cases of cardiac toxicity associated with domperidone administration (route not specified) between 1985 - 2006. Two were QTc prolongation and 4 were torsades de pointes. Authors point out that the efficacy of domperidone is not well established and its use is best avoided for minor GI symptoms.	III
Gongadze N, Kezeli T, Antelava N. Prolong QT interval and "torsades de pointes" associated with different group of drugs. *Georgian Med News* 2007;153:45-49.	A general review of the pathophysiology of drug-induced QTc prolongation. Domperidone and cisapride are mentioned briefly along with other classes of drugs that may combine to exacerbate the problem. The author mentions that erythromycin in concert with cisapride has resulted in cardiotoxicity. General caution is recommended regarding the use of multiple drugs that prolong QTc in a single patient.	III
Pham CP, de Feiter PW, van der Kuy PH, van Mook WN. Long QTc interval and torsade de pointes caused by fluconazole. *Ann Pharmacother* 2006;40(7-8):1456-61.	Case report of one 33 year old woman who was treated with domperidone and IV fluconazole, and developed torsade de pointes. Both drugs were discontinued. When fluconazole was started again subsequently, the woman again experienced torsade de pointes. Lactating women may be taking both drugs, the combination of which may increase the likelihood of cardiotoxicity with arrhythmia.	III
U.S. Food and Drug Administration, FDA Talk Paper: FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production, June 7, 2004, www.fda.gov/bbs/topics/ANSWERS/2004/ANS01292.html	FDA warning of public health risks of Domperidone based on published case reports of cardiac arrhythmias, cardiac arrest and sudden death in patients receiving an intravenous form of domperidone.	III
Newman J. Handout #19: Domperidone, January 1998. Retrieved 11/1/02, from http://bflrc.com/newman/lbreastfeeding/domperid.html	Review and instructional handout for healthcare providers and mothers on the use of domperidone as a lactogogue. No references.	III

Thyrotropin Releasing Hormone		
Peters R, Schulze-Tollert J, Schuth W. Thyrotophin-releasing hormone—a lactation-promoting agent? *Br J Obstet Gynecol* 1991;98(9):880-5.	19 women with inadequate lactation on day 5 postpartum were randomized to thyrotropin releasing hormone (TRH), 0.5 mg of nasal spray four times a day vs placebo nasal spray.They started on day 6 postpartum and received TRH or placebo for 10 full days. The women in the treatment group had a statistically significant rise in milk volume from 142 to 253 g/day. The amount would not be sufficient to fully breastfeed a term infant, however. Prolactin levels rose in the experimental group and fell in the placebo group. There were no increases in TSH, T-4, T-3 or signs of hyperthyroidism in any subjects.	I

Tyson JE, Perez A, Zanartu J. Human lactational response to oral thyrotropin releasing hormone. *J Clin Endocrinol Metab* 1976; 43:760-76.	3 studies: 1-RCT (placebo) of effect of single dose 5 mg oral TRH on prolactin levels. 2-RCT (placebo) beginning 29 days postpartum, 5 mg oral TRH bid for 4 weeks. 3-Intervention at 2 dose levels (5 mg TRH bid and 20 mg bid) in 13 women with lactational insufficiency. Found significant increase in prolactin after single dose TRH. No chronic elevations in maternal Prolactin or TSH, or in infant TSH, and no change in milk composition or infant growth in study 2. Basal prolactin concentrations markedly increased and full nursing restored in 3rd study.	I
Bose CL, D'Ercole J, Lester AG et al. Relactation by mothers of sick or premature infants. *Pediatr* 1981; 67:565.	Clinical intervention (lactation support, supplemental nursing system) and clinical research unit administration of TRH (thyrotropin-releasing hormone) with basal and 15/30 min measurement of serum prolactin concentrations, in 7 women attempting relactation (1 adoptive mother) Shorter postpartum interval and less postpartum breast involution correlated with the likelihood of successful relactation and the rapidity of the onset of lactation. Basal prolactin levels and stimulation tests were of no additional predictive value.	II-2

Sulpiride		
Ylikorkala O, Kauppila A, Kivinen S et al. Treatment of inadequate lactation with oral Sulpiride and buccal oxytocin. *Obstet Gynecol* 1984;;63(1):57-60	RCT of 36 post-partum women with insufficient lactation (mothers were asked to call investigators if they felt their milk supply was low) treated with sulpiride (50 mg po tid) or placebo for 2 weeks, supplemented with buccal oxytocin (100 IU, 300 IU, or 400 IU) or placebo preceding each breastfeeding on day 6th and 14th, and on the 7th and 13th days of oral treatment, respectively. Baseline low milk supply was defined as < 30% of a "normal" milk supply Sulpiride improved inadequate lactation, whereas exogenous oxytocin alone, or together with sulpiride, had no effect on lactation.	I
Aono T, Ari T, Koike K et al. Effect of Sulpiride on poor puerperal lactation. *Am J Obstet Gynecol* 1982; 143:927.	42 primiparous and 54 multiparous women with total milk yields < 50 mL for the 1st 3 post-partum days treated with 100 mg of sulpiride or placebo for 4 days from the 3rd post-partum day. There was a significant increase in milk yield and serum prolactin levels in the sulpiride treated group of primiparous, but not multiparous women. The ratio of primiparous mothers exclusively breastfeeding 1 month after delivery was higher in the sulpiride group (55%) than in the control group (30%), whereas there was no difference between control and sulpiride groups in multiparous women.	I
Ylikorkala O, Kauppila A, Kivinen S et al. Sulpiride improves inadequate lactation. *Br Med J (Clin Res Ed)*. 1982;285(6337):249-51.	28 mothers with inadequate lactation (mothers were asked to call investigators if they felt their milk supply was low) within the 1st 4 months post-partum, in a randomized, placebo-controlled, double-blind trial of sulpiride (50 mg po tid) for 4 weeks. Baseline low milk supply was defined as < 30% of a "normal" milk supply. Mean maternal prolactin levels and milk yield significantly increased in the sulpiride group and decreased in the control group. Three women taking sulpiride complained of mild side effects, but none occurred in the infants.	I

Human Growth Hormone		
Kaplan W, Sunehag AL, Dao H, Haymond MW. Short-term effects of recombinant human growth hormone and feeding on gluconeogenesis in humans. *Metabolism*. 2008;57(6):725-732.	Randomized, controlled blinded trial. Seven lactating women between 6 and 12 weeks postpartum were compared with 6 control women who were not pregnant or lactating. Each woman was randomized to receive either placebo or recombinant hGH during the first week. After a "washout period" of two weeks, the women underwent repeat testing with "other" drug or placebo. Milk volume in the lactating women increased by 25% after administration of 0.05 mg/kg/day of recombinant hGH compared to placebo. The main outcomes of this study were related to hormonal changes and pathways of gluconeogenesis and glycogenolysis in the mothers as the mothers were fasting or fed.	I
Milsom SR, Rabone DL, Gunn AJ, Gluckman PD. Potential role for growth hormone in human lactation insufficiency. *Horm. Res*. 1998;50(3):147-150.	16 women underwent treatment with recombinant hGH for "idiopathic lactation insufficiency" who were breastfeeding healthy infants born at term and up to 16 weeks of age. The women were randomized into three different groups for testing of different doses of recombinant hGH. The maximal response was seen with the 0.2 IU/kg/day dosage and there was a significant increase in volume of 36%. Authors point out that even though this was a positive effect, it would not be enough to completely	I

	eliminate supplementation.	
Gunn AJ, Gunn TR, Rabone DL, et al. Growth hormone increases breast milk volumes in mothers of preterm infants. *Pediatrics*. 1996;98:279-282.	Randomized controlled double blind trial. 10 mothers of preterm infants received human growth hormone (hGH) at a dose of 0.2 IU/kg/day SQ to a max of 16 IU per day, for 7 days. A control group of 10 women received the same volume of placebo. Milk volume increased by a mean of 31% in women treated with hGH while milk volume had no significant increase in the placebo group. There was an increase in all 10 hGH treated women, but a decrease in 4 out of 9 in the placebo group. No adverse effects of hGH were seen in either mothers or infants.	I
Caron RW, Janh GA, Deis RP: Lactogenic actions of different growth hormone preparations in pregnant and lactating rats***. J Endocrinol*** 1994; 142:535.	Study of the capacity of different growth hormone (GH) preparations (natural human GH, recombinant human GH, rat GH, ovine GH, bovine GH and porcine GH, and ovine prolactin, to stimulate lactogenesis in ovario-hysterectomized pregnant rats or intact lactating rats treated with bromocriptine.	I
Milsom SR, Breier BH, Gallaher BW et al. Growth hormone stimulates galactopoiesis in healthy lactating women. *Acta Endocrinol (Copenh)* 1992;127(4):337-343	Double-blind, randomized, placebo controlled trial of recombinant human growth hormone (0.1 IU/kg body Wt/day) or placebo for 7 days in 16 normally lactating women during “early lactation” (8-18 weeks post-partum). Milk volume in the hGH group increased 18.5% compared to 11.6% in placebo-treated group. No adverse effects were seen and no major changes noted in milk constituents. The hGH concentrations in milk were low and did not change with therapy. Plasma concentrations of IGF-1 increased significantly with treatment.	I

Herbals		
Damaink R, Wahlqvist ML, Wattanapenpaiboon N. The use of a putative lactogogue plant on breast milk production in Simalungan, North Sumatra, Indonesia. *Asia Pac J Clin Nutr*. 2004; 13(suppl):S118.	Randomized controlled trial comparing two dietary supplements commonly used by breastfeeding women, one of which includes fenugreek, with a plant traditionally used to augment milk volume called Torbangun. The plant increased milk quantity by 10%. No placebo group, not blinded.	I
Mennella JA, Beauchamp GK. Beer, breast feeding, and folklore. *Dev Psychobiol*. 1993;26(8):459-466.	Breastfeeding women were studied on two separate days for a four-hour period following ingestion of either alcoholic or non-alcoholic beer. On both occasions the mothers reported that they had experienced letdown, they felt that milk was still present in the breast at the end of most feedings and that the infant was satisfied with the feeding. The infants consumed a smaller volume of breastmilk following mothers’ ingestion of alcohol. The mechanism for this behavior is not known.	I
Huggins KE. Fenugreek: One Remedy for Low Milk Production. Retrieved 11/1/02 from http://www.breastfeedingonline.com/fenuhugg-print.html	Review article on the historical and current use of fenugreek for lactation augmentation with 11 references.	III
Swafford S, Berens P. Effect of Fenugreek on Breast Milk Volume. Abstract, 5th International Meeting of the Academy of Breastfeeding Medicine, Sept 11-13, 2000, Tucson, AZ.	Observational study of milk production in 10 women who were exclusively breast pumping. Each patient was her own control with daily milk volume measured at baseline for 1 week, then during 2nd week of fenugreek 3 capsules po tid. Fenugreek significantly increased average daily milk volume from 207 ml week 1 to 464 ml week 2.	II-3
Rosti L, Nardini A, Bettinelli ME, Rosti D. Toxic effects of a herbal tea mixture in two newborns. *Acta Pediatr* 1994; 83:683.	Letter to the editor case report of 2 breastfed infants with FTT whose mothers were taking “herbal tea mixtures”. Infants recovered when teas discontinued.	III
McGuffin M, Hobbs C, Upton R, Goldberg A, Eds. *American Herbal Products Association’s Botanical Safety Handbook.* CRC Press, Boca Raton, FL. 1997; p107.	Compilation of research and other reports regarding herbal products.	III
Jellin JM, Gregory PJ, et al. *Natural Medicines Comprehensive Database*. Stockton, CA: Therapeutic Research Faculty; 2009.	A compendium of primary research regarding non-prescription products including herbs and nutritional supplements.	III

Di Pierro F, Callegari A, Carotenuto D, Tapia MM. Clinical efficacy, safety and tolerability of BIO-C® (micronized Silymarin) as a galactogogue. *Acta Biomed* 2008;79:205-210.	50 breastfeeding women were divided into 2 groups to test micronized Silymarin (obtained from the plant *Silybum marianum*) in one group versus placebo in the second group. The groups were matched for demographic factors.No evaluation or standardization was done regarding feeding techniques. The volume of milk yield (feeding plus expressing) per 24 hours was significantly higher at day 30 and at day 63 following Silymarin ingestion compared to placebo. There was no difference in the qualitative analysis of the macronutrients of the milk from mothers who consumed Silymarin versus placebo.	II-1
Capasso R, Aviello G, Capasso F, Savino F, Izzo AA, Lembo F, Borrelli F. Silymarin BIO-C, an extract from Silybum marianum fruits, induces hyperprolactinemia in intact female rats. Phytomedicine. 2009 (9):839-44. Epub 2009 Mar 20.	Serum prolactin levels rose in female rats who received silymarin for 14 days (non-pregnant, non-lactating). Administration of additional silymarin after a break in therapy resulted in additional rise of prolactin. Bromocriptine reversed the effect.	II-3
Low Dog T. The use of botanicals during pregnancy and lactation. *Alt Ther Health Med* 2009;15(1): 54-58.	Excerpted from a book chapter, this review article offers several illustrative cases followed by selected review of the literature. The author gives suggested instructions for herbal preparations of fegugreeek.	III
Kim-Godwin Y. Postpartum beliefs and practices among non-western cultures. *Am J Matern Child Nurs*. 2003; 28(2):74-8.	A review and case report of non-western cultural beliefs that impact upon ethnically diverse women who give birth in the United States. A variety of countries and practices are discussed.	III
Tiran D. The use of fenugreek for breast feeding women. *Complement Ther Nurs Midwifery*. 2003;9(3):155-156.	A brief review of the properties of fenugreek as a galactogogue and a summary of potential adverse reactions to its use, primarily gathered from case reports.	III
Fraschini F, Demartini G, Esposti D. Pharmacology of Silymarin. Clin Drug Invest. 2002;22(1):51-65.	A review of the pharmacology of silymarin, primarily related to its use in blocking hepatotoxicity by other agents.	III
Koletzko B, Lehner F. Beer and breastfeeding. *Adv. Exp. Med. Biol*. 2000;478:23-28.	A review of the literature that explores the effect of beer upon breastfeeding. Although a polysaccharide derived from hops (barley) will raise prolactin levels, the authors conclude that no systematic studies address this issue and that there is no published information that justifies the recommendation of beer to augment milk synthesis.	III

Studies examining multiple medications		
Liu JH, Lee DW and Markoff E: Differential release of prolactin variants in postpartum and early follicular phase women. *J Clin Endocrinol Metab* 71(3): 605-610, Sept 1990.	Measurement of total and variant prolactin levels before and after stimulation with TRH, metoclopramide and morphine infusions in postpartum exclusively breastfeeding women, postpartum bottle-feeding women, women with galactorrhea and non-pregnant women with normal menstrual cycles under controlled conditions in a clinical research unit. TRH, metoclopramide, morphine, sleep and breastfeeding all resulted in increases in prolactin.	I
Co MM, Hernandez EA, Co BG. A Comparative Study on the Efficacy of the Different Galactogogues among Mothers with Lactational Insufficiency. Abstract, AAP Section on Breastfeeding, 2002 NCE, October 21, 2002.	40 mothers pumping for preterm infants with < 100 ml milk on day 2 randomized to metoclopramide, domperidone, malunggay capsules or pumping alone after 48 hr baseline assessed. Milk volume and prolactin levels measured days 3, 7, and 14. Volume of milk day 7 & 14 significantly higher in treated groups (domperidone> metoclopramide> malunggay) No major side effects. No correlation of serum prolactin levels with milk volume.	II-3

Research Issues and deficiencies.

The literature in this area is difficult to interpret. Studies are not standardized for the interval after delivery at the time of intervention. There are few blinded, placebo-controlled randomized trials. In particular, there are virtually no RCT's related to the use of herbal medications despite widespread anecdotal use. In

addition, the studies do not address the reasons milk supply may be low. It is possible that different interventions would have different efficacy depending on the cause of the low milk supply. (Causes could include poor management of breastfeeding, maternal hypothyroidism, history of breast surgery, etc.) There is also no standard "comparison group" for what constitutes normal or ideal milk supply. Despite these deficiencies, it appears clear that both metoclopramide and domperidone are effective and clinically useful as lactogogues.

*US Preventive Services Task Force Ranking of Evidence from Scientific Studies

I	Evidence obtained from at least one properly randomized controlled trial.
II-1	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could be regarded as this type of evidence.
III	Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees.

The Academy of Breastfeeding Medicine
Date: 12-31-2010

The Academy of Breastfeeding Medicine Protocol Committee
Nancy Brent, MD
Maya Bunik, MD, MSPH, FABM
Caroline J. Chantry MD, FABM, *Co-Chairperson*
Cynthia R. Howard MD, MPH, FABM, *Co-Chairperson*
Ruth A. Lawrence, MD, FABM
Kathleen A. Marinelli, MD, FABM, *Co-Chairperson*
Larry Noble, MD, FABM, *Translations Chairperson*
**Nancy G. Powers, MD, FABM
Julie Scott Taylor, MD, MSc, FABM

**Contributor