1 INTRODUCTION

Breastfeeding is recognised worldwide to have many health benefits for mother and baby [1-6]. There is therefore the need to provide effective breastfeeding support to mothers. Low milk supply is a common reason for discontinuing breastfeeding. Timely assessment of breastfeeding and expressing technique can identify reasons for milk insufficiency and optimal non-pharmacological support will usually improve breast milk supply. In women who still have a shortfall in milk supply despite this support, there is evidence [7-15] of domperidone efficacy for this off label indication. It is considered the galactagogue of choice due to its better safety and efficacy profile compared with other agents. Studies have found that very little domperidone is excreted in breast milk and no adverse effects have been reported in infants to date[7-17].

Mothers should receive expert help with breastfeeding technique from a Midwife, Health Visiting Team or at a Breastfeeding Clinic. Domperidone must only be used after non-pharmacological support alone has failed to improve milk supply, and it must be used with and not instead of this support and with regular monitoring thereafter **(See Appendix 2 for referral letter to GPs)**. Mothers must be informed of possible risks and benefits of its off label indication and other treatment options.

2 AIM

To define the evidence and context of domperidone off label indication for the augmentation of lactation in mothers of term and preterm babies across secondary and primary care.

3 INDICATIONS (See Appendix 1 flow chart of guideline):

When non-pharmacological methods have failed to increase milk supply after 1-2 weeks, domperidone can be used in conjunction with non-pharmacological support providing there are no contra-indications:

- in the mother of a baby unable to actively breastfeed due to prematurity / illness
- in a mother who is not meeting the nutritional needs of her baby, that is:-
    - the baby may not be gaining weight appropriately
    - the baby may be requiring formula to gain weight appropriately

3.1 DOSE

10mg three times a day for a maximum of 1 week (s**ee Appendix 1 for flow chart)**

3.2 DURATION

Use for only 1 week (**See Appendix 1 flow chart)**

3.3 RESPONSE

It may take three to four days to notice a significant effect (although some mothers notice an effect within 24 hours) [7-15]. Continued assessment of breastfeeding technique and effective milk removal, positioning and attachment are essential to obtain and maintain increased milk yield. Referral for additional or specialist breastfeeding support is recommended. If there is no increase in milk supply after one week of 10 mg three times a day, the dose should be stopped and preferably advise mother to have another review. Poor response after 1 week of may be due to other confounding factors such as stress, anaemia (FBC), hypothyroidism (TSH) and retained placenta (hCG)[14-17].

3.4 SUPPLY / PRESCRIPTION (SEE APPENDIX 2 FOR REFERRAL LETTER TO GPS):

Domperidone is a “P” medicine and can be sold under the supervision of a pharmacist in Community Pharmacies. This route of supply should not be advocated to patients unless patients are provided with all the relevant support and information to ensure safe and effective care as augmentation of lactation is an off label use of domperidone.

* **For outpatients** it should be prescribed by GPs.
* **For inpatients** it should be prescribed by a senior obstetrician until discharged.

3.5 SIDE EFFECTS

When used as a galactogogue, few side effects were reported and included:

- Mild abdominal cramp, headaches and dry mouth in **mothers**.
- The amount domperidone ingested by the infant through the breast milk is extremely low (< 0.2micrograms/kg/day) and no side effects have been reported in these **breastfed babies**.

When used for its licensed indication, side effects included:[18]

- **Common** dry mouth
- **Uncommon** side effects were loss of libido, somnolence, headache, diarrhoea, rash, pruritus, anxiety/nervousness, breast pain/tenderness
- **Of unknown frequency**: agitation, convulsion, QTc prolongation, urticaria, extrapyramidal disorder, oculogyric crisis, urinary retention, abnormal liver function tests, angiodema."

3.6 CONTRA-INDICATIONS / CAUTIONS/ INTERACTIONS[15-19]:

Avoid domperidone in:

- Women with known cardiac disease (although cardiac effects very rare after oral dose)
- Women with a diagnosis or known family history of pre-menopausal breast cancer[20].
- Active gastro-intestinal haemorrhage or ulcers.
- Mechanical obstruction or perforation.
- Hepatic and/or renal impairment.
- Ketoconazole and erythromycin [21], these drugs can reduce domperidone metabolism and concomitant use theoretically may increase the risk of QT prolongation.
- Antacids and cimetidine can reduce its absorption so avoid taking within 2 hours of these drugs.
- Opiate/opioids can antagonise its effects so be aware of this effect.
- It contains lactose and may be unsuitable for patients with lactose intolerance, galactosaemia or glucose/galactose malabsorption.
- Careful consideration required before use in women with existing or recent history of depression and or anxiety.

Caution with use when treating patients who have existing prolongation of cardiac conduction intervals (particularly QTc); significant electrolyte disturbances; or underlying cardiac diseases such as congestive heart failure. There is some evidence primarily in an older population on long term therapy and or at higher doses (>30mg/day) that domperidone may be associated with an increased risk of serious ventricular arrhythmias[22-23]. **Patients should be advised to seek prompt medical attention if symptoms such as syncope or tachyarrhythmia appear during treatment**.

4 ASSOCIATED DOCUMENTS:

Breastfeeding Assessment Tool – Can be found on the Intranet or UNICEF website.
Breastfeeding support groups – Information for local groups can be found on parentclub website
UK-WHO growth charts - http://www.rcpch.ac.uk/growthcharts accessed Feb 2012

Appendix 1 – Domperidone for augmentation of lactation – Guideline Flowchart
Appendix 2 – Referral letter to GP – domperidone for augmentation of lactation
Appendix 3 - Assessment of breastfeeding, expressing and non-pharmacological breastfeeding support.
Appendix 4 – Active management of breastfeeding (Patient information leaflet)

5. REFERENCES

1 Horta BL et al. Evidence on the long-term effects of breastfeeding. WHO 2007
2 Hoddinott P, Tappin D, Wright C. Breast feeding. BMJ 2008;336:881
3 Ladomenou F et al. Protective effect of exclusive breastfeeding against infections during infancy: a prospective study. Arch Dis Child 2010:16
4 Duijts L et al. Prolonged and exclusive breastfeeding reduces the risk of infectious diseases in infancy. Pediatrics 2010;126:e18-25.
5 Quigley MA et al. Breastfeeding and hospitilization for diarrheal and respiratory infection in the United Kingdom Cohort Study. Pediatrics 2007;119:e837-842.
6 Ip S et al. Breastfeeding and maternal health outcomes in developed countries. AHRQ Publication No 01-E007. Rockville, MD: Agency for Healthcare Research and Quality. 2007
7 Ingram J et al. Metoclopramide or domperidone for increasing maternal breast milk output:a randomised controlled trial. Arch Dis Child Fetal Neonatal Ed 2011
8 Campbell-Yeo ML et al. Effect of domperidone on the composition of preterm human breast milk. Pediatrics 2010;125:e107-114
9 Wan EWX et al. Dose effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply & its transfer into milk. Br J Clin Pharmacol 2008;66(2):283-9
10 Da Silva OP, Knoppert DC, Angelini MM, Forret PA. Effect of domperidone on milk production in mothers of premature newborns: a randomised, double-blinded, placebo controlled trail. CMAJ 2001;164(1):17-21
11 Gabay MP. Galactogogues: Medications that induce lactation. J Hum Lact 2002;18:274–9
12 Petralgia F et al. Domperidone in defective and insufficient lactation. Eur J Obstet Gynae Reprod Biol 1985;19:281-7
13 Hopmeyer GJ, van Idelekinge B. Domperidone and lactation (letter). Lancet 1983:1:647
14 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)
15 UKMi Q&A 73-3. Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011
16 Anderson PO et al. A critical review of pharmaceutical galactagogues. Breastfeeding Medicine 2007;2:229-42.
17 Christine Betzold. Is domperidone safe for breastfeeding mothers? J Midwifery and Women Health 2004;49:151-4
18 Aurobindo Pharma, 2021. Domperidone 10mg Tablets. [online] available from : https://www.medicines.org.uk/emc/product/556/smpc [accessed 28/10/21]
19 Harvey JA et al. Increase in mammographic breast density associated with the use of domperidone. The Breast J 2004: 10 (3):256-8.
20 Robinson P. Dosage and drug interactions of domperidone. Am J Gastroenterol 2008;103 (4):1049
21 Patterson D, Abell T, Rothstein R et al. A double-blind multicenter comparison of domperidone and metoclopramide in the treatment of diabetic patients with symptoms of gastroparesis. American Journal of Gastroenterology 1999; 94(5):1230–1234.
22 Van Noord C. et al. Domperidone and ventricular arrhythmia or sudden cardiac death: A population-based case-control study in the Netherlands. Drug Saf 2010; 33 (11): 1003-1-14.
23 Dewey KG et al. Risk factors for suboptimal infant breastfeeding behaviour, delayed onset of lactation and excess weight loss. Pediatrics 2003; 112: 607-19.

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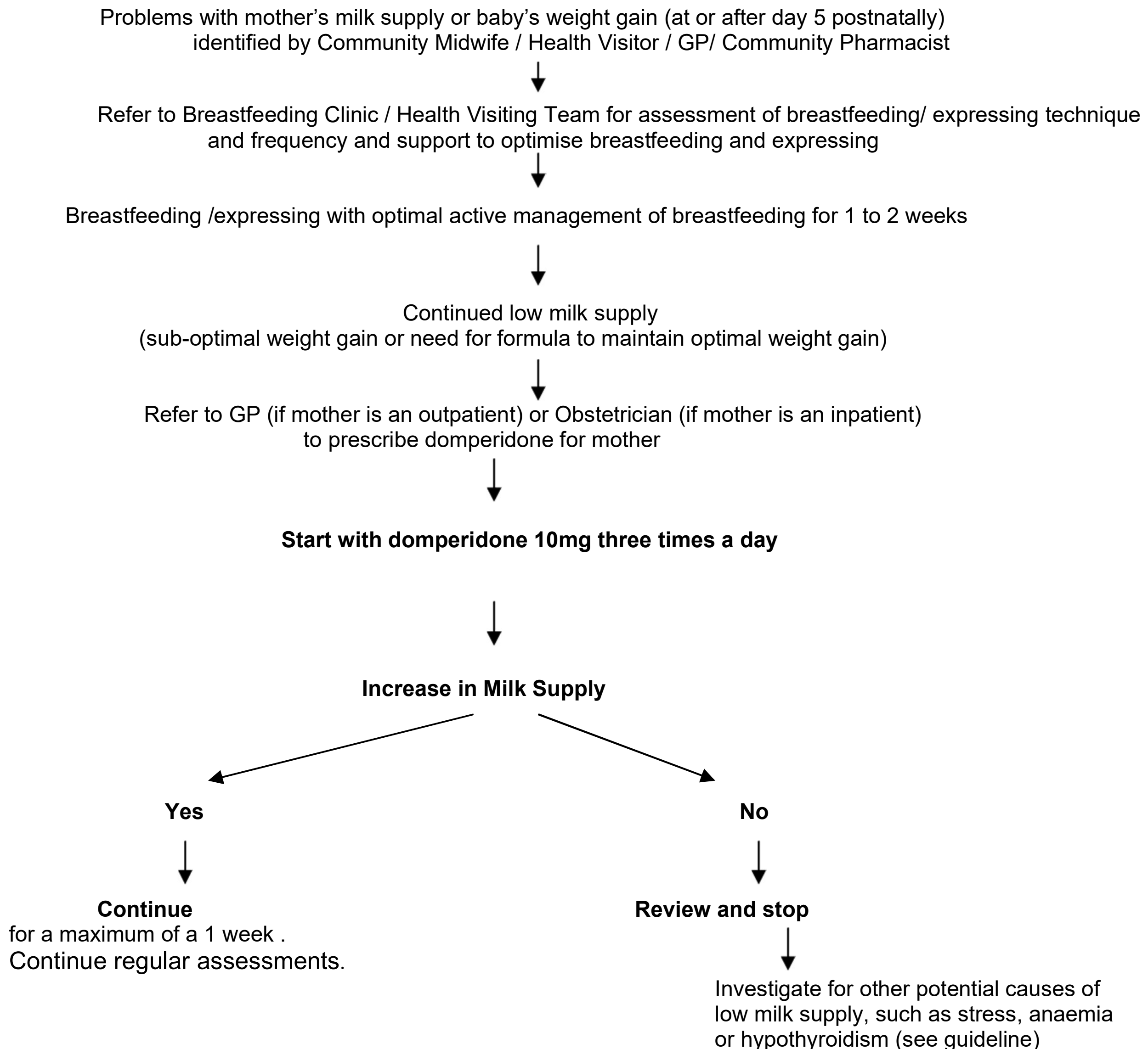
Author 3: Dr Nirmala Mary, Consultant Obstetrician, Women's CMT, NHS Lothian Tel 0131 536 1000 Bleep 4086

Appendix 1

DOMPERIDONE for Augmentation of lactation – Guideline Flowchart

Domperidone should be used only after assessment and improvement of breastfeeding and expressing techniques have failed to increase milk supply adequately (Appendix 3). Domperidone should then be used in combination with these techniques and regular assessment of breastfeeding /expressing. (Appendix 4)



Appendix 2: Referral letter to GP for domperidone for augmentation of lactation

Breast Feeding Clinic/Health Visiting Team
(Address sticker or write contact details)
……………………………………..
……………………………………….
……………………………………….
………………………………………..

Patient Details

Name …………………………………
DOB …………………………………..
Address ……………………………

Breastfeeding Clinics in Lothian-
http://www.nhslothian.scot.nhs.uk/Services/A-Z/BreastfeedingSupport/Pages/default.aspx

GP details
Name………………………………………………….
Address……………………………………………….
…………………………………………………………
…………………………………………………………
…………………………………………………………
…………………………………………………………

Date…………………………………

Dear Doctor……………………

Mrs/Ms ....has been seen at the Lothian Breastfeeding Clinic and/or by her Health Visiting Team for additional support with breastfeeding as her milk supply is not meeting her baby's needs, despite optimal breastfeeding technique and management.

Domperidone has been approved for this off label indication for the augmentation of lactation by the Drugs and Therapeutics Committee and the Lothian Joint Formulary (LJF) in specific situations. **Please see the LJF link (section 7.1) for the "Domperidone for augmentation of lactation" guideline.**

If you decide that there are no contra-indications to the use of domperidone for your patient, we would be grateful if you could assist her by prescribing domperidone 10mg three times a day. If there is no response after one week, then request another review and stop. We advise a total maximum duration of 1 week. We would urge women to have regular assessment at one of the Breastfeeding Clinics to assess their response and support breastfeeding. Domperidone should not be used without optimal support with breastfeeding technique and management.

Attached is the flow chart summary of the approved guideline. Please contact the Maternity Services Lothian staff listed below if you require any further information.

Yours sincerely

(Sign and print)
Health Visiting Team / Lothian Breastfeeding Clinic (delete as appropriate)

Contacts – Dr Nirmala Mary, Consultant Obstetrician (01315361000 then Bleep 4086)
Yvonne Fairholm, Infant Feeding Advisor, (0131 242 2490)
Christine Filion-Murphy, Clinical Pharmacist (01315361000 then bleep 2256)

Appendix 3

1 **Assessment of breastfeeding**
2 **Assessment of expressing technique and frequency**
3 **Non-pharmacological breastfeeding support**

1 ASSESSMENT OF BREASTFEEDING TECHNIQUE

http://www.unicef.org.uk/Documents/Baby_Friendly/Guidance/4/bf_assessment_tool.pdf?epslanguage=en

2 ASSESSMENT OF EXPRESSING TECHNIQUE AND FREQUENCY

Close attention must be given to good expressing technique & frequency of expressing. Breast compression and massage can be used to assist with milk removal during feedings or while pumping. See Stanford University video clip “Maximising milk production with hands on pumping”. In this 10 minute video, Dr Jane Morton explains her research on how breast compression and hand expressing combined with using a breast pump helps mothers to express more milk in less time. http://newborns.stanford.edu/Breastfeeding/MaxProduction.html.

If the infant is unable to breastfeed, or is breastfeeding ineffectively, the mother usually must pump her milk at least 6 - 8 times per day for 15 - 30 minutes with a good quality electric pump. A short-term program of “**Active management of breastfeeding (AMB)” (Appendix 4)** can provide a supportive framework to enable a sustainable cycle of breastfeeding, supplementing, and expressing tailored to the needs of each mother-baby dyad.

3 NON PHARMALOGICAL BREASTFEEDING SUPPORT

About 10% of babies may breastfeed ineffectively in the early weeks of life[23] and if this is not recognised promptly and managed appropriately, it may lead to a low milk supply. Where there is a shortfall in milk supply, the reasons for this need to be recognised and non-pharmacological breastfeeding support offered to improve the situation. These mother and baby dyads may need to use **AMB** techniques **(Appendix 4),** while the baby gradually begins to breastfeed more effectively. AMB combines breastfeeding for a limited time, supplementing with EBM (and/or formula as necessary) and effective expressing of both breasts at each feeding. Mothers need skilled support to implement AMB effectively, and to gradually modify the active management of feeding as the baby’s breastfeeding improves.

Appendix 4

NHS Lothian

Active Management of Breastfeeding

Active management of breastfeeding is an approach to supporting mother and baby with breastfeeding that can help in some problem situations. About 10 per cent of healthy term babies need this kind of support in order to take enough milk in the early weeks of life. Active management can help the mother's milk supply to increase and ensures the baby gets enough milk as he or she gradually begins to breastfeed more effectively. With active management of breastfeeding, most of these babies are breastfeeding well by around six weeks of age.

WHEN is it useful?
The approach can be useful when your baby is still learning how to breastfeed effectively and may have a:

- large weight loss (more than 10 per cent of birth weight)
- slow weight gain (less than 3-4 ounces or 90-120g a week)
- need for supplements of expressed milk or formula in order to gain weight.

It can also be useful when your milk supply needs to increase.

WHAT does it do?
Active management of breastfeeding:

- allows your baby to breastfeed as well as they are able.
- ensures your baby gets as much milk as they need to grow well.
- gives you time for regular expressing to bring in and maintain a good milk supply
- gives you time to relax and enjoy your new baby.

HOW is it done?
At each feed:

1. **Breastfeed** your baby, keeping them actively sucking and swallowing, using switch nursing and breast compression (see below) as needed to keep them feeding well for a maximum of 30 minutes
2. **Supplement** (with milk you expressed at the previous feed – or with formula if needed) by cup, finger feeding or bottle (get help with technique for each of these) until your baby is full. This takes about 15 minutes.
3. **Express** both breasts to get the milk your baby has left behind. This also takes about 15 minutes.

The entire feed (breastfeed, supplement and expressing) will take about one hour

- Your baby will breastfeed as well as they are able.
- Your baby gets the extra milk they need to grow well and to have the energy to feed well.
- You have time to express after each breastfeed to get the milk the baby has left behind, which tells your body to make lots more milk.

WHAT else do parents need to know about active management of breastfeeding?

Feed your baby whenever they give you early feeding cues.
When you are following an active management plan, your baby will need to feed at least six times in 24 hours in order to grow well. If your baby feeds fewer than six times in 24 hours, get help to learn how to help them feed more frequently.

Get help with basic positioning and attachment; **with switch nursing and breast compression**; **and with expressing.**

Switch nursing

- Breastfeed your baby on the first breast, keeping them actively sucking and swallowing (one or two sucks per audible swallow), with short pauses.
- When your baby stops swallowing regularly or falls asleep, take them off the breast, gently rouse them and switch them to the other breast.
- Allow them to feed on the second breast as long as they are actively sucking and swallowing.
- Keep switching as often as necessary to keep your baby actively feeding.

Breast compression
When your baby's regular sucking and swallowing slows down, or if they pause for too long between sucking bursts, place your thumb and fingers either side of your breast a few inches from your baby's mouth, and gently squeeze and release. This will give your baby a little milk, which often causes them to begin swallowing and sucking again.

"Maximising milk production with hands on pumping"
This 10 minute internet video by Dr Jane Morton at Stanford University shows how to express more milk in less time. Search for "Hands on pumping" – it's excellent!

If your baby is making no effort to suck and swallow when they are at the breast
Continue expressing and giving them as much milk as they wish by cup, finger feeding or bottle. Visit a breastfeeding clinic near you (ask your health visitor, midwife, GP or community pharmacist for details) as soon as you are able, to learn about other techniques that can help in this situation.

Gradually reducing active management of breastfeeding
As your baby's breastfeeding improves, you will notice a better sucking pattern – you will hear more swallowing and your baby will need only one or two sucks for each swallow. Your baby will breast feed more eagerly and for longer.
As this happens, many babies begin to take less supplementary milk, and may even refuse a supplement after some feeds. This is a good sign! Your health visitor or breastfeeding specialist will help you to make a plan to gradually reduce the active management and move smoothly to just breastfeeding on its own.

Follow-up
When using active management of breastfeeding, mother and baby will be followed closely by their health visiting team. They will usually visit a breast feeding clinic weekly at first then every two weeks until baby is feeding well, usually at around six to eight weeks of age.