PHARMACOLOGICAL TREATMENT of INADEQUATE LACTATION in BREASTFEEDING MOTHERS – NEONATAL CLINICAL GUIDELINE

1. Aim/Purpose of this Guideline

1.1 To provide information on when it might be appropriate to use drug treatments to improve the failing milk supply of a breast feeding mother.

1.2 This guidance is intended primarily for the infant’s parents and GP but will guide medical, nursing and midwifery staff on the neonatal and postnatal wards.

2. The Guidance

2.1 Background

Insufficient milk supply, although rare, is a common concern and one which causes mothers to stop breastfeeding.

The clearest indicator of an adequate milk supply is normal infant weight loss and then gain, passing soft yellow stools at least twice daily by 5 days and at least 6 heavy wet nappies daily by 5 days.

The most common causes of an inadequate milk supply are:
• poor attachment and/or
• not feeding or expressing frequently enough

If these measures are not successful it may be appropriate for the G.P. to consider drug treatment to start or improve breast milk supply and to support a mother’s wish to breastfeed.  The timing of introduction of medication remains uncertain but, currently, no studies support the use of medications just in case the milk supply dries up.

There are no medicines licensed in the UK for the use of increasing breast milk supply, but there are two medications that increase milk production by increasing the hormone prolactin, as a side effect of their main treatment (usually as a drug for nausea and vomiting).

This Clinical Guideline simply provides the information required for health professionals adequately to support a mother’s wish to continue to breastfeed her baby.  It consists of three pieces of information any of which may be printed to assist in this process.  These are:

1. Increasing your breast milk supply  Shanahan and Heard  RCHT  Jan 2014
   (Appendix 3 – available as Trust Patient Information Leaflet)

2. Letter to Parents/GP  Munyard et al  RCHT  June 2015
   (Appendix 4 - reproduced below and also available as a letter via. Maxims.  Clinicians should be involved in the decision to use it and may consider it a template - modified appropriately and as they feel best suits the patient and the situation.

3. Statement by the National Infant Feeding Network  December 2014
3. Monitoring compliance and effectiveness –

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Appropriate use of the letters</th>
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<tbody>
<tr>
<td>Lead</td>
<td>Philip Dale</td>
</tr>
<tr>
<td>Tool</td>
<td>Discussion with breastfeeding leads – Helen Shanahan and NNU Nurse Lead</td>
</tr>
<tr>
<td>Frequency</td>
<td>Annually</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Neonatal and Obstetric Leads</td>
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<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Philip Dale Neonatal Consultant led guidelines group</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Helen Shanahan and Neonatal Unit Nurses</td>
</tr>
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4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>PHARMACOLOGICAL TREATMENT of INADEQUATE LACTATION in BREASTFEEDING MOTHERS</th>
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<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>MARCH 2016</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>MARCH 2016</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>MARCH 2019</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Philip Dale/Departments of Child Health and Pharmacy</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252590</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Advice sheet and letter to advise parents and GPs on the use of pharmacological agents to stimulate breast milk production.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Newborn. Neonate. Neonatal Lactation; Drug Treatment</td>
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<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>March 2016</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Title unchanged</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Neonatal Unit Consultant led Guidelines Group</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>David Smith</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>None</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</td>
<td>Name: Dr Raj Srikantaiah</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
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PHARMACOLOGICAL TREATMENT of INADEQUATE LACTATION in BREASTFEEDING MOTHERS – NEONATAL CLINICAL GUIDELINE

Related Documents:

5. MHRA. Domperidone: risks of cardiac side effects - indication restricted to nausea and vomiting, new contraindications, and reduced dose and duration of use. Drug Safety Update 2014;7(10):A1
9. UKMi Q&A 73.5 Drug treatment of inadequate lactation October 2014
10. Increasing your breastmilk supply Shanahan and Heard RCHT January 2014

Training Need Identified? No
## Appendix 2. Initial Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed (hereafter referred to as policy) (Provide brief description): PHARMACOLOGICAL TREATMENT of INADEQUATE LACTATION in BREASTFEEDING MOTHERS</th>
<th>Directorate and service area: Women’s and Children’s Health</th>
<th>Is this a new or existing Policy? Existing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of individual completing assessment: Philip Dale</td>
<td>Telephone: Ext 2590</td>
<td></td>
</tr>
</tbody>
</table>

**1. Policy Aim**
Who is the strategy / policy / proposal / service function aimed at?

Aimed at breast feeding mothers and their partners

**2. Policy Objectives**

To provide balanced, supportive information about the potential use of medicines to enhance lactation and to involve the mother’s GP in their prescription

**3. Policy – intended Outcomes**

A better informed mother

**4. How will you measure the outcome?**
N/A

**5. Who is intended to benefit from the policy?**
Mother, neonatal and midwifery medical and nursing staff, GPs

**6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?**

No. Consultant approved guideline

b) If yes, have these groups been consulted?

C). Please list any groups who have been consulted about this procedure.

### 7. The Impact

Please complete the following table.

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
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<tr>
<td>Age</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, transgender / gender reassignment)</td>
<td>√</td>
<td></td>
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</tbody>
</table>

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| Race / Ethnic communities /groups | ✓ |
| Disability - Learning disability, physical disability, sensory impairment and mental health problems | ✓ |
| Religion / other beliefs | ✓ |
| Marriage and civil partnership | ✓ |
| Pregnancy and maternity | ✓ |
| Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian | ✓ |

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.   Yes   No   ✓

9. If you are not recommending a Full Impact assessment please explain why.
Full impact assessment not applicable

This is a document which can only be applicable to breast feeding women and therefore there will be no impact on other groups.

Signature of policy developer / lead manager / director
Philip Dale

Date of completion and submission
1 JUNE 2016

Names and signatures of members carrying out the Screening Assessment
1.
2.

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed Philip Dale

Date 1 JUNE 2016
Appendix 3.

Increasing your breastmilk supply  (Sample Information Leaflet – Trust Patient Information Leaflet available elsewhere)

Concern about lack of milk is one of the three main reasons why mothers give up breastfeeding in the early weeks.

Lack of milk may be perceived – for example, your baby may feed very frequently, perhaps every 2hrs, which is very common in the early weeks but if you had expected the baby to feed 4 hourly, then you may believe that you do not have enough milk or that your milk is not good enough. Please be reassured that as long as baby is feeding frequently enough and effectively, you will produce enough milk and that your milk will always be of the right quality for your baby.

OR you may really not be producing enough milk. The two main reasons for this are

- Poor positioning and attachment
- Not feeding frequently enough

In either or both of these situations, milk is not being adequately removed from your breasts, and so your breasts respond by gradually reducing the amount of milk that is made. Sometimes this has happened in the first hours or days after birth and before you begin to notice an effect on the baby, for example slow weight gain or infrequent wet and dirty nappies.

How to increase your milk supply

The most important thing to remember is that milk is made on a supply and demand basis, so in order to increase the amount of milk being produced, you must increase the amount of milk being removed from your breasts.

1. Improve positioning and attachment, so that it is as good as possible and your baby is feeding effectively. Seek help from your midwife, maternity support worker, health visiting team and local breastfeeding peer support group
2. Make sure that your baby is being fed at least 8 times in every 24 hrs, including at least once at night. Wake and stimulate your baby for extra feeds if he/she is sleepy and not asking for feeds. This may be particularly important if baby is using a dummy, as this may otherwise ‘mask’ feeding cues.
3. Offer your baby both breasts at every feed, to ensure your baby gets as much milk as possible and you get as much stimulation as possible. This means feeding baby on one side until he lets go spontaneously and then, after winding and changing him, if he is still awake and interested, offering the other breast too for him to feed from for as long as he wants.
4. Feed at least once at night – ‘night time breastfeeds make more milk’ because your prolactin (the milk production hormone) levels are higher at night so night time feeds are especially effective at increasing your supply for the coming day
5. Spend as much time as possible skin to skin with your baby
6. Express milk if your baby is not feeding effectively at the breast, so that your breastmilk is removed properly, thus continuing to stimulate more milk to be made.
For the vast majority of mums, taking steps 1-6 as above will be very effective at increasing your milk supply. For a very small minority of women, there are herbal supplements and drug treatments which can be prescribed to increase milk supply, but these should only be used in addition to steps 1-6 and will not be effective at sustaining an improved milk supply unless these other measures are also taken. Please discuss this with your midwife, health visitor, NNU staff or GP if you feel this may apply to you.

There is no evidence to show that eating any particular foods, drinking any special drinks or resting more will make you make more milk. You only need to eat and drink according to your body's hunger and thirst signals. Try to fit in whatever sleep/rest periods you can manage, while feeding/expressing/visiting the baby if on NNU and spending time with the rest of your family.

Sometimes mums are recommended something like 'Tiger milk', to increase their milk supply. This is a smoothie-like concoction of full cream milk, bananas and Brewer’s yeast tablets. There is no evidence that such a recipe will make you produce more milk, although there may be a placebo effect for some mums when they take it. Also, if your baby’s feeds are very frequent or prolonged, you may be eating and drinking very little and may feel hungry and tired so the ‘Tiger milk’ may give you a fluid/calorie boost, but it does not directly improve your milk supply.

Helen Shanahan/ Stephanie Heard
Infant Feeding Co-ordinators
January 2014
Appendix 4

Departments of Pharmacy and Child Health
Royal Cornwall Hospital
TRURO
Cornwall

Dear Parent/Doctor,

Medication to Improve Breast Milk Supply

The staff of the neonatal unit, following adequate discussion with the parents and other health professionals, is always keen to promote breast feeding. Insufficient milk supply, although rare, is a common concern and one which causes mothers to stop breastfeeding.

The clearest indicator of an adequate milk supply is normal infant weight loss and then gain, passing soft yellow stools at least twice daily by 5 days and at least 6 heavy wet nappies daily by 5 days.

The most common causes of an inadequate milk supply are:

• poor attachment and/or
• not feeding or expressing frequently enough

For further advice on these practical supportive measures such as attachment, correct fit of pumps, hand expression etc. see advice from Shanahan and Heard in an RCHT Information Sheet.

If these measures are not successful it may be appropriate for the G.P. to consider drug treatment to start or improve breast milk supply and to support a mother’s wish to breastfeed. The timing of introduction of medication remains uncertain but, currently, no studies support the use of medications just in case the milk supply dries up.

There are no medicines licensed in the UK for the use of increasing breast milk supply, but there are two medications that increase milk production by increasing the hormone prolactin, as a side effect of their main treatment (usually as a drug for nausea and vomiting)

Domperidone (prescription only medicine) produces significant increases in prolactin levels and has proved useful in enhancing lactation including use in mothers of preterm infants and critically ill neonates and for augmentation of lactation after caesarean delivery at full term. Domperidone is generally well tolerated by treated mothers and no adverse effects in breastfed infants have been reported mainly because little drug passes in to the breast milk. Evidence suggests that once sufficient milk production is established it is maintained without the use of domperidone.

There were warnings in the U.S. in 2004 about the use of domperidone in inadequate lactation due to concerns over its effects on the heart rhythm. As discussed above, amounts of the drug in milk are very low and lactation experts did not consider the warnings relevant to its use in inadequate lactation. Similar advice PHARMACOLOGICAL TREATMENT of INADEQUATE LACTATION in BREASTFEEDING MOTHERS – NEONATAL CLINICAL GUIDELINE
has been issued in Europe and the U.K. concerning any patient of any age taking domperidone. It should be used “…..at the lowest effective dose and for the shortest possible duration. The maximum treatment duration should not usually exceed one week.”

Domperidone should not be used where the mother or infant has a cardiac disorder or is receiving treatment with certain drugs known to affect the heart rhythm. Despite the concerns it is probably the drug of choice in these mothers and should be used at a dose of 10 mg three times daily for 1 week.

Metoclopramide (prescription only medicine), like domperidone, increases prolactin levels and has been used in mothers of preterm infants.

The effect depends on the dose and some mothers will not respond. Side effects such as gastric cramping and diarrhoea may limit its use and if no effect is seen within 7 days, it is unlikely that longer therapy will be effective. Metoclopramide is not suitable for women with a prior history of depression. The suggested dose is 10 mg three times daily for 5 to 7 days and then slowly weaning down the dose.

Summary
• A health professional should always be involved in the decision to use medication
• Drugs to manage inadequate lactation should only be used when the diagnosis has become clear and where non-drug methods have failed.
• There are no drugs licensed in the UK to improve lactation.
• As long as the possible cardiac effects are taken into account domperidone is considered to be the agent of choice for inadequate lactation because of lesser side-effects, effectiveness and minimal passage into breast milk.
• Domperidone should not be used for inadequate lactation where the mother or infant has a cardiac disorder or is receiving treatment with drugs known to affect the QT interval e.g. erythromycin, in which case metoclopramide is preferred.
• A maternal daily dose of 30mg domperidone should not be exceeded. The maximum treatment duration should not usually exceed one week.
• There are insufficient data to support the use of herbal remedies.

Drs P Munyard, Y Kumar, M Thorpe, A Collinson (Consultant Paediatricians with a Special Interest in Neonatology)

Mr P Dale (Paediatric and Neonatal Pharmacist)

Royal Cornwall Hospitals Trust