NHS FORTH VALLEY

THE DIAGNOSIS AND TREATMENT OF GASTRO-OESOPHAGEAL REFLUX (GOR) AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) IN INFANTS

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## Consultation and Change Record – for ALL documents

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THE DIAGNOSIS AND TREATMENT OF GASTRO-OESOPHAGEAL REFLUX (GOR) AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) IN INFANTS

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1. Introduction
Gastro-oesophageal reflux (GOR) is a normal physiological process. It affects at least 40% of infants and often begins before the infant is 8 weeks old. It may be frequent i.e. up to 6 episodes or more/day and becomes less frequent over time (resolves in 90% of babies by 1 year old), however this often improves when baby is in a more upright position and on the introduction of solid food. Simple reflux does not usually need further investigation or treatment.

In contrast, gastro-oesophageal reflux disease (GORD) is present when the effects of GOR cause troublesome symptoms and/ or complications.

2. Policy Statement
This guideline has been developed to improve patient care by supporting health professionals in both primary and secondary care to diagnose and treat reflux in infants effectively. It is not intended to substitute clinical judgement.

3. Scope
This guideline is intended to be used by Primary care and Secondary care health professionals who assess infants who present with reflux. The guideline is for use in term infants.
4. Definitions

Infant- child under 1 year of age
Term infant- infant born at ≥ 37 weeks gestation

5. Diagnosis and Management of GOR and GORD

Refer to Table 1 below for the management of GOR and GORD. Please note that infants may not present with all of these symptoms.

Table 1: The symptoms and management of GOR and GORD in infants

<table>
<thead>
<tr>
<th>Presenting Symptoms</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Possetting post feed and between feeds</td>
<td><strong>STEP 1</strong></td>
</tr>
<tr>
<td>• Reluctance to feed/ fussy with bottle</td>
<td>• Reassurance normal behaviour</td>
</tr>
<tr>
<td>• General irritability</td>
<td>• Advise recommended daily intake of formula (&lt;6months old - 150ml/kg per day)</td>
</tr>
<tr>
<td>• Evening colic</td>
<td>• Avoid over feeding/ recommend small frequent feeds</td>
</tr>
<tr>
<td><strong>Symptoms above plus:</strong></td>
<td>• Positioning advice (see Reflux leaflet)</td>
</tr>
<tr>
<td>• Larger frequent vomits</td>
<td>• Provide parent/ carer with Reflux leaflet (Appendix 1)</td>
</tr>
<tr>
<td>• Distressed</td>
<td><strong>STEP 2:</strong></td>
</tr>
<tr>
<td>• Back arching</td>
<td>Breast fed babies:</td>
</tr>
<tr>
<td>• Faltering weight</td>
<td>• Breastfeeding assessment and observation of a breastfeed by a person with appropriate expertise (liaise with Health Visitor)</td>
</tr>
<tr>
<td>• Hoarseness and/ or Chronic cough</td>
<td>For both breast &amp; bottle fed babies:</td>
</tr>
<tr>
<td>• Please note babies with ‘silent’ reflux may present with above symptoms without vomiting</td>
<td></td>
</tr>
</tbody>
</table>

**NB:**
If at any stage the infant is presenting with any of the above symptoms and any of the following:
- frequent and/ or loose stool
- blood in stool
- eczema
- family history of cows’ milk allergy (CMA)
Consider referral to the Paediatric Dietitians for possible CMA.

Management as above plus:
**STEP 2:**

Breast fed babies:
- Breastfeeding assessment and observation of a breastfeed by a person with appropriate expertise (liaise with Health Visitor)

For both breast & bottle fed babies:
- Consider use of Instant Carobell for a trial period of up to 2 weeks (for use and dose see appendix 1)
- If some improvement on Carobell however symptoms remain problematic go to step 3
- If no improvement with Carobell go to step 4

**STEP 3:**
- Continue Carobell and consider 4 week trial of H2 receptor antagonist (H2RA) Ranitidine– see Appendix 2 or BNF for children for dose
- If symptoms improve, continue and review monthly or as required for dosage increase
- If symptoms not controlled go to step 6
STEP 4:  
- Discontinue Carobel and consider use of Infant Gaviscon for up to 2 weeks  
- If some or no improvement on Infant Gaviscon and symptoms remain problematic go to step 5.

STEP 5:  
- Continue Infant Gaviscon and consider 4 week trial of H₂RA (Ranitidine)- see Appendix 2 or BNF for children for dose  
- If symptoms improve, continue and review monthly or as required for dosage increase  
- If symptoms not controlled go to step 6  
(Be aware Infant Gaviscon can be constipating and may require treatment of constipation)

STEP 6:  
- Discontinue Ranitidine  
- Consider 4 week trial of Proton pump inhibitor (PPI) Omeprazole- see Appendix 2 or BNF for children for dose. AND refer to Paediatrician for further management and/or investigations  
- Consider referral to Paediatric Dietitian for possible cow’s milk allergy

IMPORTANT INFORMATION  
- You will notice in the reflux leaflet that the dosage for Instant Carobel differs for bottle or breast fed infants. This is to limit the additional amount of water a breastfed baby would potentially need to take which would compromise nutritional intake. However if a mother is expressing a large quantity of breast milk they can follow the directions for formula fed babies. The dosage recommended in the reflux leaflet differs slightly to the manufacturer’s guidance. This is to make it practical for parents to administer the Instant Carobel. It has been trialled and tested by Registered Dietitians.  
- It is very important that Infant Gaviscon and Instant Carobel are used correctly and consistently to be effective. If either is found to be effective then it should be stopped at regular intervals to see if the infant has recovered  
- Do not use Infant Gaviscon with Instant Carobel or with a thickened infant milk (section 5.2) as it poses risk of obstruction from agglutinated feed
• Do not offer H$_2$RAs or PPIs to treat overt regurgitation in infants occurring as an isolated symptom

• Do not offer metoclopramide, domperidone or erythromycin to treat GOR or GORD without seeking specialist advice and taking into account their potential to cause adverse effects

• If considering a milk change ie to a hydrolysed or amino acid based formula, please refer to Paediatric Dietitian first (the referral will be prioritised and dealt with within 24 hours).

5.1 Red Flag Symptoms

Please note red flag symptoms, which would warrant further investigation and suggest referral to specialist paediatric services (full detail in appendix 3):

• Frequent, forceful (projectile) vomiting
• Bile-stained (green or yellow-green) vomit
• Haematemesis (blood in vomit) with the exception of swallowed blood, for example, following a nose bleed or ingested blood from a cracked nipple in some breast-fed infants
• Onset of regurgitation and/or vomiting after 6 months old
• Blood in stool- consider referral to Paediatric Dietitian for possible cows’ milk allergy
• Abdominal distension, tenderness or palpable mass
• Chronic diarrhoea
• Persistent faltering growth
• Appearing unwell, fever
• Dysuria
• Bulging fontanelle
• Rapidly increasing head circumference
• Altered responsiveness, for example, lethargy or irritability
• Infants with, or at high risk of, atopy
• Recurrent aspiration pneumonia
• Unexplained apnoeas

If you feel the referral is urgent, please contact the on-call Paediatrician via FVRH switchboard (01324 566000).

5.2 Thickened Infant Milks

There are 4 thickened infant milks available:

• Aptamil Anti-reflux (Danone)
• Cow & Gate Anti-reflux (Danone)
• SMA Staydown (SMA Nutrition)
• Enfamil AR (Mead Johnson)
These milks are all available to buy over the counter. Two of them are available on prescription, however if a parent/carer would like to try these then they should be bought (rather than prescribed) after a discussion with a health professional.

Adding Carobel to standard formula milk is favoured over using thickened infant milk. This is due to several disadvantages of the thickened infant milk:

- The viscosity of the milk cannot be altered like with Carobel
- SMA Staydown and Enfamil AR both thicken in the stomach due to the acidity, therefore they cannot be used with acid reducing medicines
- Manufacturer guidance on how to prepare these milks do not follow current UK guidance on making up infant formula safely as they suggest using cold or hand-hot water rather than water that is above 70°C.

6. Useful information:

Leaflets produced for the guideline:

- Reflux- information for parents and carers
- Weaning a baby with reflux- information for parents and carers
- Ranitidine parent leaflet:
  
http://www.medicinesforchildren.org.uk/ranitidine-for-acid-reflux

7. References

8. Appendices

Appendix 1: Reflux leaflet for parents/carerers

What is Reflux?

Gastro-oesophageal Reflux (GOR), also known as reflux, is when the stomach’s contents come back up into the food pipe (oesophagus). It is very common in babies and if it is mild then it is normally left untreated. If it is a big problem, then there are possible ways to fix this which are discussed in this leaflet.

Symptoms vary greatly but may include:

♦ Vomiting
♦ Refusing to feed/ only taking small amounts due to pain when feeding
♦ Hoarseness and/or a cough lasting a long time
♦ Weight loss or poor weight gain if vomiting is present
♦ Irritable/ unsettled during and/or between feeds
♦ Back arching

Babies can have 1 or a combination of these symptoms. Reflux often improves at around 6 months and normally resolves by about 1 year of age.

How can it be managed?

There are a range of things that can help in the treatment of reflux. These include:

♦ Making feeding time calm and quiet
♦ Don't bounce your baby after feeding
♦ Keep your baby upright after feeding for as long as possible (at least 30 minutes)
♦ Try smaller more frequent feeds
♦ Avoid fast flowing teats to prevent your baby choking or gulping too quickly
♦ If breastfeeding, your Health Visitor may carry out a breastfeeding assessment and observe a breastfeed. She can provide suggestions of different feeding positions

What else can help?

If these practical tips have not helped, a milk thickener should be tried. These thicken the milk with the aim of reducing vomiting.

In Forth Valley, Instant Carobel is the preferred thickener used for bottle and breast fed babies.

It can be prescribed by your baby’s GP.

How to use instant carobel

It is recommended that the Carobel is introduced slowly to see how much is needed to settle the reflux. As the feed becomes thicker, a faster flow or variable teat may be required.
Formula fed infants:

Formula should be made as per manufacturer’s instructions and Carobel added as below – shake for 30-60 seconds and then leave for 3-4 minutes – shaking again before feeding.

Day 1- add ½ scoop Carobel (supplied in pack) per 90ml (3oz) formula milk
Day 2- add ¾ scoop Carobel per 90ml (3oz) formula milk if needed
Day 3- add 1 scoop Carobel per 90ml (3oz) formula milk if needed

This can increase up to a maximum of 1½ scoop per 90ml (3oz).

Remember to add Carobel to every bottle feed.

NB: The Carobel should be added to the milk once it has been cooled (cold or hand warm). Always use the smallest amount of Carobel required.

Breast fed infants:

Give from a sterilised teaspoon, syringe, open cup or bottle before each breastfeed (up to a maximum of 8 times daily). Breastfed babies can cluster feed (commonly in the evening) - you do not have to give before every feed when baby is cluster feeding.

Day 1- add ¼ scoop Carobel (supplied in pack) to 10ml cool boiled water or Expressed Breast Milk (EBM)
Day 2- add ½ scoop Carobel to 20ml cool boiled water or EBM if needed
Day 3- add 1 scoop Carobel to 40ml cool boiled water or EBM if needed

CAUTION- For a very young baby (less than 8 weeks), mix the Carobel with EBM not cooled boiled water, as this is too large a volume of water to give and would fill the baby up. If you are both breast and formula feeding then you can mix the Carobel with formula milk and give before breast feed.

Other Medicines

Infant Gaviscon and Ranitidine can be used to treat reflux in both breast fed and formula fed babies. These medicines may be considered if Carobel is not working after using it as prescribed for 2 weeks.

Infant Gaviscon and Carobel should NEVER be used together as they can thicken formula too much and become a choking risk.

All of these medicines should be stopped every now and again to see if your baby still needs it. Discuss this with your GP or Health Visitor.

Thickened Infant Milk

Some formula milks are available, which have added thickeners. They cannot be used with Infant Gaviscon and some of them cannot be used with acid reducing medicines like Ranitidine.

One of the disadvantages of these milks is that they can only be made to one level of thickness, unlike when Carobel is added to milk.

If you are considering buying one of these milks, please discuss this with your Health Visitor or GP first.
What happens if none of these treatments work?

Speak with your baby's GP or Health Visitor for further treatment options.

If your baby is on maximum treatment for reflux and is still having symptoms, then prescribed formula milk may be tried.

Your baby may be referred to the Dietitian for further assessment and advice.
Appendix 2: Dosage of Anti-reflux Medicines

These dosages are correct at the time of writing this guideline. Please refer to the up to date BNF for Children which can be found at Medicines Complete https://www.medicinescomplete.com/mc/login.htm using your Athens password. Please refer to BNF for Children for full list of contraindications, cautions and side effects.

**Infant Gaviscon**
Infants less than 4.5kg (10lb) - ½ dual- sachet (1 dose) with feeds
Infants more than 4.5kg (10lb) - 1 dual-sachet (2 doses) with feeds
Do not give more than 6 times in 24 hours

**Bottle fed Infants:**
- Mix ½ dual- sachet into 115ml (4floz) of formula

**Breast fed infants:**
- Mix ½ dual- sachet with 5ml (1 teaspoon) of cooled boiled water or EBM until a smooth paste is formed
- Add another 10ml (2 teaspoons) of cooled boiled water or EBM and mix
- Give via a sterilised teaspoon, syringe, open cup or bottle ideally part way through each feed

NB- Each half of the dual- sachet is identified as “1 dose”. It should always be prescribed in terms of “doses” in order to avoid confusion.

**H₂ receptor antagonist- Ranitidine**
Oral solution- 75mg/5ml (15mg/ml)

**Age 1- 5 months**
Start with minimum dose of 1mg/kg three times a day with gradual increase to a maximum of 3mg/kg three times a day if required.

NB The oral solution is unlicensed in children less than 3 years old

**TABLE 1: Example doses of Ranitidine for infant’s age 1-5months using oral solution of 75mg/5ml- please note there is more than one strength available and it is the responsibility of the prescriber to calculate the volume required.**

<table>
<thead>
<tr>
<th>Weight of Infant (kg)</th>
<th>Dose at 1mg/kg</th>
<th>Dose at 2mg/kg</th>
<th>Dose at 3mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td><strong>3mg</strong> three times a day (0.2ml three times a day)</td>
<td><strong>6mg</strong> three times a day (0.4ml three times a day)</td>
<td><strong>9mg</strong> three times a day (0.6ml three times a day)</td>
</tr>
<tr>
<td>4</td>
<td><strong>4mg</strong> three times a day (0.25ml three times a day)</td>
<td><strong>8mg</strong> three times a day (0.5ml three times a day)</td>
<td><strong>12mg</strong> three times a day (0.75ml three times a day)</td>
</tr>
<tr>
<td>5</td>
<td><strong>5mg</strong> three times a day (0.3ml three times a day)</td>
<td><strong>10mg</strong> three times a day (0.6ml three times a day)</td>
<td><strong>15mg</strong> three times a day (0.9ml three times a day)</td>
</tr>
<tr>
<td>6</td>
<td><strong>6mg</strong> three times a day (0.4ml three times a day)</td>
<td><strong>12mg</strong> three times a day (0.8ml three times a day)</td>
<td><strong>18mg</strong> three times a day (1.2ml three times a day)</td>
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</table>
**Age 6 months- 1year**
2-4mg/kg twice a day
Oral solution- 75mg/5ml (15mg/ml)

**TABLE 2: Example doses of Ranitidine for infants 6 months- 1yr using oral solution of 75mg/5ml- please note there is more than one strength available and it is the responsibility of the prescriber to calculate the volume required.**

<table>
<thead>
<tr>
<th>Weight of Infant (kg)</th>
<th>Dose at 2mg/kg</th>
<th>Dose at 3mg/kg</th>
<th>Dose at 4mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>12mg twice a day (0.8ml twice a day)</td>
<td>18mg twice a day (1.2ml twice a day)</td>
<td>24mg twice a day (1.6ml twice a day)</td>
</tr>
<tr>
<td>7</td>
<td>14mg twice a day (0.9ml twice a day)</td>
<td>21mg twice a day (1.4ml twice a day)</td>
<td>28mg twice a day (1.8ml twice a day)</td>
</tr>
<tr>
<td>8</td>
<td>16mg twice a day (1.0ml twice a day)</td>
<td>24mg twice a day (1.6ml twice a day)</td>
<td>32mg twice a day (2.0ml twice a day)</td>
</tr>
<tr>
<td>9</td>
<td>18mg twice a day (1.2ml twice a day)</td>
<td>27mg twice a day (1.8ml twice a day)</td>
<td>36mg twice a day (2.4ml twice a day)</td>
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**Proton Pump Inhibitor- Omeprazole**

Age 1 month - 1 year
700micrograms/kg once daily, up to a maximum of 3mg/kg once daily (maximum of 20mg once daily)
Prescribe as dispersible tablets which can be dissolved in minimum amount of water.
Do not prescribe the oral solution as it is a special formulation and is very costly.
NB: Unlicensed in children less than 1 year old.
Appendix 3:
TABLE 3: Red flag symptoms suggesting disorders other than GOR (Adapted from NICE Guideline, Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people 2015)

<table>
<thead>
<tr>
<th>Symptoms and signs</th>
<th>Possible diagnostic implications</th>
<th>Suggested actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent, forceful (projectile) Vomiting</td>
<td>May suggest hypertrophic pyloric stenosis in infants up to 2 months old</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Bile-stained (green or yellow-green) vomit</td>
<td>May suggest intestinal obstruction</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Haematemesis (blood in vomit) with the exception of swallowed blood, for example, following a nose bleed or ingested blood from a cracked nipple in some breast-fed infants</td>
<td>May suggest an important and potentially serious bleed from the oesophagus, stomach or upper gut</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Onset of regurgitation and/or vomiting after 6 months old</td>
<td>Late onset suggests a cause other than reflux, for example a urinary tract infection (also see the NICE guideline on urinary tract infection in children) Persistence suggests an alternative diagnosis</td>
<td>Urine Microbiology investigation Paediatric Referral</td>
</tr>
<tr>
<td>Blood in stool</td>
<td>Most likely cause is cows’ milk allergy (also see the NICE guideline on food allergy in children and young people) - consider referral to Paediatric Dietitian. May suggest other conditions including, bacterial gastroenteritis or an acute surgical condition</td>
<td>Consider referral to Paediatric Dietitian Stool Microbiology investigation Paediatric referral</td>
</tr>
<tr>
<td>Abdominal distension, tenderness or palpable mass</td>
<td>May suggest intestinal obstruction or another acute surgical condition</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Chronic diarrhoea</td>
<td>May suggest cows' milk protein allergy (see NICE guideline on food allergy in children and young people)</td>
<td>Paediatric referral Consider referral to Paediatric Dietitian</td>
</tr>
<tr>
<td><strong>Systemic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearing unwell Fever</td>
<td>May suggest infection (also see the NICE guideline on feverish illness in children)</td>
<td>Clinical assessment and urine Microbiology investigation</td>
</tr>
<tr>
<td>Condition</td>
<td>Possible Cause</td>
<td>Referral Advice</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Dysuria</td>
<td>May suggest urinary tract infection (also see the NICE guideline on urinary tract infection in children)</td>
<td>Clinical assessment and urine microbiology investigation</td>
</tr>
<tr>
<td>Bulging fontanelle</td>
<td>May suggest raised intracranial pressure, for example, due to meningitis (also see the NICE guideline on bacterial meningitis and meningococcal septicaemia)</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Rapidly increasing head circumference</td>
<td>May suggest raised intracranial pressure, for example, due to hydrocephalus or a brain tumour</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Altered responsiveness, for example, lethargy or irritability</td>
<td>May suggest an illness such as meningitis (also see the NICE guideline on bacterial meningitis and meningococcal septicaemia)</td>
<td>Paediatric referral</td>
</tr>
<tr>
<td>Infants with, or at high risk of, atopy</td>
<td>May suggest cows' milk protein allergy (also see the NICE guideline on food allergy in children and young people)</td>
<td>Consider referral to Paediatric Dietitian</td>
</tr>
</tbody>
</table>

NB: If you feel the referral is urgent, please contact the on-call Paediatrician via FVRH switchboard (01324 566000).
Appendix 4:
Referral Details
Paediatric Dietitians- Refer via SCI gateway
Telephone Contacts:
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Stirling District and Clackmannan - Stirling Community Hospital- 01786 434097
9. Quality Assurance

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Does your policy / guideline / protocol / procedure / ICP have the following on the front cover?

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Lead Author: Joanna Stewart  Date: 27 / 01 / 2016

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