

Infant Feeding Guidelines

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Definition and Facts

- Infantile Colic has had an internationally agreed but not well known clinical definition for many years
- Inconsolable crying with limb flexure in an otherwise healthy, thriving infant, which lasts for more than 3 hours per day, occurs on 3 or more days per week, has persisted for more than 3 weeks starting in the first weeks of life and ceasing around 3 to 4 months of age¹
- Understandably many parents will seek medical help for their unsettled infants - whose crying falls short of these defined clinical criteria
- It occurs in both formula fed and breast fed infants
- It is common – affecting up to 20% of infants²
- The cause or causes of colic are very poorly understood
- **Be aware of the following “WARNING SIGNALS”- pointing to alternative more serious possible diagnoses:** Bile-stained vomiting, forceful vomiting, vomiting onset after 6 months of age, faltering growth, abdominal tenderness/distension, fever, lethargy, enlarged spleen and/or liver, bulging anterior fontanelle, small or enlarged head circumference, seizures, significantly disturbed stool pattern, sudden onset inconsolable crying, documented or suspected genetic/metabolic syndrome.

Non Pharmacological Management

- Exclude common causes of excessive crying e.g. hunger, thirst, dirty nappy, extremes of temperature
- Try holding infant, burping post-feeds, gentle motion (pushing pram or ride in the car), “white noise” (vacuum cleaner, hairdryer etc.), bathing in warm bath, parental support (getting parents to “take a break”, if relatives or friends can look after infant), CRY-SIS support group can offer support for families with excessively crying, sleepless and demanding babies. Website address: www.cry-sis.org.uk
- Reassure parents re: that their infant is well, they are not doing something wrong, their infant is not rejecting them, and the natural history is usually towards a relatively early remission
- Maternal smoking has been shown to be associated with infantile colic³
- Consider other causes e.g. Gastro-oesophageal Reflux Disease (GORD). [See algorithm for Reflux](#)
- Consider referral if parents are finding it difficult to cope or if there is diagnostic doubt

Possible Causes/ Pharmacological Treatments and Their Evidence
Transient Lactase Deficiency :

- There is no good evidence that it either occurs or if it does, that it could cause infantile colic
- Therefore there is **no support** for prescribing either Colief®, a partially hydrolysed, low-lactose formula e.g. Comfort® (Aptamil, Cow & Gate or SMA) or a lactose-free formula e.g. SMA® LF or Enfamil® O-Lac

Intestinal Gas

- There is no good evidence that excess intestinal gas causes infantile colic
- Therefore there is **no support** for prescribing Infacol® or Dentinox Colic Drops® (Simeticone) or supporting the use of Gripe water or Herbal teas

Cow’s Milk Allergy- CMA ([see CMA Guideline](#))

There is evidence that a small subset - perhaps 10% - of infants with infantile colic have Cow’s Milk Allergy⁴. Consider particularly when:

There is a positive history of atopic eczema, allergic rhinitis, asthma or food allergy in a 1st degree relative (mother, father or siblings)

- + or - other upper or lower gut dysmotility signs e.g. vomiting, regurgitation, food refusal, loose stools - which may be offensive and/or mucousy, perianal excoriation
- + or - skin signs e.g. apparent itching, flushing, urticaria, angioedema, eczema flares - especially with or following feeding.

Therefore a diagnostic dietary elimination trial of cow’s milk protein could be considered...

Formula Fed Infant: For colic only: 2 week trial of an Extensively Hydrolysed Formula (eHF) e.g. Casein based Nutramigen® Lipil 1 or Whey based Milupa Aptamil Pepti® 1 with a then planned reintroduction. See CMA Algorithm. **Do Not Prescribe:** Soya, goats, other mammalian milks or lactose free milks e.g. SMA® LF or Enfamil® O-Lac. There is also no place for using a partially hydrolysed, low lactose formula such as Comfort® (Aptamil, Cow & Gate or SMA) to carry out such an initial diagnostic dietary elimination trial. ([See CMA Guideline](#))

Breast Fed Infant: A carefully supervised and strict maternal cow’s milk protein free diet for 2 to 4 weeks with a then planned reintroduction. The mother will need 1,250mg of calcium and 10 mcg of vitamin D daily during the elimination trial. Early dietetic referral advised. ([See CMA Guideline](#))

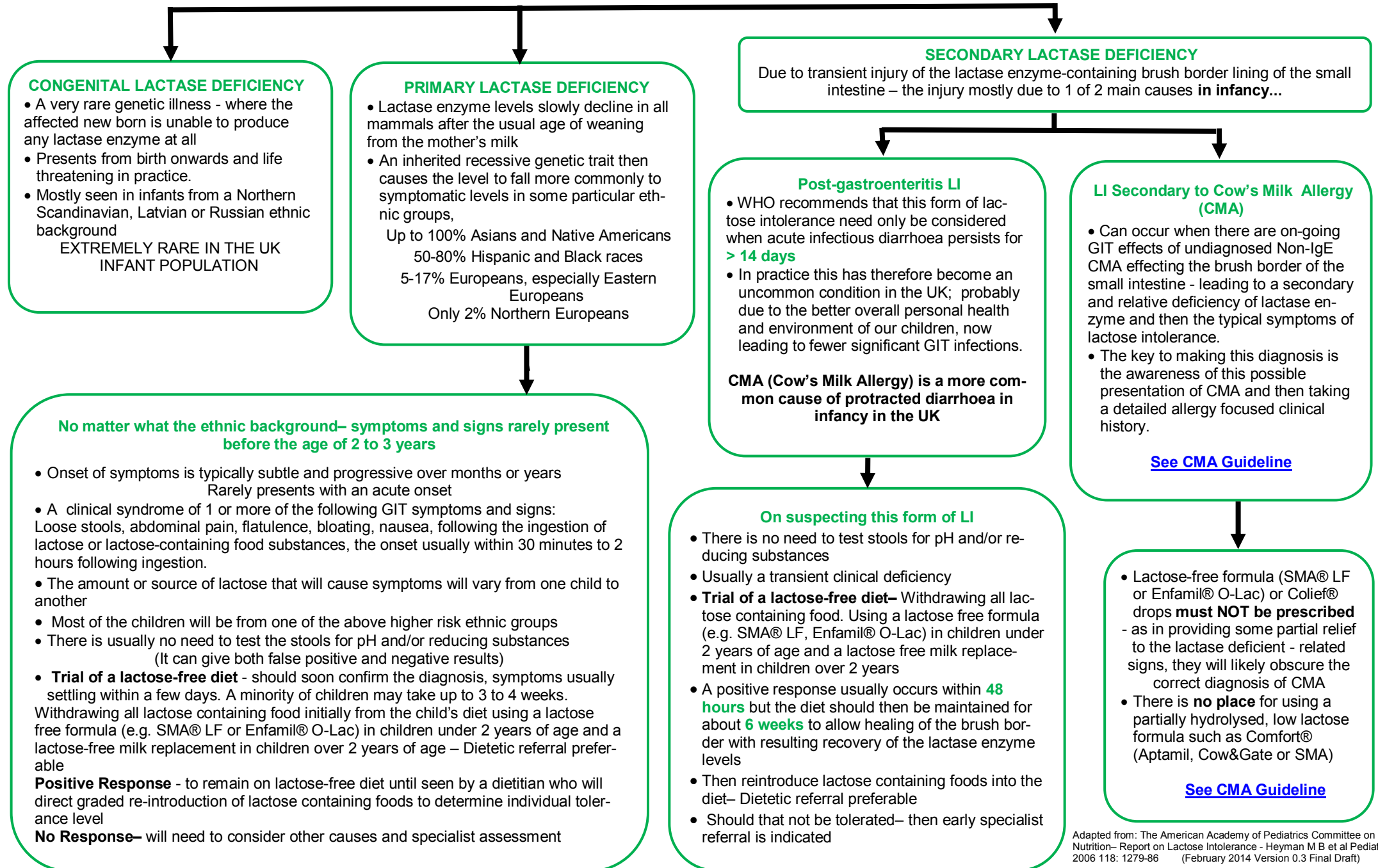
¹Wessel M A et al *Pediatrics* 1954; 14 : 421-424 Garrison M M et al *Pediatrics* 2000; 106 1Pt2 184-190

²Lucassen P L et al *Arch Dis Child* 2001; 4: 398-403

³Reijneveld S A et al *Arch Dis Child* 2000; 83(4): 302-3

⁴Jakobsson I et al *Acta Paediatrica* 2000 89(4); 18-21

(B) PRIMARY CARE MANAGEMENT OF LACTOSE INTOLERANCE (LI) IN CHILDREN (THE CLINICAL EXPRESSIONS— resulting from the different causes of Lactase Enzyme Deficiency)



Gastro - Oesophageal Reflux – GOR

Defined as :The effortless passage of gastric contents into the oesophagus with or without **Regurgitation** or **Vomiting**

Regurgitation: The passage of such refluxed gastric contents into the pharynx or mouth which are then mostly swallowed back into the stomach. Sometimes seen to be expelled effortlessly out of the mouth - terms such as 'possetting' (mostly UK) and 'spitting-up' (mostly USA) often are used and can be considered to be equivalent to regurgitation

Vomiting: A coordinated autonomic and voluntary motor response, causing forceful expulsion of gastric contents through the mouth

GOR is a normal physiological process often occurring several times a day in healthy infants and is not thought to be uncomfortable. It occurs in both formula fed and breast fed infants and can be expected to resolve spontaneously in most of these infants by 12 to 14 months of age - often earlier

See 'Reflux' Management Algorithm [\(Page 3.2\)](#) – 'Simple Measures' for uncomplicated GOR

Gastro - Oesophageal Reflux DISEASE - GORD

When the reflux of the gastric contents is thought to cause certain troublesome symptoms and/or complications in infants:

- Recurrent and significant regurgitation, vomiting +/- with faltering growth
- Oesophagitis symptoms – irritability, back-arching, hiccups, feeding aversion, blood in refluxate
- Possible associated lower airway signs – apnoea, wheezing, recurrent infection, even ALTEs (acute life-threatening events)

The differential diagnosis between simple GOR and GORD can be difficult in the clinically milder cases

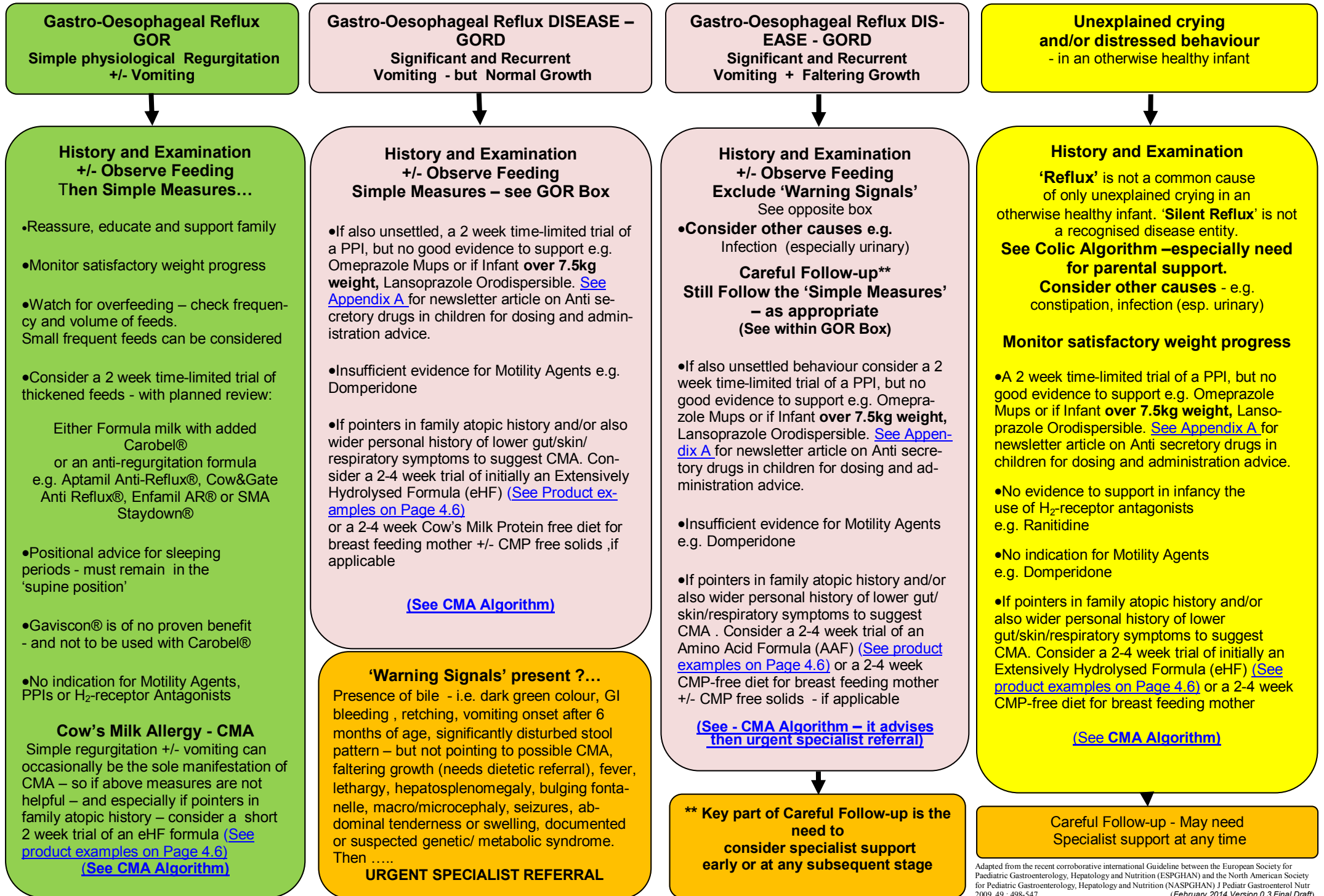
- there is no symptom or symptom pattern that is diagnostic of GORD or predicts response to therapy

See 'Reflux' Management Algorithm [\(Page 3.2\)](#)

Prescribing Notes:

- Anti-regurgitation infant formulas such as Aptamil Anti Reflux®, Enfamil AR® or SMA Staydown® should **not** be prescribed along with other thickening agents such as Carobel® or Gaviscon® Infant sachets. In addition these anti-regurgitation infant formulas require an acid environment in order to thicken and therefore will not work properly when prescribed along with antacid medications such as omeprazole or ranitidine.
- Gaviscon® Infant sachets should **not** be used with thickening agents or infant milk preparations containing a thickening agent, as this could lead to over-thickening of the stomach contents. They should therefore not be prescribed along with Carobel®.

(C) PRIMARY CARE MANAGEMENT OF 'REFLUX' IN INFANCY



(D) Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life Primary Care Guideline

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Dietitian Referral Guidance

Please forward all Dietetic Referrals to the designated Dietetic Department for your Trust– and the child and family will then be referred to an appropriately trained dietitian

BOX 2 Allergy-focused clinical history NICE Food Allergy Guideline 116 February 2011

Adapted from the NICE Guideline which is for all expressions of Food Allergy
 - to better reflect Cow's Milk Allergy presenting in Infancy

Ask about:

- Any Family History of atopic disease (asthma, atopic eczema, allergic rhinitis or food allergy) in parents or siblings
- Any Personal History of early atopic disease - atopic eczema and less commonly in the 1st year of life - upper and lower airway signs
 - any obvious allergic reactions to other foods
- The infant's feeding history
 - whether breast fed or formula fed
 - If breast fed
 - exclusively or whether early CMP post-natal top-up formulas were briefly given
 - timing of introduction of later CMP top-up formulas and/or CMP in weaning food
 i.e. '**Mixed feeding**' - as referenced in the Algorithms
 - details of the maternal diet, especially dairy but also egg, soya, wheat, nuts, and fish
 - If formula fed
 - details of which formulas
 - If weaning commenced
 - age of starting and details of foods to date – especially what other forms of dairy have been introduced and whether any possible allergic symptoms and signs might have coincided with this
 - any suspected reactions to other weaning foods
- Presenting signs and symptoms that may be indicating possible CMA – [see BOX 1](#)
 - Including :
 - age of onset
 - speed of onset of symptoms and signs
 - duration, severity and frequency
 - reproducibility of signs on repeated exposure
 - what form of cow's milk protein ingested and quantity that caused an apparent reaction/s
- Details of previous management, including any medication and the perceived response to any management
- Has anyone raised concern about possible food allergy, who that is and why do they think it may be food allergy
- Any attempts to change the diet, details and perceived response

Take account of cultural and religious factors that might influence the infant's or mother's diet

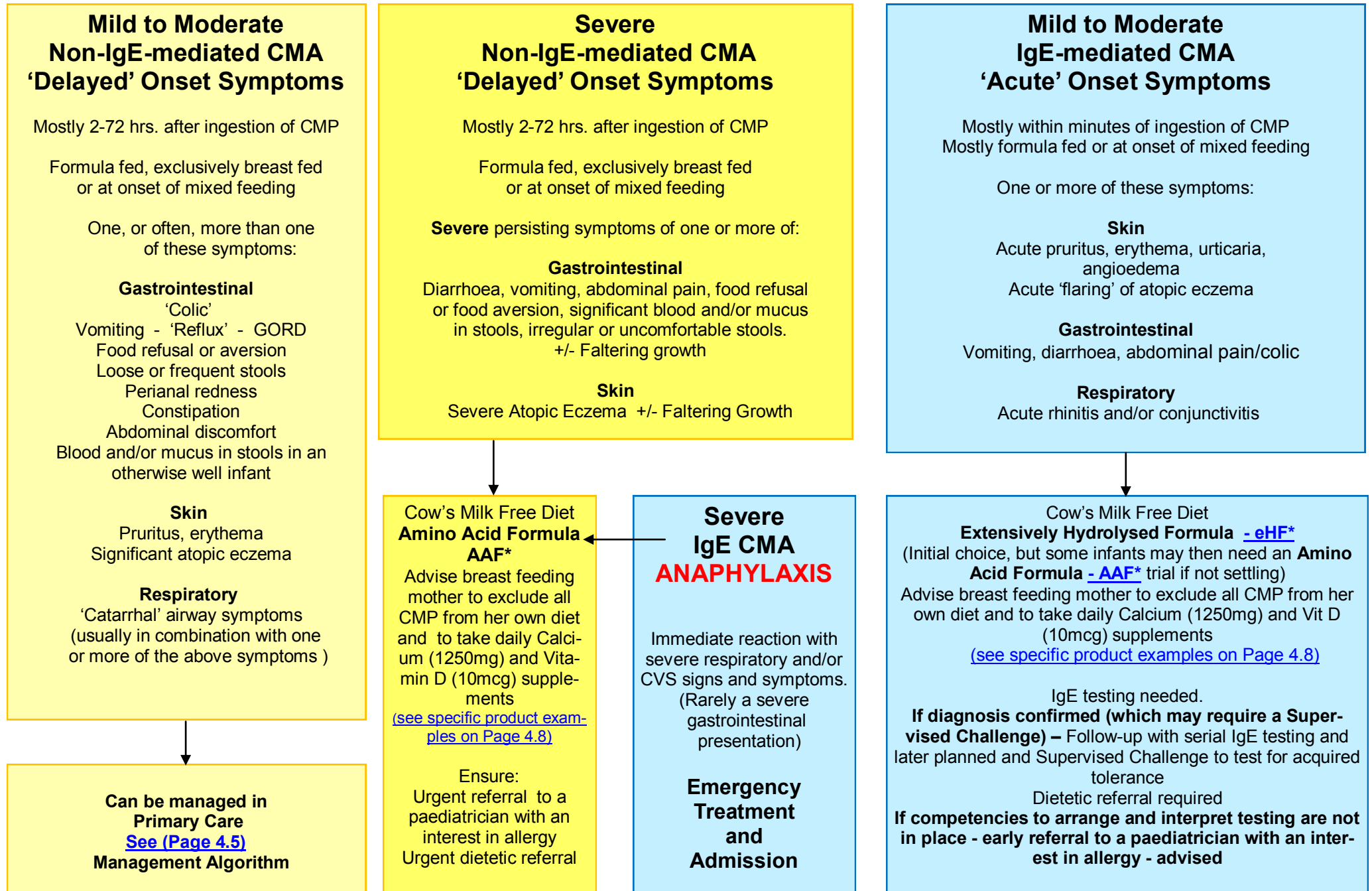
Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life - Primary Care Guideline

- Cow's Milk Allergy currently affects 2-4% of all infants in the UK
 - the large majority of CMA first presents in infancy and in the primary care setting
- **Most of these infants will clinically present early - within days or within a few weeks of first ingesting Cow's Milk Protein (CMP).**
- Infants are exposed to CMP in normal infant formula, via breast milk if the mother is consuming cow's milk or cow's milk-containing foods in her own diet or when solids are introduced during the weaning period
- Consider the diagnosis in any infant showing any of the signs and symptoms in Box 1 from the NICE Food Allergy Guideline (No. 116 Feb 2011) - See BOX 1 opposite
 - especially if there is any family history of atopic eczema, allergic rhinitis, asthma or food allergy in a 1st degree relative (i.e. mother, father or sibling)
- **Pay particular attention to persistent signs or symptoms that involve different organ systems in the same infant – see BOX 1 opposite**
- Distinguish between signs or symptoms that present acutely following ingestion and those that have run a more chronic course.
 - Acute signs or symptoms mostly occur within minutes of ingestion of CMP and certainly within 2 hours – they are usually **'IgE-antibody-mediated'**.
 - Delayed signs or symptoms mostly occur 2 or more hours following ingestion and may be delayed for up to 48 hours or more – they are usually due to a **'Non-IgE-mediated'** pathway of the Immune System (the former term often used here was Cow's Milk Protein Intolerance)
 - A minority of infants with CMA may either present with or evolve to a **'Mixed IgE and Non- IgE'** clinical pattern of both acute and delayed onset signs and symptoms – in which case the IgE pathway needs to be primarily followed
- Particularly consider CMA in any infant who has been treated for such clinical presentations as moderate to severe atopic eczema, GORD or other persisting gastrointestinal symptoms (including 'colic', loose stools, constipation) but they have not responded to the usual initial therapeutic interventions.
 - especially if there is any family history of atopic eczema, allergic rhinitis, asthma or food allergy in a 1st degree relative
 - In these infants faltering growth is not a consistent feature and good growth does not in any way exclude the possibility of the diagnosis of CMA

BOX 1 Signs and Symptoms of possible Food Allergy NICE Food Allergy Guideline 116 Feb 2011

IgE-mediated	Non-IgE-mediated
The Skin	
Pruritus Erythema Acute urticaria localised or generalised Acute angioedema most commonly of the lips, face and around the eyes	Pruritus Erythema Atopic Eczema
The Gastrointestinal System	
Angioedema of the lips, tongue and palate Oral pruritus Nausea Colicky abdominal pain Vomiting Diarrhoea	Gastroesophageal Reflux Disease Loose or frequent stools Blood and/or mucus in stools Abdominal pain Infantile colic Food refusal or aversion Constipation Perianal redness Pallor and tiredness Faltering growth - plus one or more GIT symptoms above (with or without significant eczema)
The Respiratory System - usually in combination with one or more of the above signs and symptoms	
Upper Respiratory Tract Nasal itching, sneezing, rhinorrhoea or congestion (+/- conjunctivitis)	Isolated respiratory symptoms are usually not indicative of IgE or Non-IgE-mediated food allergy
Lower Respiratory Tract - Cough, chest tightness, wheezing or shortness of breath	
Anaphylaxis or other systemic allergic reactions	

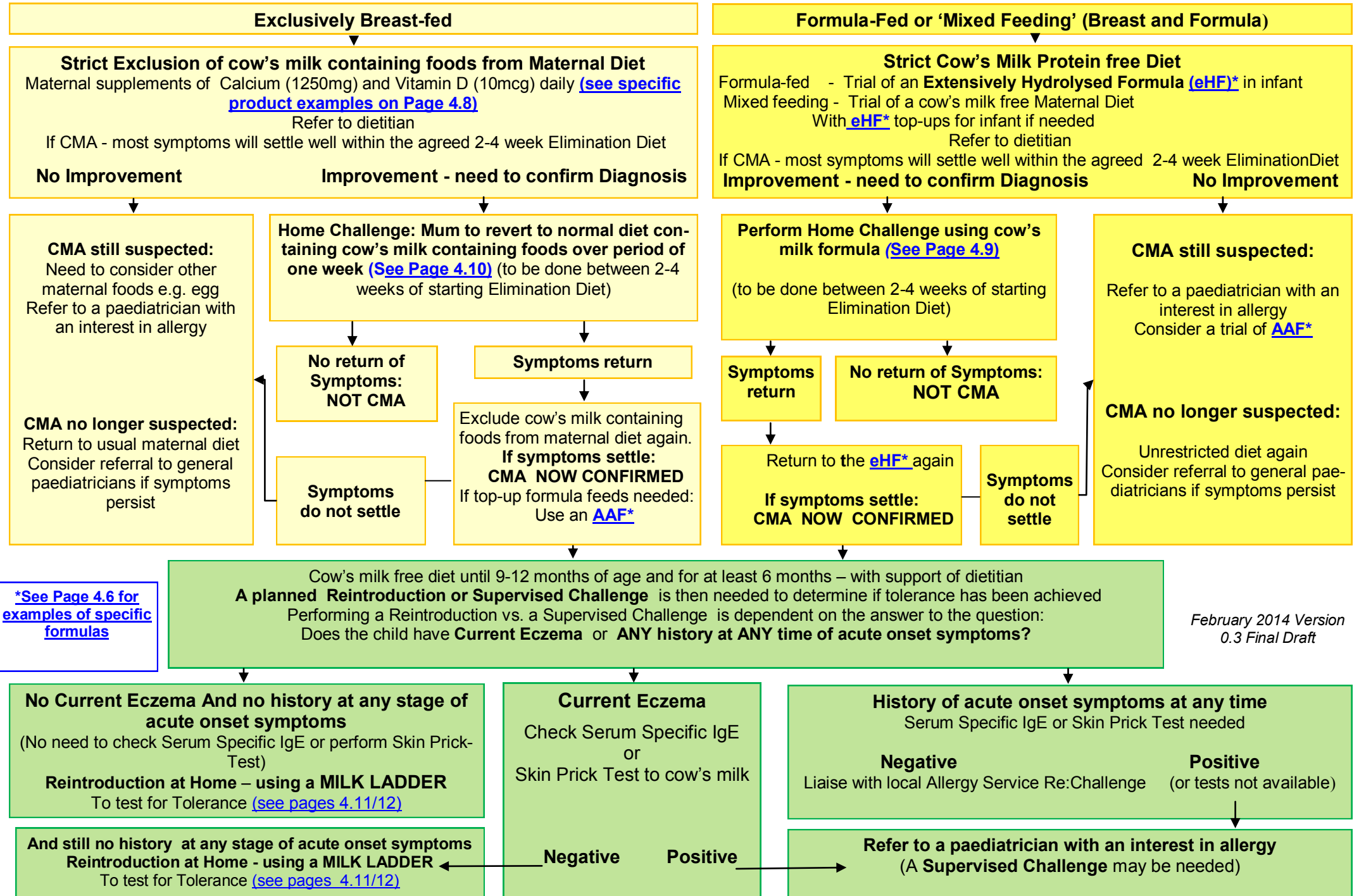
Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life - having taken an Allergy-focused Clinical History



*See Page 4.6 for examples of Specific Formulas

Primary Care Management of Mild to Moderate Non-IgE CMA

(No initial IgE Skin Prick Tests or Serum Specific IgE Assays necessary)



[*See Page 4.6 for examples of specific formulas](#)

The Hypoallergenic Formulas

The constituents vary between the different individual Extensively Hydrolysed Formulas (eHFs) available and also between the different individual Amino Acid Formulas (AAFs) available. This then can sometimes influence both an infant's tolerance and even their perceived apparent palatability of that formula.

The Hypoallergenic Formulas currently most commonly used in the infant age group in the UK for term infants are:

Extensively Hydrolysed Formulas - eHFs

Casein-based constituents

Nutramigen LIPIL 1	Birth onwards	Mead Johnson	400g tin
Nutramigen LIPIL 2	> 6 months of age	Mead Johnson	400g tin
Similac Alimentum	Birth onwards	Abbott Nutrition	400g tin

Whey-based constituents

Althéra	Birth onwards	Vitaflo	450g tin
Milupa Aptamil Pepti 1	Birth onwards	Milupa	400g or 900 g tin
Milupa Aptamil Pepti 2	> 6 months of age	Milupa	400g or 900g tin

Both the whey based extensively hydrolysed formulas contain Lactose

Amino Acid-based Formulas - AAFs

Neocate LCP	Birth onwards	Nutricia SHS	400g tin
Nutramigen AA LIPIL	Birth onwards	Mead Johnson	400g tin

**The Amino Acid-based Formulas are significantly more expensive than the Extensively Hydrolysed Formulas
Please ensure that an AAF is only prescribed if the CMA Algorithm recommends its use**

Examples of recommended Initial Trial Elimination Periods – there is no good evidence base, but most recent guidelines support

Simple GOR or Simple Colic in Formula Fed Infants	- 2 weeks	- See also 'Reflux' and Colic Regional Algorithms
GORD or more complex GIT symptoms	- 4 weeks	- See also 'Reflux' Regional Algorithm
Severe GIT symptoms or Significant Atopic Eczema	- Up to 6 weeks	- See also NICE Guideline on Atopic Eczema

The Initial Introduction of a Hypoallergenic Formula to a Suspected CMA Infant

• In all suspected **IgE-mediated** and in severe **Non-IgE-mediated CMA** for clinical reasons the Hypoallergenic Formula may need to be introduced directly and without delay.

- Refer the infant promptly to a Paediatric Dietitian.

See Algorithm Page 4.4

• In suspected **Mild to Moderate Non-IgE CMA** a gradual transitioning onto the Extensively Hydrolysed Formula may be needed over several days. This is because such formulas have a very different flavour and smell compared to either breast milk or cow's milk based formula.

See Algorithm Page 4.5

Transitioning Example:

Day	Volume of Boiled Water (mls)	Hypoallergenic Formula No. of Scoops	Cow's Milk Formula No. of Scoops
Day 1	180	1	5
Day 2	180	2	4
Day 3	180	3	3
Day 4	180	4	2
Day 5	180	5	1
Day 6	180	6	0

*Make up each bottle of the day in exactly the same way

*Do not interchange scoops

*The full schedule needs to be completed- continuing to give any mixture of both Hypoallergenic Formula and Cow's Milk Formula is not acceptable

Practical tips for all infants

- Be patient and persistent - it may take at least 10 days to establish the infant on a reasonable volume of the new Hypoallergenic Formula
- You may need to encourage "dream feeds" if volumes are poor
- During the introduction period encourage the new formula as the main drink and avoid 'baby juices'
- If the infant is of weaning age– use the formula to make baby rice or cow's milk free breakfast cereal and add fruit puree.
-also try offering the formula in a closed beaker alone or mixed with a little fruit puree

If the infant is not achieving adequate volumes of the Hypoallergenic Formula – Refer promptly to a Paediatric Dietitian

Recommended Daily Supplements

The dietary exclusion of cow's milk and cow's milk products by a breastfeeding mother will have nutritional implications
- especially in achieving calcium and vitamin D daily requirements.

Breastfeeding Mother on a Cow's Milk Free Diet

RNI for lactation in mothers aged 19 years and over: 1250mg of calcium, 10µg (400 IU) of Vitamin D daily.
Dose depends on mum's intake of calcium fortified foods.

Recommended Product

NATECAL D3® (Chiesi)

1 tablet contains: 600mg Calcium, 10µg Vitamin D

Dose: Usually 2 tablets daily

Paediatric Dietitian or Community Pharmacist can also provide advice on many other suitable non-proprietary calcium and vitamin D products

DOH Advice - On Vitamin D Supplements for 'At Risk Groups'

The DoH and Chief Medical Officers in the UK (2012), have advised prophylactic Vitamin D supplementation for ALL mothers during pregnancy and for certain infants.

See link: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132508.pdf

The Formula Fed Infant - Fully formula fed or taking formula to complement breast feeds

Checklist

1. DO NOT challenge if the infant is unwell; if airways are compromised or if eczema is flared up.
2. DO NOT challenge if the infant is receiving medication that may adversely affect the gut e.g. a course of antibiotics.
3. DO NOT introduce any other new foods during the milk challenge.
4. It may be helpful to ask the parents to keep a record of the infant's oral intake, stool pattern and signs during the challenge.

IF SIGNS RETURN

STOP THE CHALLENGE - RETURN TO THE FULL EXCLUSION REGIME

The infant who shows signs again on the Home Challenge – the mother and infant should be promptly seen by a Dietitian for on-going support

IF NO SIGNS RETURN - THE INFANT DOES NOT HAVE COW'S MILK ALLERGY

- and may continue to consume cow's milk-based formula and milk containing products
Cow's milk itself is NOT A SUITABLE DRINK FOR INFANTS under 12 months of age

EXAMPLE

DAY 1 30mls of Cow's Milk Formula into ONE morning bottle only.

DAYS 2 to 7 Continue to increase the cow's milk formula and reduce the Hypoallergenic Formula using the following example.

Following Days	Volume of Boiled Water (mls)	Hypoallergenic Formula No. of Scoops	Cow's Milk Formula No. of Scoops
Day 2	180	5	1
Day 3	180	4	2
Day 4	180	3	3
Day 5	180	2	4
Day 6	180	1	5
Day 7	180	0	6

*Make up each bottle of the day in exactly the same way
*Do not interchange scoops
*The full schedule needs to be completed– continuing to give any mixture of Hypoallergenic Formula and Cow's Milk Formula is unacceptable

4.10 Home Challenge to Confirm the Diagnosis of Mild to Moderate Suspected Non-IgE CMA

The Exclusively Breast Fed Infant

Checklist

1. DO NOT challenge if the infant is unwell; if airways are compromised or if eczema is flared up
2. DO NOT challenge if the infant is receiving medication that may adversely affect the gut e.g. a course of antibiotics
3. It may be helpful to ask the parents to keep a record of the infant's stool pattern and symptoms during the challenge

Simply advise the mother to reintroduce cow's milk and milk containing foods gradually back into her own diet over a 1 week period

IF SIGNS RETURN

STOP THE CHALLENGE - RETURN TO THE FULL EXCLUSION REGIME

The infant who shows signs again on the Home Challenge - the mother and infant should continue to receive on-going support from the Dietitian

IF NO SIGNS – THE INFANT DOES NOT HAVE COW'S MILK ALLERGY

The mother may continue to consume cow's milk and milk containing products

The infant then on weaning, can be introduced to both dairy products and cow's milk in their solids

Home Challenge to Confirm the Clinical Remission of Mild to Moderate Non-IgE CMA

After a Period of Planned Avoidance

- Usually at 9-12 months of age - or after at least 6 completed months of exclusion

Checklist

If the child now has additional confirmed or suspected food allergies. DO NOT carry out a Home Challenge without Dietetic advice

1. DO NOT challenge if the child is unwell; if airways are compromised or if eczema is flared up
2. DO NOT challenge if the child is receiving medication that may adversely affect the gut e.g. a course of antibiotics
3. DO NOT introduce any other new foods during the milk challenge
4. It may be helpful to ask the parents to keep a record of the infant's oral intake, stool pattern and signs during the challenge
5. DO introduce the new food early in the day to allow the parents to observe any signs during daytime

The Dietitian can give individualised directions for moving through the stages of the home challenge - if necessary

IF NO SIGNS RETURN

- and the Challenge has been completed,
the child no longer has Cow's Milk Allergy

IF SIGNS RETURN-

DO NOT PROCEED FURTHER WITH THE CHALLENGE

However - the child can be allowed milk proteins at the Stage (if any) that was tolerated

The Challenge will need to be repeated at 4-6 monthly intervals - provided there was no escalation in reaction

Children who do develop signs on the Home Challenge - should be reviewed early by the Dietitian

Home Challenge to Confirm the Clinical Remission of Mild to Moderate Non-IgE CMA

– usually at 9-12 months of age – or after at least 6 completed months of exclusion

Stage	Directions	Suitable Foods
<p>Stage 1 Usually 1 week</p> <p style="text-align: center;">Baked Foods containing Cow's Milk</p>	<p>Choose a food item containing milk as a minor ingredient. Use the same type of food initially, <u>then try other suitable foods</u> The mother or Dietitian can adjust portions with age</p> <p>Day 1 Eat ½ a portion Day 2 Eat 1 portion Day 3 Eat 1-2 portions Day 4 Continue to eat foods containing milk as a minor ingredient more freely; at least for a few more days</p>	<p>Examples of Baked Foods - containing milk as a minor ingredient:</p> <p>Plain Biscuits e.g. Malted Milk, Digestive, Custard Cream, Certain Crackers</p> <p>Breads e.g. breads such as Wheaten or Soda Bread, Pancake (if tolerant of egg)</p>
<p>Stage 2 Usually 1 week</p> <p style="text-align: center;">Milk Puddings and Continue to eat Baked Foods containing Cow's Milk</p>	<p>Choose one type of milk pudding initially. Increase amount daily or on alternate days– as felt indicated</p> <p>Day 1 Offer 1 teaspoon of milk pudding Day 2 Offer ½ a portion e.g. 60g of custard Day 3 Offer 1 portion e.g. 120g (individual pots may vary) Day 4 If no symptoms, continue introducing milk puddings Allow 1 portion daily for a further 3 days</p> <p>If wished– butter can also be introduced now</p>	<p>Some may prefer to initially challenge with “Cooked” milk puddings first e.g. custard, semolina, creamed rice. Then move on to use “Uncooked” milk puddings e.g. yoghurt (natural or with fruit), fromage frais If child refuses or dislikes milk pudding, try gradually introducing cheese over a few days - before moving onto fresh milk</p>
<p>Stage 3 Usually 1-2 weeks</p> <p style="text-align: center;">Fresh Cow's Milk and Continue to eat Baked Foods and Cow's Milk Products</p>	<p>Gradual introduction helps the child adjust to the new taste of cow's milk</p> <ul style="list-style-type: none"> - Introduce 30mls cow's milk early in the day e.g. in cereal - Gradually increase over 2-3 days until the whole serving is made with cow's milk - Continue using cow's milk in cereal and also in cooking - Then begin to gradually replace drinks of the milk substitute with age appropriate formula or cow's milk <p><u>You have now successfully reintroduced both milk products and cow's milk into the child's diet</u></p>	<p>Under 12 months - use infant formula as milk drink (if not breast fed) Over 12 months, encourage cup for all drinks 12-24 months - Use full cream milk Over 24 months - Can use semi-skimmed milk</p> <p>If milk products are poorly accepted look for calcium fortified breads or cereals– Further Dietetic support may then be needed</p>

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Member of the NICE Guideline Development Group for Anaphylaxis

Member of the UK National Food Allergy Paediatric Care Pathway Development Group

Executive Member of the Primary Care Group of both the British Society for Allergy and Clinical Immunology and the European Academy of Allergy and Clinical Immunology

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(E) Acknowledgements

It is also acknowledged that the following UK experts provided invaluable assistance to help finalise this regional guidance initiative. This group, led by Dr Trevor Brown have published a set of Primary Care focused CMA Algorithms (The MAP Guideline – Milk Allergy in Primary Care) which can be accessed at <http://www.ctajournal.com/content/3/1/23>. This Northern Ireland guideline is consistent with The MAP guideline.

Any practical NI regional feed-back which might further improve the primary care clinical applicability of these guidelines would be welcomed by Dr Brown. Please email any comments to: trevorbrown65@hotmail.co.uk

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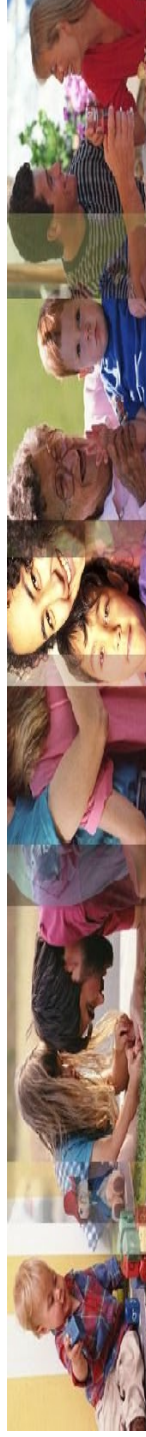
Appendix A

NORTHERN IRELAND MEDICINES MANAGEMENT



October 2013

NEWSLETTER Special Supplement — Anti-secretory drugs in Children



Due to differences between product licences and clinical practice, product choice of anti-secretory drugs for infants can be problematic. The purpose of this Supplement is to assist clinicians and pharmacists in selection and administration of suitable products. Last year, unlicensed 'specials' of omeprazole, lansoprazole and ranitidine cost the NHS in Northern Ireland over £800,000. Such 'specials' cost on average £220 per bottle. While a suspension may be needed in some patients, it is not always the best option.

HSCB Guidance on managing reflux in infants (January 2013)

If clinically indicated, a 2 week time-limited trial of a proton pump inhibitor (PPI) may be considered. However, evidence to support this is limited. There is no evidence to support the use of H2-receptor antagonists in infancy e.g. ranitidine. Please refer to website for full details on managing reflux http://www.hscboard.hscni.net/medicinesmanagement/Prescribing%20Guidance/045%20InfantFeedingGuidelines_Feb2013.pdf.

'Off-label' use or unlicensed 'special'?

The General Medical Council advises that licensed medicines and indications should be used where possible. If this is not an option, consider using a licensed medicine in an unlicensed manner ('off-label' use). 'Specials' are unlicensed and are not required to meet the same standards as licensed preparations. Prescribers assume greater liability when using them and they are considerably more expensive than licensed medicines.¹² Practice-generated scripts for omeprazole or lansoprazole suspension will result in an unlicensed product being dispensed to the patient.

Choice of PPI — lansoprazole or omeprazole?

Royal Belfast Hospital for Sick Children (RBHSC), are moving away from using omeprazole as the first choice PPI in preference to lansoprazole in infants $\geq 7.5\text{kg}$. This is due to difficulties administering low doses in infants, bioavailability issues with omeprazole suspension and problems with enteral feeding tube blockage. Therefore you may see more requests from secondary care to prescribe lansoprazole orodispersible. Other local Trusts are currently still using omeprazole as the first line PPI of choice.

Need for review

As with any medicine, it is important to review the continued need for PPI use. Risks associated with long-term use of PPIs have been reported — see Medicines Management Newsletter article, Feb 2013 (http://www.hscboard.hscni.net/medicinesmanagement/Medicines%20Management%20Newsletter/Volume%2004/index.html#P-1_0). If there is need for continued use, i.e. the child continues to be symptomatic, dose escalation of the PPI may be required as the child gains weight. Practices may wish to consider a prescribing audit of PPI suspensions to draw attention to inappropriate repeat prescriptions.

Paediatric license: omeprazole is licensed for use in children from 1 year and > 10kg for the treatment of reflux oesophagitis, symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease.^{5,6} In clinical practice, omeprazole is also used off license in children under 1 year.³

Preparations: 10mg and 20mg tablets (MUPS®), 10mg and 20mg capsules, 2mg/mL suspension (manufactured extemporaneously or ordered as a special). MUPS® tablets should be used where possible.¹ There is only limited evidence of efficacy for the omeprazole suspension. Furthermore the sodium bicarbonate in the suspension gives it an unpleasant taste and a high sodium content. The suspension is usually reserved for children with feeding tubes under 12Fr in size.

Oral administration:

Administration of MUPS® tablets to children <1year not spoon fed
Follow the same procedure as Zofon FasTab®. See administration box.
If a dose of 5mg is required, halve the tablet (using a tablet cutter) before dispersing: aliquots are not suitable for administering doses under 10mg.¹

Administration of MUPS® tablets to children who are spoon fed

Break the tablet and disperse it in a spoonful of non-carbonated water. If so wished, the dispersion may then be mixed with fruit juice or apple sauce. Always stir just before drinking and rinse down with half a glass of water. Do not use milk or carbonated water. Do not chew the enteric-coated pellets.⁶

Enteral Feeding administration:

Omeprazole capsules and MUPS® tablets are unlicensed via enteral feeding tubes but, in practice, MUPS® tablets will flush through tubes ≥ 12Fr. Omeprazole suspension or lansoprazole orodispersible tablets may be considered in finer bore tubes.^{1,8,11}

Omeprazole Dosage ²	
Age/weight	Dose
Neonate	700 micrograms/kg daily (max. 2.8mg/kg)
1mth to 2yr	700 micrograms/kg daily (up to 3mg/kg; max.20mg)
10 to 20kg	10mg daily (max.20mg)
Child >20kg	20mg daily (max.40mg)

It is important that calculated doses are practical in terms of available products. **In practice, children with a weight of ≥ 3.4kg are given a dose of 10mg daily.**³ A 5mg dose is usually only prescribed in the hospital setting for babies of low weight.³

The suspension is usually reserved for children with feeding tubes un-

Omeprazole 2mg/mL suspension Extemporaneous Formulation⁴

Ingredients:

Omeprazole capsules 20mg x 28

Sodium bicarbonate 8.4% x 280mL

Method: Open the omeprazole capsules and place contents in a mortar. Crush the granules and mix with a little sodium bicarbonate 8.4%. Make up to volume with the remainder of the sodium bicarbonate solution. Transfer to an amber bottle with an adaptor, label appropriately, and supply with an oral syringe.

COSH requirements: wear gloves

Expiry: 28 days in fridge (2 to 8C)

Unlicensed Specials

Omeprazole suspension is available as an unlicensed preparation from several specials companies. These can be costly and often are formulated in the same way as the extemporaneous formulation, i.e. using omeprazole capsules in sodium bicarbonate. See 'Special-order Manufacturers' in BNF for a list of NHS hospital manufacturers.

5.5

Paediatric license: Lansoprazole is not licensed in children due to limited clinical data.⁷ However there is increasing clinical experience and the Children's BNF provides information on use of lansoprazole in infants.

Preparations: 15mg and 30mg Fastabs[®]

Oral administration

Lansoprazole Dosage ^{2,3}		
<i>BNFC gives a dose of 0.5-1mg/kg once daily.</i>		
RBHSC use 1mg/kg daily for ≥ 7.5 kg body weight:		
Body weight	Dose	Preparation
7.5kg	7.5mg once daily	Half a 15mg tablet
7.5kg to 15kg	7.5mg once daily (use clinical judgement closer to 15kg)	Half to one 15mg tablet
16kg to 30kg	15mg once daily	One 15mg tablet
≥ 30 kg	15 to 30mg once daily	One 15mg or one 30mg tablet

Administration of FasTabs[®] to children <1year who are not spoon fed
See administration box. If a dose of 7.5mg is required, halve the tablet (using a tablet cutter) before dispersing: aliquots are not suitable for administering doses under 15mg.¹

Administration of FasTabs[®] to children who are spoon fed

Break the tablet and disperse it in a spoonful of non-carbonated water. The FasTabs[®] may also be administered with apple juice or orange juice.¹¹ Always stir just before drinking and rinse down with half a glass of water.

Enteral feeding administration

FasTabs[®] are licensed for administration via nasogastric tube and will fit through feeding tubes of size ≥ 8 Fr.^{7,8}

Administration of a lansoprazole FasTab[®] or an omeprazole MUPS[®] tablet via an oral/enteral syringe:

Place the tablet (or half of a tablet) in the barrel of an oral syringe. Replace the plunger and draw up 10mL water. The resulting dispersion will contain enteric coated pellets.

Ensure that all of the pellets are drawn up in the syringe and administered: pellets tend to settle to the bottom in oral syringes and there is a risk that the child may not receive the full dose.

Flush with another 10mL of water for enteral feeding. The dispersion should be given immediately (or within 30 minutes).

Lansoprazole suspension

Extemporaneous Formulation

An oral suspension has been made with sodium bicarbonate, but is not as stable as omeprazole in sodium bicarbonate.

Unlicensed specials

A suspension is available as an unlicensed preparation from several specials companies. These can be costly and offer no advantage over other available products.

RANITIDINE

Ranitidine should not routinely be used to treat reflux in infants. If ranitidine is ordered, the licensed 75mg/5mL liquid should be used with a 1mL syringe to administer small doses to children, e.g. 0.29mL for 4.3mg. This approach should be used instead of diluting the licensed product or ordering unlicensed specials. Rosemont and Zantac[®] liquids are sucrose-free but contain 8%w/w alcohol.^{1,2} However, this generally is considered insignificant when given in such small quantities to infants.

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This newsletter has been produced for GPs and Pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

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