Blackpool Teaching Hospitals NHS
NHS Foundation Trust

Document Type: **GUIDANCE**		**Unique Identifier:** COMM/GUID/002
Title: **Guidelines For Formula Fed Babies With Suspected Lactose Intolerance, Suspected Cows Milk Protein Allergy Or Suspected Cows Milk Protein Intolerance**		**Version Number:** 1
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Review dates may alter if any significant changes are made		**Review Date:** 01/05/2015
Does this document meet the requirements of the Equality Act 2010 in relation to Race, Religion and Belief, Age, Disability, Gender, Sexual Orientation, Gender Identity, Pregnancy & Maternity, Marriage and Civil Partnership, Carers, Human Rights and Social Economic Deprivation discrimination? Initial Assessment		

Contents

1 PURPOSE

The purpose of this guideline is to provide information to health professionals within a primary care setting who are working with carers / parents who have a formula fed baby where lactose intolerance, cow's milk protein allergy or intolerance is suspected.

Blackpool Teaching Hospitals NHS Foundation Trust (BTHFT) Community Health Division is committed to the belief that breastfeeding is the healthiest way for a woman to feed her baby as there are important health benefits now known to exist for both the mother and her child. For those babies who are not breastfed, it is important to ensure the proper and appropriate use of breast milk substitutes when they are necessary.

2 SCOPE

This guideline is to provide information for all staff that work with families of children. This guideline is also recommended to General Practitioners, for their information.

3 GUIDELINES

3.1 Guidelines for Formula Fed Babies with Suspected Lactose Intolerance

3.1.1 Symptoms

Symptoms, where lactose intolerance is suspected, may include:

- Colicky
- Fussy around feeds
- Feeding frequently
- Vomiting
- Bloating
- Explosive stool (often green and frothy)

(If cow's milk protein allergy or intolerance is suspected see 4.2 and 4.3).

3.1.2 Indications

3.1.2.1 First look at the possibility of overfeeding (see Appendix 1):

- Listen to the whole story; is the baby feeding little and often in a "normal" pattern?
- Look at family history
- Talk about how the milk is made up
- Ask about which milk is being used
- Ask about amounts of milk being fed, note that current guidelines state:
  - 150-200 millilitre(ml) / kilogramme (kg)baby / day
    0 - 6 months (this will vary from baby to baby)
  - (note amounts for preterm infants vary)

3.1.2.2 If not overfeeding then consider colic.

- Colic is very common in formula fed babies; one of the features is excessive production of wind.
- Typical symptoms are abdominal pain and cramping. Typical colic is late onset – around 3 - 4 weeks and can get worse before it gets better, usually by 3 months.
- Symptoms tend to occur same time of the day, typically evenings, often crying

drawing knees up.

- Although there are many “remedies” for infantile colic, most studies of their effectiveness have been found to have flawed methodology.

3.1.2.3 If not colic then consider Lactose Intolerance

Note: True Congenital Lactose Intolerance is rare and present from birth. Babies present as ill enough to need secondary care, and are usually not well enough to leave hospital early on. Symptoms are explosive diarrhoea and colic, poor weight gain, failure to thrive and Paediatricians will be involved very early on.

Secondary Lactose Intolerance is caused by damage to the gut, possibly after an episode of gastro enteritis which is why it is so important formula fed babies are protected from unsafe preparation of feeds. Symptoms are likely to be explosive diarrhoea caused by the osmotic effect of undigested lactose. The next step is to do the Reducing Substances Test, which the health visitor or GP will organise.

The Reducing Substances Test (RST) is done with a stool sample which needs to be as fresh and as large as possible (see Appendix 2). It is most cost effective to do this before prescribing specialist milks.

Staff or the parent will need to document on the request card whether the sample is collected from a nappy or non absorbent material, as this influences whether further testing with sugar chromatography is required. Sample pots and forms are available from GP practices.

Best practice for optimum accurate interpretation of results particularly on the first test, requires collection on a non absorbent surface (not a nappy) as the more liquid part of the stool contains the higher concentration of reducing substances. A practical solution to this is to use a small plastic bag (without holes, such as a freezer or sandwich bag) inserted into the nappy to collect as much liquid stool as possible.

If RST does not show Lactose Intolerance the next step is to investigate cow’s milk protein intolerance.

Lactose malabsorption (which may or may not be due to lactose intolerance) is indicated by stool pH <6, detection of reducing substances and the presence of lactose on sugar chromatography.

If lactose intolerance is diagnosed then a prescription will be required for one of specialised lactose free milks (see Appendix 3). Note the Chief Medical Officer’s comments about Soya based infant formulae (Appendix 4). There should be a marked improvement in the stools within 3 days, if no improvements within a week then refer to GP. If there is an improvement, after a period of time (advice varies from 8-12 weeks) there should be a “Challenge” – by re-introducing the regular formula. **If this is tolerated and no further symptoms manifest then continue with normal infant feeding formula.**

When re-introducing the normal formula follow these guidelines:

Over the 1st week start off at 30 ml a day in a separate bottle for the first few days then 60 ml a day for the remainder of the week. Continue to gradually increase until 4th week when the baby should be fully back on the normal formula. Keeping a record of the gradual increases may be helpful for the parent.

If the child has problems when normal formula is re-introduced then return to specialised formula and challenge again in 4 weeks. This process can be repeated again on a 4 week basis, until no problems. These children can be managed in primary care.

If the child has not managed a successful lactose re-introduction, then refer to a dietician for advice regarding a suitable weaning diet.

3.2 Guidelines for Formula Fed Babies with Suspected Cow's Milk Protein Allergy- IgE Mediated Immediate Allergy

Infants have an immediate consistent reaction to a small amount of cow's milk protein. Reaction can be very severe with Anaphylaxis (drop in blood pressure with possible circulatory collapse and swelling of the airways leading to suffocation) or less severe such as a skin rash – see Appendix 5. These infants should be immediately referred to secondary care **and should be advised to completely avoid cow's milk protein.**

3.3 Guidelines for Formula Fed Babies with Suspected Cows Milk Protein Intolerance-Non IgE Mediated Allergy

Symptoms may include:

- Colicky
- Fussy around feeds
- Faltering growth
- Vomiting
- Bloating
- Explosive stool (often green and frothy)
- Diarrhoea
- Constipation
- Reflux
- Skin rash
- May be mucousy

First follow the pathway for Suspected Lactose Intolerance. If symptoms include non-gastric ones, such as skin rash or wheeziness this will be cow's milk protein intolerance rather than lactose.

If the Reducing Substances Test is negative, then trial for up to 4 weeks on a cow's milk protein free formula (see Appendix 3). The younger the child the quicker the improvement. If this is the cause you would expect a gradual improvement in symptoms over 4 weeks.

If the trial works and indicates intolerance to cow's milk protein then the child should avoid cow's milk and cow's milk products until 12 months of age. As weaning commences it is suggested that the health professional refers to the dieticians for advice regarding suitable weaning foods.

After that gradually introduce cows milk PRODUCTS (not cows milk to start with) and try

one product at a time in small amounts then leave for 3 days before trying another product and gradually build up a range of foods.

3.4 Duties

All healthcare professionals are responsible for their own actions and must exercise their own professional judgment at all times. Any decisions to vary from the agreed BTHFT procedures or guidelines should be documented in the patient care plan, and include the reason for the variance and the subsequent action taken.

BTHFT Community Health Division (CHD) Registered nurses are accountable for their own practice and must work within legislation and abide by The Code (Nursing and Midwifery Council (NMC), 2008).

CHD Senior Managers responsible for BTHFT community nursing are responsible for the operational implementation of this policy and associated procedures, and for ensuring that it is made available to all registered nurses.

CHD Clinical Leaders in community nursing are responsible for ensuring that registered nurses using these guidelines have undertaken the appropriate training and are competent to practice safely.

All qualified healthcare practitioners, primary care assistants and support staff are responsible for ensuring their practice complies with this policy.

4 ATTACHMENTS	
Appendix Number	**Title**
Appendix 1	Pathway for Suspected Secondary Lactose Intolerance
Appendix 2	Reducing Substances Test (RST)
Appendix 3	Alternative formulas
Appendix 4	Soya based Infant Formulae
Appendix 5	Pathways for suspected cows milk protein allergy and intolerance
Appendix 6	Monitoring Audit Form
Appendix 7	Process for Monitoring Compliance
Appendix 8	Equality Impact Assessment Tool

5 ELECTRONIC AND MANUAL RECORDING OF INFORMATION
Electronic Database for Procedural Documents
Held by Policy Co-ordinators/Archive Office

6 LOCATIONS THIS DOCUMENT ISSUED TO		
Copy No	**Location**	**Date Issued**
1	Intranet	12/06/2012
2	Wards and Departments	12/06/2012

7 OTHER RELEVANT/ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
CORP/POL/116	Infection Prevention and Control Policy
CORP/POL/409	Newborn Feeding (including Breastfeeding) Policy
NHSB/Clin106	Guidance on Clinical Diagnostic Testing and Screening Procedures (speak to Sue Wild)
CORP/PROC/102	Consent to Examination or Treatment Procedure
NLTPCT/Clin29	Policy for the management of risks associated with clinical diagnostic tests or screening (Speak to Sue Wild)

8 SUPPORTING REFERENCES/EVIDENCE BASED DOCUMENTS
References In Full
British Dietetic Association Paediatric group position statement: *Use of Infant Formulas based on Soy protein for Infants,* (March 2009)
British Nutrition Foundation (2000) *Lactose Intolerance*
Bottle feeding Department of Health publications (278959) Nov 2007
Guidance from Food Standards Agency on making up bottles of formula
http://www.food.gov.uk/news/newsarchive/2007/jul/nonsterile
Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment: *Report on Phytoestrogens and Health* (TOX/2003/03)
DoH – CMO's Update No. 37 January 2004: *Advice issued on soya-based infant formulas*
Levene, M. I., Tudehope, D. I & Thearle, M. J. (2000) *Essentials of Neonatal Medicine* 3rd ed. Blackwell Science, London
Osborn DA, Sinn J. *Soy formula for prevention of allergy and food intolerance in infants*. Cochrane Database of Systematic Reviews. 2006, Issue 4.
Osborn DA, Sinn JKH. *Formulas containing hydrolysed protein for prevention of allergy and food intolerance in infants*. *Cochrane Database of Systematic Reviews* 2006, Issue 4.
Scientific Advisory Committee on Nutrition: *Response to The Committee on Toxicity on the draft report Phytoestrogens and Health* (12/03)
UNICEF UK Baby Friendly Initiative: The health professional's guide to:" A guide to infant formula for parents who are bottle feeding" March 2010

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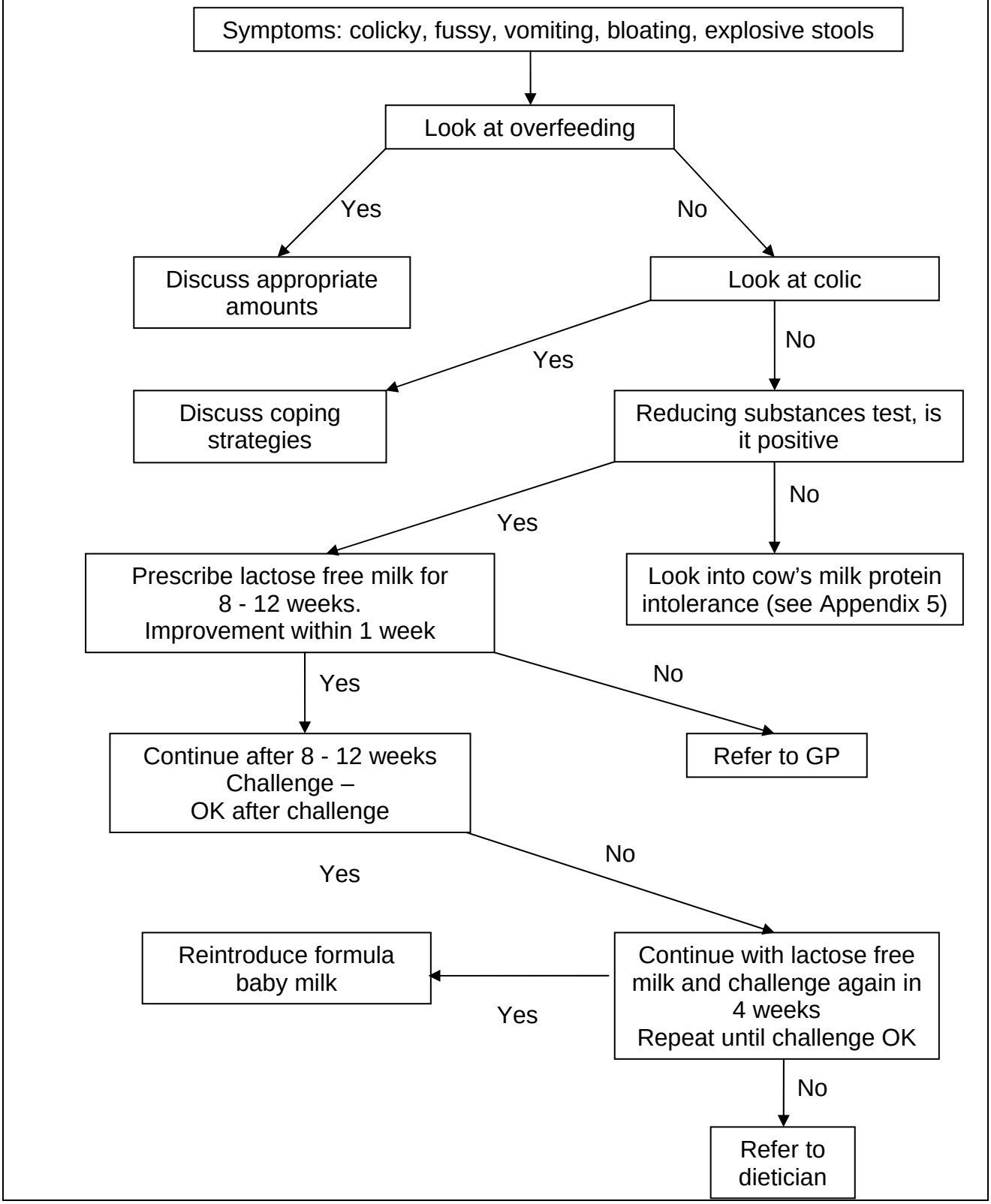
10 DEFINITIONS/GLOSSARY OF TERMS	

11 AUTHOR/DIVISIONAL/DIRECTORATE MANAGER APPROVAL			
Issued By	Jane Putsey	**Checked By**	E Holt
Job Title	Infant Feeding Consultant	**Job Title**	Director of Community Health Services
Date	June 2012	**Date**	June 2012

Appendix 1: Pathway for Suspected Secondary Lactose Intolerance for Formula Fed Babies



Appendix 2: Reducing Substances Test (RST)

This test does not diagnose lactose intolerance, but does indicates if there is a malabsorption problem, which could be as a result of other conditions i.e. cows milk protein allergy, GI infection etc.

- First test for reducing substances, any result other than negative requires further testing by the laboratory (on same sample).
- Results are on a scale from negative upwards, greater than 1% indicates a definite abnormal result.
- If negative, is reported as FRED (faecal reducing substances) not detected also faecal Ph x.yz (result) e.g. 6.74.
- Second test, sugar chromatography, a more labour intensive test (therefore more costly). All samples with anything other than a negative result currently have this second test. It is important that the sample is fresh and it is documented on the request card whether it is collected from a nappy or non absorbent material, as this influences whether sample requires sugar chromatography test.
- Sample pots and request forms are available from GP practices. The sample is to be taken as soon as possible to the laboratory either by the parent or to the surgery. If the latter, then a time to be arranged with the health visitor who will know when routine sample collection is scheduled for the respective surgery in question to maximise the opportunity for testing as soon as possible.
- If a sample is collected from a nappy the stool water is absorbed. When this occurs the measurement of reducing substances may not reflect the sugars present in the whole 'watery stool' – giving a misleading low percentage of reducing substances. Ideally, faeces should be collected into a non-absorbable bag. The whole specimen including watery fluid should be sent to the laboratory immediately (>1% is significant if stool is collected into non-absorbent material).
- Reported following second test –

    1. Trace – not clinically indicative of malabsorption. Future laboratory reports could include a comment stating this, to clarify interpretation of result.
    2. Positive
    3. Markedly positive

If baby has had specialist formula followed by a trial back on regular formula with a recommencement of symptoms, a further sample could be tested.

Appendix 3: Alternative Formulas

Alternative formulas for infants with suspected Lactose Intolerance

Note this is NOT an exhaustive list and is not in any particular order

Lactose free milks
Enfamil O-Lac previously known as Enfamil lactofree
SMA LF

Alternative formulas for infants with suspected Cows Milk Protein Intolerance

Extensively hydrolysed whey based milks
Pepti (contains lactose)
Pepti Junior

Extensively hydrolysed casein based milks
Nutramigen 1 (under 6 months)
Nutramigen 2 (over 6 months)

Free amino acids
Neocate
Nutramigen AA

Note some extensively hydrolysed milks (particularly the case in ones) may taste unpalatable to older babies. If a baby is refusing to feed it may be necessary to mix with the existing formula and gradually increase the proportion. Although not generally best practice to mix different milks there may be rare occasions when this might be necessary.

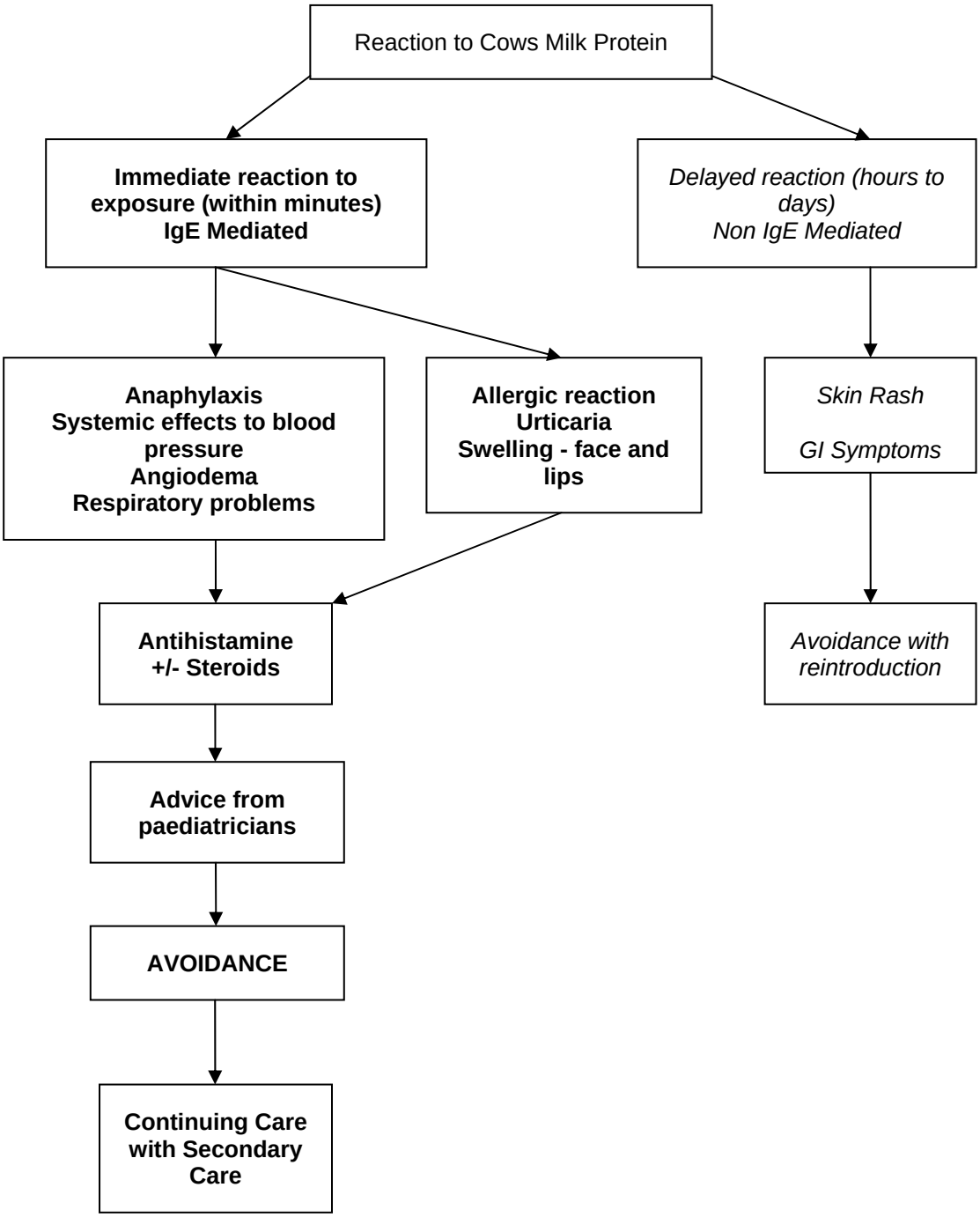
Appendix 4: Soya based Infant Formulae

In January 2004 the Chief Medical Officer (CMO) restated that soya based infant formulae should not be used as the first choice for management of infants with proven cows milk sensitivity, lactose intolerance, galactokinase deficiency and galactosaemia. The Committee on Toxicity of Chemicals in Food (COT) are concerned that soya based infant formulae have high phytooestrogen content and **may** pose a risk to long-term reproductive health. In addition, the Scientific Advisory Committee on Nutrition (SACN) has advised that there is no particular health benefit associated with the consumption of soya based infant formula by infants who are healthy (no clinically diagnosed conditions) SACN also advised that there is no unique clinical condition that particularly requires the use of soya based infant formulae.

Appendix 5: Pathways for suspected cows milk protein allergy and Intolerance

This pathway is for information for staff in primary care, to give an insight into where secondary care is, note key is:

Bold – Secondary Care *Italic* – Primary Care



Appendix 6: Monitoring Audit Form

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Appendix 6

Guidelines for Formula Fed Babies
(With suspected Lactose Intolerance, suspected Cows Milk Protein Allergy or suspected Cows Milk Protein Sensitivity)

Monitoring tool

The monitoring tool is for use by Health Visiting staff and any other staff who use the guidelines. Community Health Services will contact Health Visiting staff 6 months after the publication of the guidelines and ask them to complete the monitoring tool. The tool will be forwarded electronically to all Health Visiting staff by the Clinical Audit Team.

Instructions - please answer the questions by ticking within the box

	Yes	No
Are you aware of the 'Guidelines for Formula Fed Babies'?	☐	☐
Have you read 'Guidelines for Formula Fed Babies'?	☐	☐
Did you find the guidance clear and understandable?	☐	☐
Have you used the guidance?	☐	☐
Did the guidance provide all the information you needed to give the appropriate support?	☐	☐

If 'NO' what did you feel was missing?

Are there any areas that could be improved?

Appendix 7: Process for monitoring Compliance

	Minimum requirement to be monitored		Process for monitoring e.g. audit	Responsible individual/ group/ committee	Frequency of monitoring	Responsible individual/ group/ committee for review of results	Responsible individual/ group/ committee for development of action plan	Responsible individual/group/ committee for monitoring of action plan and Implementation	
	a)	monitoring compliance with these guidelines and updating as necessary	multi disciplinary team that looks at information about infant feeding using the monitoring forms in Appendix 6	Infant Feeding Information Team (IFIT),	monthly	IFIT will ensure these guidelines get communicated through the appropriate channels			

Appendix 8: Equality Impact Assessment Tool

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To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Would the relevant Equality groups be affected by the document? (If Yes please explain why you believe this to be discriminatory in Comment box)

Title & Identification Number of the Document: Guidelines for Formula Fed Babies with Suspected Lactose Intolerance, Suspected Cows Milk Protein Allergy or Suspected Cows Milk Protein Intolerance Comm/Guid/002

	Questionnaire	Yes/No Double click and select answer	Comments
1	Grounds of race, ethnicity, colour, nationality or national origins e.g. people of different ethnic backgrounds including minorities: gypsy travellers and refugees / asylum seekers.	No	
2	Grounds of Gender including Transsexual, Transgender people	No	
3	Grounds of Religion or belief e.g. religious /faith or other groups with recognised belief systems	No	
4	Grounds of Sexual orientation including lesbian, gay and bisexual people	No	
5	Grounds of Age older people, children and young people	No	
6	Grounds of Disability: Disabled people, groups of physical or sensory impairment or mental disability	No	
7	Is there any evidence that some groups are affected differently?	No	
8	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
9	Is the impact of the document/guidance likely to be having an adverse/negative affect on the person (s)?	No	

10	If so can the negative impact be avoided?	N/A	
11	What alternatives are there to avoid the adverse/negative impact?	**Please Comment**	
12	Can we reduce the adverse/negative impact by taking different action?	N/A	**Please Identify How**

13 Q1 (a) **Is the document directly discriminatory?** No (under any discrimination legislation) • Racial Discrimination • Age Discrimination • Disability Discrimination • Gender Equality • Sexual Discrimination	**Q2 (b) (i)** Is the document indirectly discriminatory? No **b (ii)** If you said yes , is this justifiable in meeting a legitimate aim N/A	**Q3 (c)** Is the document intended to increase equality of opportunity by positive action or action to redress disadvantage N/A Please give details To safeguard vulnerable adults

14 If you have answered **no** to all the above questions **1-13** and the document does not discriminate any Equality Groups please go to **section 15**

If you answered **yes** to Q1 (a) and **no** to Q3 (b) this is unlawful discrimination.

If you answered **yes** to Q2 (b) (i) **no** to Q2 (b) (ii) and **no** to Q3 (c), this is unlawful discrimination

If the content of the document is not directly or indirectly discriminatory, does it still have an adverse impact?

No

Please give details

If the content document is unlawfully discriminatory, you must decide how to ensure the organisation acts lawfully and amend the document accordingly to avoid or reduce this impact

15 Name of the Author completing the Equality Impact Assessment Tool.

Name Janey Putsey

Signature

Designation Infant Feeding Consultant

Date April 2012