National Institute for Health and Clinical Excellence

Food allergy in children
Scope Consultation Table
11/01/10 – 08/02/10

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Alder Hey Children's NHS Foundation Trust	2.00	3.1 (a)	Why is there 'gastrointestinal anaphylaxis' and just 'anaphylaxis'? What does gastrointestinal anaphylaxis' mean, do we mean gastro symptoms such as nausea, vomiting, diarrhoea etc, if so why doesn't it just say gastro symptoms such as... (And then list the symptoms). Think we should list things like wheeze, cough, and difficulty in breathing – not just have the word asthma. Some allergic individuals do not have asthma, but may well have respiratory symptoms in an allergic episode.	Noted. 'Gastrointestinal anaphylaxis' has been removed from the scope. The scope has been amended to include respiratory symptoms.
SH	Alder Hey Children's NHS Foundation Trust	2.01	3.1 (g)	Take out 'some' before tree nuts, just have tree nuts.	Noted. The scope has been amended.
SH	Alder Hey Children's NHS Foundation Trust	2.02	4.3 (c)	We would never expect oral food challenges, DBPCFC or atopy patch testing to be done in Primary Care. Also most of the diagnostic tests SPT or RAST tests, patch tests etc. will not be performed in every GP surgery	Noted. Evidence relating to those diagnostic tools listed (including the oral food challenge and atopy patch test) will be considered as they are diagnostic tests for food allergy. Specifically, DBPCFC has been included as a comparator. The GDG will also consider the appropriate use of such tests in the primary care setting.
SH	Alder Hey Children's NHS Foundation Trust	2.03	4.3 (f)	We consider these tests 'alternative' rather than complementary. I would never encourage a patient/family to go down this route of testing, though We agree often is desperation many families do just that due to poor access to allergy services. The	Noted, the scope has been amended accordingly.

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				evidence base / value of these tests need to be ascertained from scientific point of view; hopefully scrutiny will clarify the assumption that these tests are not good value.	
SH	Alder Hey Children's NHS Foundation Trust	2.04	General	The draft scope is limited to food allergy care in primary care and excludes secondary and tertiary care. Will it not be more useful and productive if the allergy care and evidence base for the current allergy practice is scrutinized? This should provide more universal applicable evidence based guidelines for allergy in children. Like asthma, then levels of care can be defined i.e. what should be available in primary care and when to refer to secondary /tertiary care	Thank you, and while we recognise the importance of diagnosis within secondary and tertiary care , these issues are outside the specific remit provided by the Department of Health. For more information about the topic selection process please see the link below: http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp We also anticipate that recommendations on appropriate referral will be made.
SH	Association of Breastfeeding Mothers	3.00	Section 18, page 14	Ongoing management: When a baby or child is still breastfed, due consideration should be given to child-led weaning	Thank you for your comments and although we recognise the importance of this, management of food allergy is outside the remit provided by the Department of Health..
SH	Association of Breastfeeding Mothers	3.01	Section 21, page 15	Contact with School and Early Years Liason: The importance of breastfeeding to avoid allergies, asthma and rhinitis should be be stressed in appropriate situations; consideration given to late introduction of potentially allergenic foods, and support given to the mother-baby/child dyad to continue breastfeeding for as long as mutually desired. Annectodal reports suggest that some babies at risk of allergies benefit from a prolonged period of exclusive nursing and the late introduction of solid foods to their diets. This should be considered, alongside supportive monitoring, for young babies.	Thank you for your comments, and although we recognise the importance of this, prevention of food allergy is outside the remit provided by the Department of Health.
SH	Breastfeeding Network	4.00	General	We feel it would be useful to consider prevention,	Thank you for your comments, and while we

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				within the scope of this document.	recognise the importance of preventing food allergy, this is outside the remit provided by the Department of Health.
SH	Breastfeeding Network	4.01	General	We recognise there is potential for conflicts of interest in the development of this guidance. We feel it is crucial to include research papers, studies and the panel, funded independently of industry – including not only those who manufacture and promote foods and products, but also those manufacturers and suppliers with a financial interest in this topic, including those manufacturing allergy testing machines and equipment.	We will do a systematic search for all relevant research and other papers relating to this topic. The inclusion/exclusion of the papers will be reviewed by the guideline development group (GDG) who will be appointed under NICE's recruitment policy, which will include health care professionals and patient members, none of which will be represented or funded by industry.
SH	Breastfeeding Network	4.02	General	We would welcome inclusion of the importance of exclusive breastfeeding for around 6 months, as this is the norm. It would be good to see that this guideline supports the other NICE guidance in particular - Maternal and Child Nutrition and others, which include the importance of breastfeeding.	While we recognise the importance of the prevention of food allergy, this is outside the remit provided by the Department of Health. The team will also review the evidence before making definitive distinctions between the age specific sub-groups.
SH	Breastfeeding Network	4.03	General	We would welcome more information on the testing kits and what the results mean in terms of health.	Thank you for your comment..
SH	British Dietetic Association	5.00	3.1 a)	For non-Ig-E characteristics, atopic eczema and faltering growth should be included in this list ('proctitis or proctocolitis' could be put under 1 bullet point to shorten list length if necessary).	Noted. This has been amended on the scope.
SH	British Dietetic Association	5.01	4.1.1 a)	A decision needs to be made as to whether the guideline is going to cover 0-19yrs as suggested in point a) or 0-18 yrs as mentioned throughout the rest of the document [4.1.1c), 4.1.2a), 4.3.2b) . The Children and Young Peoples' Plan and the DH Healthy Child Programme work to 0-19yrs, so perhaps the document should mirror these. Linked to comment 1, re the list of conditions, key	Thank you. To clarify, the guideline will cover children and young people up to, but not including, their 19th birthday (i.e. 0-18 years). The list represents a range of symptoms that may be experienced and are not exhaustive; however, these are both now listed.

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				symptoms missing from this section include angioedema and faltering growth.	
SH	British Dietetic Association	5.02	4.1.2c)	?typo – should be protease inhibitors	Thank you. This has been corrected
SH	British Dietetic Association	5.03	4.2 b)	List would be better extended to read, following on from home and health visits as... 'childrens' centres and other child care health settings, pre-schools, schools, community pharmacy, community dietetic and community paediatrician services.'	We have amended the scope to add 'childrens' centres and community paediatrician services.
SH	British Dietetic Association	5.04	4.3 c)	Food elimination. We presume this will allow for guidance to be given on the appropriate use of infant formula substitutes, to address the ongoing issue of soya infant formula being prescribed by GP's in infants under 6 mths age, and for provision of dietary information to enable patients to undertake food allergen avoidance. [this however forms part of initial management, which is explicitly stated as not being included (4.3.2 d)]. Assuming that the above will occur, perhaps 4.3.2 d) should therefore mention '…..treatment of food allergy, other than that required to elicit a diagnosis, in children…..'	Noted. Food elimination will only be considered in the context of diagnosing food allergy and separate guidance will not be produced on the appropriate use of formula substitutes.
SH	British Dietetic Association	5.05	4.4 b)	We don't recall debate around the use of the term 'rates of referral to secondary care'. In the previous draft scope, it just stated referral to…and we suggested altering terminology to 'identify appropriate referral to secondary care'. The aim of improving the diagnosis of allergy in primary care is not for every child to then be referred to secondary care for treatment – resource, timeliness and cost issues would be prohibitive and it may also not be in the best interests of the patients. Given appropriate competency, a large proportion of food allergy can be managed within primary care with support from a community dietitian (refer to RCPCH food allergy	Thank you, however this refers to the outcomes reported in research papers and does not relate to the intended outcomes of the recommendations..

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				care pathway). Or perhaps it is referring to rates of referral for allergy testing, some of which will have to be done in secondary care. If so, it needs to state this. It might be useful information to audit, as would auditing appropriate referral for management to secondary care	
SH	British Dietetic Association	5.06	5.1	It may read better as 'The RCPCH is currently developing a series of evidence based care pathways for children with allergies, including a national care pathway for children with food allergy' (not food and GI allergy)	Of the pathways that are being developed by the RCPCH, we feel that the 'Food and Gastrointestinal Allergy Care Pathway' has the most relevance to this guideline, and are working closely with this working group to ensure good communication between the two groups.
SH	British Paediatric Allergy, Immunity & Infection Group	6.00	3.1 a	The list of IgE mediated symptoms seems rather arbitrary – the vast majority are urticaria/angioede,a and these should feature lore prominently. For non IgE eczema and faltering growth are important omissions.	Thank you. The lists represent the range of symptoms characterised by IgE and non IgE mediated food allergy, they are not exhaustive and have been listed in alphabetical order. The scope has been amended to incorporate atopic eczema and faltering growth.
SH	British Paediatric Allergy, Immunity & Infection Group	6.01	3.1c	6-8% prevalence relates only to IgE mediated allergy and thus is likely to be a gross underestimate of all food allergy	Noted. The rates of food allergy are reported within a range and the scope does acknowledge that there are inconsistencies in reported prevalence figures.
SH	British Paediatric Allergy, Immunity & Infection Group	6.02	3.1g	Sesame is a more common allergen than banana	Noted. These are examples of other less common foods to which children and young people are allergic to and are not exhaustive. The scope has been amended to include sesame.
SH	British Paediatric Allergy, Immunity & Infection Group	6.03	3.1i	This point seems to be missing what might be considered the most compelling reason for the guideline. Many children, particularly with nonIgE mediated allergy have the role of food left unrecognised and unexplored and suffer, often for extended periods, completely unnecessarily. This is a greater priority than avoiding overdiagnosis.	Noted. The scope has been adjusted to incorporate this.
SH	British Paediatric Allergy,	6.04	3.2b	The most common 'other' consultant to see food	Thank you for your comment. The section is

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	Immunity & Infection Group			allergic children is a general paediatrician	describing current practice in primary care and community settings, rather than once a child has been referred to secondary care .
SH	British Paediatric Allergy, Immunity & Infection Group	6.05	3.2c	The Map of medicine model rests on the requirement for the practitioner to suspect food allergy in the first instance. A priority needs to be considering possible food allergy in certain presentations eg eczema, reflux even when the parent has not made the link	Noted. The map of medicine model has been included to reflect current practice within the diagnosis of food allergy. Re the priority of increased awareness, we do specify that children at a higher risk of allergy (even without parental suspicion of food allergy) are included. In addition, we would anticipate that the guideline would raise awareness of food allergy in primary and community care.
SH	British Paediatric Allergy, Immunity & Infection Group	6.06	4.1c	In infancy, the pathway will differ according to whether the child is exclusively breast fed or not. Should this not be considered a useful seaparation?	Noted however, the team will review the evidence for these different groups, and where appropriate, make specific recommendations for exclusively breast fed infants and children.
SH	British Paediatric Allergy, Immunity & Infection Group	6.07	4.1.2	As this guideline does not relate to treatment but just to assessment/diagnosis, it is difficult to see how non immune mediated food hypersensitivity reactions can be disentangled and thus need to be considered as differentials.	Noted. Non-immune mediated food hypersensitivity reactions fall outside the scope and while no separate guidance will be produced for the diagnosis of these conditions, we will consider them in the context of diagnosing food allergy.
SH	British Paediatric Allergy, Immunity & Infection Group	6.08	4.3.1b	Diaries are of both symptoms and also foods ingested	Thank you for your comment. This has been changed within the scope.
SH	British Paediatric Allergy, Immunity & Infection Group	6.09	General	Whilst no management issues are covered, the choice of feed for elimination diets in milk allergy will very much cross over into management issues	Noted. Although guidance will not be produced on the management of milk allergy, food elimination diets will be considered within the context of diagnosing food allergy, rather than as a treatment option.
SH	Department of Health	7.00	General	As drafted, the guideline may prove unhelpful in the diagnosis of non-IgE mediated food allergy affecting the gut. In our view, the assessment including family history and sometimes investigations (such as	Thank you for your comment. We have advertised for a paediatrician with a special interest in gastroenterology and hope to appoint to include one on the GDG.

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				immunoglobulins, including total IgE and non food related specific IgE) can be useful in diagnosing atopy, which may then influence the diagnosis of non IgE mediated food allergy affecting the gut. We feel that it would be beneficial if the guideline development group were to include an expert in paediatric gastroenterology.	
SH	Food Standards Agency	8.00	General	The Food Standards Agency welcomes the development of this important clinical Guideline. We do not have any comments to make on the draft Scope which would seem to have taken good account of the discussions and suggested amendments made at the stakeholder scoping meeting. We would comment that the composition of the Stakeholder Drafting Group will be critical to the Guideline's success, and we would strongly urge that there is adequate representation from expert paediatrician's with interests in **food** allergy on this Group, in addition to some representation from paediatrician's with interests in fields related to allergy (such as gastroenterology, dermatology and immunology)	Thank you for your comment. We have taken into account all the comments from the stakeholder workshop. We have advertised for paediatricians with a special interest in food allergy, in addition to paediatricians with interests in related fields including dermatology, gastroenterology and as this is a community and primary care based setting, a community paediatrician. We hope to appoint all relevant specialities onto the GDG.
SH	Imperial College Healthcare NHS Trust	9.00	2	We are delighted that NICE will be conducting this short guideline into the diagnosis and assessment of food allergy in children but disappointed that this is only focused on primary care and community settings. There is a need to understand the issues that relate to secondary and tertiary care as well.	Thank you for your comment. While we recognise the importance of diagnosing food allergy within secondary and tertiary care,This is outside the remit provided by the Department of Health
SH	Imperial College Healthcare NHS Trust	9.01	3.2 A	The division of food allergy into IgE and non-IgE mediated responses is reasonable. However, this does sometimes cause confusion. Some more delayed responses which are a consequence of eosinophil migration to the tissues can still be IgE	Noted. The scope has been amended to include mixed IgE mediated responses and eczema has been added to the list of non-IgE mediated reactions. Gastrointestinal anaphylaxis has been removed from the scope.

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				mediated with release of eosinophil chemoattractants. Furthermore there is even a suggestion that predominantly cell mediated responses can also be, to a certain extent, initiated by IgE which is fixed to antigen presenting cells and facilitates a sensitisation process. Our preference is to discriminate between mask cell and basophil mediated responses and those involving other cells such as eosinophils and / or lymphocytes. The list of conditions which are characterised as IgE mediated includes a category "gastrointestinal anaphylaxis". This may cause confusion. While on occasions fluid loss into the bowel can lead to hypotension and therefore anaphylaxis many cases involving acute onset of diarrhoea, abdominal pain and vomiting are not life threatening. Non IgE mediated reactions should include eczema.	
SH	Imperial College Healthcare NHS Trust	9.02	3.1 F	The frequency with which perceived food reactions are confirmed on challenge varies from publication to publication but is more consisently around 25% rather than 30-40%.	Noted. The scope has been amended accordingly.
SH	Imperial College Healthcare NHS Trust	9.03	3.1 G	Should include sesame seed. Kiwi fruit allergy is now rather common and certainly well within the league table listed. It is not a less common allergy.	Noted. The scope has been changed to reflect this.
SH	Imperial College Healthcare NHS Trust	9.04	3.1 I	One of the most important components of making an accurate diagnosis and giving appropriate support is to avoid nutritional deficiencies as a consequence of badly supervised dietary avoidance.	Noted. The scope has been amended to incorporate this.
SH	Imperial College Healthcare NHS Trust	9.05	3.2 A	We are concerned that assessment of severity should also include a risk assessment of the probability that future exposures might generate more severe reactions. Merely indicating that those who have previously more severe reactions does not take account of dose response relationships. Thus a	Thank you for your comments. This section reflects current practice within the diagnosis of food allergy and is not a reflection of what the guideline will cover.

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				minor skin reaction to being kissed by somebody who has previously eaten a food allergen producing local urticaria may be an indication of marked sensitivity and a risk of anaphylaxis on oral ingestion. This is also relevant to 3.2 C in that map of medicine does not iterate the issues related to dose response relationships.	
SH	Imperial College Healthcare NHS Trust	9.06	4.1.2	We are concerned that non-immunologically mediated reactions are not the subject of this guideline. It is often very difficult to disentangle toxic reactions such as to scromboid fish where acute reactions are a consequence of histamine poisoning and will produce identical symptoms. The imperative here is to discriminate. Furthermore, many cows' milk protein intolerant children have associated lactose intolerance and therefore there are big overlaps between conditions.	Noted. Although guidance will not be produced on the diagnosis of non-immunologically mediated reactions, they will be considered in the context of diagnosing food allergy.
SH	Imperial College Healthcare NHS Trust	9.07	4.1.2 E	Again, patients who have psychological reactions to food with food avoidance require appropriate diagnosis to avoid inappropriate dietary avoidance and potential for nutritional impairment.	Noted, however the diagnosis of psychological reactions to food falls outside the scope.
SH	Imperial College Healthcare NHS Trust	9.08	4.3.1	If only community settings are being evaluated then oral food challenge whether double blind or open has the potential to be dangerous. It should only be done in a setting where appropriate skill and treatment is available to handle a severe reaction. There are additional tests beginning to become available for the diagnosis of food allergy and intolerance of which perhaps the basophil activation test is the one nearest to application. There is also a need to consider whether component resolved diagnostics should be incorporated into the IgE antibody evaluations.	Thank you. Oral food challenges will be considered as a possible diagnostic tool and the evidence will be reviewed before making any definitive decisions and recommendations. Component resolved diagnostics has been incorporated into the search strategy, however tests that are currently not in use will not be reviewed**.** With regard to the component resolved diagnostics, we will review the evidence as appropriate.
SH	Imperial College	9.09	4.5	As has been discussed at the joint meeting between	The QALY is NICEs preferred method for measuring

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	Healthcare NHS Trust			NICE and the Royal College of Paediatrics and Child Health (RCPCH) a concern that using quality adjusted life year evaluations which are based on adult insights are not appropriate for children. There is a need to understand the way in which quality of life of food allergic children affects their schooling, education, career attainments etc. There is a quality of significantly impaired self-esteem and exclusion from activities in school. There are also considerable indirect effects on other members of the family including siblings.	health outcomes (see NICE guidelines manual 2006 section 8.2) as it captures the majority of the aspects of a person's quality of life. In the case of children instruments such as the HUI 3 have been validated in children to help measure quality of life. Alternatives will be considered by the GDG in the absence of appropriate data.
SH	Imperial College Healthcare NHS Trust	9.10	5.1	We are pleased that NICE have noted the RCPCH project group working on care pathways for children with food allergy. As I am chairman of the project as a whole I will ensure that our outputs are forwarded as soon as they are available. Indeed it would be sensible to have a discussion to ensure there are no conflicts as the two guidelines are being evolved.	Staff from NICE have been attending the Food and Gastrointestinal Allergy Care Pathway's working group as observers and have retained close contact with the project manager of the project. We will continue to liaise closely with the groups and would welcome a discussion with the chairman of the project as a whole.

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SH	Manchester Community Health	10.00	2	What a wasted opportunity by the DH to only focus on the remit of 'diagnosis and assessment' of food allergy. Could the scope not be changed to better promote equality of opportunity in relation to 'Prevention and Treatment' for us professionals working with children and young people in primary care and community settings? Page 2 (b) states that 'Food allergy in the population is among the most common allergic disorders and has been recognised as a major paediatric health problem in western countries', therefore, doesn't this support the evidence that more needs to be done regards 'prevention'? What's the relevance of knowing how to diagnose and assess if you haven't got the evidence to practice and manage safely, effectively and efficiently?	Thank you for your comment and while we recognise the importance of preventing and treating food allergy, this is outside the remit provided by the Department of Health. For more information about the topic selection process please see the link below: http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp
SH	Manchester Community Health	10.01	3.2a	More evidence to support the fact that we need evidence-based , agreed, 'Treatment pathways', ' referral criteria' or 'service models'	Thank you. The purpose of this guideline is to produce recommendations on the diagnosis of food allergy and will address referrals to secondary or specialist care. While we recognise the importance of management and treatment issues, this is outside the remit provided by the Department of Health
SH	NHS Direct	11.00	General	NHS Direct welcome the guideline and have no comments on the scope.	Thank you
SH	Nottingham Community Nutrition and Dietetic Department	12.00	3.1 a)	For non-Ig-E characteristics, atopic eczema and faltering growth should be included in this list ('proctitis or proctocolitis' could be put under 1 bullet point to shorten list length if necessary)	Noted. This has been amended on the scope.
SH	Nottingham Community Nutrition and Dietetic Department	12.01	4.1.1 a)	A decision needs to be made as to whether the guideline is going to cover 0-19yrs as suggested in point a) or 0-18 yrs as mentioned throughout the rest of the document [4.1.1c), 4.1.2a), 4.3.2b) . The Children and Young Peoples' Plan and the DH Healthy Child Programme work to 0-19yrs, so	Thank you. To clarify, the guideline will cover children and young people up to, but not including, their 19th birthday (i.e. 0-18 years). The list represents a range of symptoms that may be experienced and are not exhaustive.

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				perhaps the document should mirror these. Linked to comment 1, re the list of conditions, key symptoms missing from this section include angioedema and faltering growth.	
SH	Nottingham Community Nutrition and Dietetic Department	12.02	4.1.2c)	?typo – should be protease inhibitors	Thank you. This has been corrected
SH	Nottingham Community Nutrition and Dietetic Department	12.03	4.2 b)	List would be better extended to read, following on from home and health visits as... 'childrens' centres and other child care health settings, pre-schools, schools, community pharmacy, community dietetic and community paediatrician services.'	We have amended the scope to add 'childrens' centres and community paediatrician services.
SH	Nottingham Community Nutrition and Dietetic Department	12.04	4.3 c)	Food elimination - presume this will allow for guidance to be given on the appropriate use of infant formula substitutes, to address the ongoing issue of soya infant formula being prescribed by GP's in infants under 6 mths age, and for provision of dietary information to enable patients to undertake food allergen avoidance. [this however forms part of initial management, which is explicitly stated as not being included (4.3.2 d)]. Assuming that the above will occur, perhaps 4.3.2 d) should therefore mention '…..treatment of food allergy, other than that required to elicit a diagnosis, in children…..'	Noted. Food elimination will only be considered in the context of diagnosing food allergy and separate guidance will not be produced on the appropriate use of formula substitutes.
SH	Nottingham Community Nutrition and Dietetic Department	12.05	4.4 b)	I don't recall debate around the use of the term 'rates of referral to secondary care'. In the previous draft scope, it just stated referral to…and we suggested altering terminology to 'identify appropriate referral to secondary care'. The aim of improving the diagnosis of allergy in primary care is not for every child to then be referred to secondary care for treatment – resource, timeliness and cost issues would be prohibitive and it may also not be in the best interests of the patients. Given appropriate	Thank you, however this refers to the outcomes reported in research papers and does not relate to the intended outcomes of the recommendations .

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				competency, a large proportion of food allergy can be managed within primary care with support from a community dietitian (refer to RCPCH food allergy care pathway). Or perhaps it is referring to rates of referral for allergy testing, some of which will have to be done in secondary care. If so, it needs to state this. It might be useful information to audit, as would auditing appropriate referral for management to secondary care.	
SH	Nottingham Community Nutrition and Dietetic Department	12.06	5.1	It may read better as 'The RCPCH is currently developing a series of evidence based care pathways for children with allergies, including a national care pathway for children with food allergy' (not food and GI allergy)	Of the pathways that are being developed by the RCPCH, we feel that the 'Food and Gastrointestinal Allergy Care Pathway' has the most relevance to this guideline, and are working closely with this working group in the development of both the pathway and the NICE guideline
SH	Phadia Ltd	13.00	4.3.1	Recommend including Allergen Component testing for food allergen components. This can help define prognosis, risk of severe reactions to food and cross reactions with pollen allergens.	Noted. Component resolved diagnostics has been incorporated into the search strategy. With regard to the component resolved diagnostics, we will review the evidence as appropriate.
SH	Phadia Ltd	13.01	4.3.1	Recommend to remove the complimentary testing methods, there are many references pointing these out as inappropriate for diagnosing food allergy. Example references: Allergy 2008;63:793-796 J Investig Allergol Clin Immunol 2005;15 (2) 86-90 Eur Ann Allergy Clin Immunol 2004; 36 (4) 139 – 145 Curr Opin Allergy Clin Immunol 2003;3 (3) :217 - 221	Noted, however the team will review all the evidence before making decisions.
SH	Poole and Bournemouth PCT	14.00	3.2	The first step need to be raising the educational standards for GPs re allergy.	Noted. However this is outside of the remit provided by the Department of Health. This may be an issue that can be raised with the Implementation team later in the development process.
SH	Poole and Bournemouth PCT	14.01	3.2	We need to involve Health Visitors (mainly for cows milk allergy) and Practice Nurses, who will need	We agree that Health Visitors and Practice Nurses should be involved in the development of this

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				education as well as experience of sitting in on allergy clinics	guideline and as such have advertised for both for membership of the GDG. Re the education, this may be raised with the Implementation team later in the development process.
SH	Poole and Bournemouth PCT	14.02	4.3.1	Investigations like skin prick tests and serum IgE are easy to perform but quite difficult to interpret, especially for foods. The last thing we want is for investigations being done, and child then being referred to an allergy clinic as GP does not know how to interpret	Thank you. All evidence will be reviewed and critically appraised before recommendations are made by the guideline development group. And we anticipate that issues such as interpretation of results and experience of conducting tests will be part of the detailed deliberations,
SH	Poole and Bournemouth PCT	14.03	4.3.1	There is already an inappropriate amount of prescribing of Epipen autoinjectors in primary care. This can get much worse if results of tests are over-interpreted. These decisions are best left to those with a good experience in allergy	Noted. Guidance will not be produced on the management and treatment of food allergy as it falls outside the remit provided by the Department of Health. For more information on the topic selection process please see the link below: http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp We would also anticipate that issues such as interpretation of results will be part of the detailed deliberations.
SH	Poole and Bournemouth PCT	14.04	General	We need to motivate and train GPs to develop an interest in Childrens Allergy (GPwSI)	Noted. However this is outside of the remit provided by the Department of Health. We hope that the guideline will be a valuable document to GPs, and have included a GP as a member of the GDG. Re the motivation, this may be raised with the Implementation team later in the development process, and we would also hope that professional organisations would develop training and standards to support the final guideline.
SH	Poole and Bournemouth PCT	14.05	General	It should be mandatory for those running primary care paediatric allergy services to have at leat a Diploma, if not an MSC in Allergy. Excellent courses	Noted. However this is outside of the remit provided by the Department of Health. NICE will produce guidelines on 'Diagnosis and assessment of food

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				at Imperial Hospital, London and at Southampton	allergy in children and young people in primary care and community settings'. Re the training, this may be raised with the Implementation team later in the development process, and we would also hope that professional organisations would develop training and standards to support the final guideline.
SH	Poole and Bournemouth PCT	14.06	General	As a Paediatrician with Allergy interest, I have been inundated with referrals for paediatric allergy. I have therefore, recently started a Primary Care Paediatric Allergy Clinic on the request of Poole and Bournemouth PCT (a national first I believe). I aim to train up interested GPs who can then branch out and provide further services in the region, but this will take years.	Thank you for this information. Also please see the comment above about training.
SH	Royal College of Nursing	15.00	General	The Royal College of Nursing welcomes proposals to develop this guideline.	Thank you.
SH	Royal College of Nursing	15.01	General	The draft scope is very clear and concise.	Thank you.
SH	Royal College of Nursing	15.02	General	Even though the scope will not cover/discuss diagnosis of food intolerance, we think the guideline should state what food intolerance is.	When developing the guideline we will clarify what is meant by food intolerance within the glossary
SH	Royal College of Paediatrics and Child Health	16.00	General	The College welcomes the development of this clinical guideline, and thinks it and could be a driver for improved practice in primary and secondary care. Its primary outcome would not lie in medication advice, but improved diagnosis and awareness. We note that the draft scope is well designed and look forward to seeing the GDG's recommendations.	Thank you.
SH	Royal College of Paediatrics and Child Health	16.01	2	We are disappointed that the scope covers primary care and community settings only. We recommend that the scope also cover secondary and tertiary care settings; we note this is where the majority of children with suspected food allergy are seen.	Thank you for your comments, while we recognise the importance of diagnosing food allergy within secondary and tertiary care, this is outside the remit provided by the Department of Health.
SH	Royal College of	16.02	3.1	We recommend adding, "Sensitisation to food and	Noted, the scope has been amended.

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	Paediatrics and Child Health			inhalant allergens increases with increasing eczema disease severity, suggesting a role for the skin barrier in initiating allergic disease."	
SH	Royal College of Paediatrics and Child Health	16.03	3.1	We recommend adding, "Published threshold levels for specific IgE to milk, egg, peanut and cod enable the clinician to predict the probability of clinical reactivity to specific foods prior to introduction." See Sporik R et al. Specificity of allergen skin testing in predicting positive open food challenges to milk, egg and peanut in children. Clin Exp Allergy; 2000; 30, 1541-1546.	Your comments are acknowledged, however we anticipate we will be addressing these issues in the guideline.
SH	Royal College of Paediatrics and Child Health	16.04	3.1	We recommend adding, "Non-IgE mediated food allergy reactions are generally in form of food intolerance and present as diarrhoea, vomiting, etc. These are slow in onset and may need the opinion of a paediatrician or paediatric gastroenterologist."	Noted, the scope has been amended.
SH	Royal College of Paediatrics and Child Health	16.05	3.1.a	We note that delayed reactions may still involve (all) the symptoms listed for acute reactions, though usually with less severity.	Noted. The list of symptoms is not exhaustive and are intended to include the most common symptoms.
SH	Royal College of Paediatrics and Child Health	16.06	3.1 a	We note that 'gastrointestinal anaphylaxis' is not a recognised term.	Noted. This has been amended in the scope.
SH	Royal College of Paediatrics and Child Health	16.07	3.1 a	We note that atopic eczema can be aggravated by both IgE and non-IgE (delayed) mechanisms and these should be mentioned. We think it would be a missed opportunity for patients with atopic eczema if non-IgE mechanisms were not considered as there is considerable overlap of allergies in this group.	Acknowledged, the scope has been amended to reflect this.
SH	Royal College of Paediatrics and Child Health	16.08	3.1 g	We think the list of common food to which children and young people are allergic should include sesame seed and legumes.	Noted. We have included sesame to the list of common foods to which children and young people are allergic.
SH	Royal College of Paediatrics and Child Health	16.09	3.2 a	We note that patients are often appropriately seen first by paediatric dermatologists who provide the majority of care for atopic eczema patients. Liaison	Thank you. Paediatric dermatologists are included 'within children's services.'

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				with allergists is then undertaken as required.	
SH	Royal College of Paediatrics and Child Health	16.10	3.2 d	See Vandenplas Y et al. Guidelines for the diagnosis and management of cow's milk protein allergy in infants. ADC 2007;92:902-8.	Thank you and we will be searching for relevant guidelines as part o the development process.
SH	Royal College of Paediatrics and Child Health	16.11	4.1.2	We note that reactions to milk (whether cows' milk allergy, cows' milk protein intolerance, soya protein intolerance, lactose intolerance) may all co-exist with gastro-oesophageal reflux in younger children (especially under 2 years). We therefore recommend that thought be given to whether this issue will be excluded or included in the guidance.	Thank you, your comments are acknowledged however intolerance to milk and other foods will only be considered within the context of diagnosing food allergy.
SH	Royal College of Paediatrics and Child Health	16.12	4.1.2 b	We note that the difference between intolerance and allergy is important. We would like clarification on whether there will be recommendations in the guideline on how to exclude children with intolerance (and therefore how to diagnose it), e.g. lactose intolerance, which is uncommon but is often mislabelled as cows' milk protein allergy.	Thank you. Intolerance will only be reviewed in the context of diagnosing food allergies, however all the evidence will be reviewed before any recommendations are made. We also anticipate that this will be an important part of the GDG deliberations.
SH	Royal College of Paediatrics and Child Health	16.13	4.1.2 b	We note that wheat intolerance is seen very commonly in differential with wheat allergy. We would like clarification on whether Coeliac disease screening will feature as part of screen where wheat allergy or intolerance are considered.	Noted. Separate guidance has been produced for the recognition and assessment of Coeliac disease and differentiating between food allergy and intolerance will only be done in the context of diagnosing food allergy.
SH	Royal College of Paediatrics and Child Health	16.14	4.3.1 e	We recommend specifying specialists (e.g. allergists, dieticians, respiratory medicine specialists, ENT, immunologists, general paediatricians).	Noted. This has been amended on the scope.
SH	Royal College of Paediatrics and Child Health	16.15	4.3.1 f	The College thinks it very important that the message in community and primary care be clear that the diagnostic tools (either alone or in combination), including skin prick tests or specific IgE tests, are not "allergy tests". Anecdotal evidence supports that parents come to the allergy clinic wanting an "allergy" test for their child.	Thank you, your comment is acknowledged. We have also added patient information and support needs as a clinical issue.

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				Paediatricians spend a long time explaining to parents that these tests are for "sensitization", rather than for allergy, and what the tests can and cannot tell us.	
SH	Royal College of Paediatrics and Child Health	16.16	4.3.2.a	We feel that diagnosis of food intolerance (i.e. non-IgE mediated reaction) is a crucial part of this guidance. We think its omission will cause confusion in use of guideline. A fundamental clinical question is in differentiating "allergy" (both IgE and non-IgE mediated), "intolerance", reactions to proteins, reactions to sugars. This area generates huge confusion (not least due to poor terminology) in both generalists and specialists, and we think that the guideline could be a mechanism to clarify this if the scope included "food intolerance". As an example, anecdotal evidence supports that many currently term "protein intolerance" and "non-IgE mediated food reaction" as the same thing, so it is unusual to include one description of a condition, and exclude another description (of the same condition). To note, the scope considers lactose (sugar) intolerance in 4.1.2.b, but avoids the crucial issue of protein intolerance.	Noted, however we can only work within the remit provided by the Department of Health. Food intolerance will only be considered within the context of diagnosing food allergy.
SH	Royal College of Paediatrics and Child Health	16.17	GDG	The GDG member role does not include the possibility of having a dermatologist on the panel. As atopic eczema is a large part of this topic a consultant dermatologist should be included in the possible list of participants	We agree that the inclusion of a dermatologist is important to the development of this guideline, and have advertised for, and hope to appoint a paediatric dermatologist to be on the GDG.
SH	Royal College of Pathologists	17.00	3.1a), page 1	Suggested re-phrase of paragraph - 'Food allergy is an adverse immune response to food allergens. It can be classified into IgE mediated allergy and non-IgE mediated (including T cell, IgG and eosinophil	Noted. The scope has been changed.

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				mediated) allergy. The IgE mediated reactions are acute, frequently have rapid onset and are characterised by:'	
SH	Royal College of Pathologists	17.01	3.1a), page 1, bullet pt 2	- 'gastrointestinal anaphylaxis' is not a recognised diagnosis and should be removed from this list - eczema is missing and should be included in the list as it is (probably) at least partially IgE-mediated	Noted. This has been removed from the scope.
SH	Royal College of Pathologists	17.02	3.1a), page 2, bullet pt 1	'oesophagitis' mis-spelt	Thank you. This has been corrected
SH	Royal College of Pathologists	17.03	3.1a), page 2 at top	Suggested re-phrase of 'These are delayed onset reactions' to 'These are frequently delayed onset conditions'	Thank you. This has been amended in the scope
SH	Royal College of Pathologists	17.04	3.1b), page 2, line 1	Insert 'of' between '…common' and 'allergic…'.	Thank you. This has been added in the scope
SH	Royal College of Pathologists	17.05	3.1d), page 2	Suggested re-phrase of paragraph – 'In the UK there have been concerns expressed about the prevalence of food allergy in the general population, especially from individuals and families affected by food allergy, healthcare staff, schools, food producers and government health departments.'.	Thank you. This has been amended in the scope
SH	Royal College of Pathologists	17.06	3.1f), page 2	The figure of 30-40% of self-reported food allergy being confirmed as true clinical food allergy should be checked/referenced. This seems too high. Young et al, Lancet 1994;343:1127-30 reported less than 2% of patients self reporting food allergy produced positive symptoms on DBPCFC. The estimated prevalence of food allergy was 1.4-1.8%. Does the figure of 30-40% refer to a specific paediatric sub-group? (reference)	Noted. The rates of food allergy are reported within a range and the scope does acknowledge that there are inconsistencies in reported prevalence figures.
SH	Royal College of Pathologists	17.07	3.1i), page 3	Suggested re-phrase of paragraph – 'Correct diagnosis of food allergy, followed by counselling and advice based on reliable criteria, is important because it will help decrease the incidence of adverse food reactions resulting from true food allergies and also help prevent the unnecessary	Thank you. This has been amended in the scope

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				dietary exclusion of foods which are safe and which should be eaten as part of a normal, healthy, balanced diet.	
SH	Royal College of Pathologists	17.08	3.2a), page 4, bullet pt 2	Re-phrase – 'in an allergy clinic run by a consultant immunologist or allergy-trained specialist in an organ-based specialty (such as respiratory medicine or gastrointestinal medicine) or paediatrics'.	Thank you. This phrase was taken directly from the DOH review
SH	Royal College of Pathologists	17.09	3.2a), page 4	Add additional bullet point (as number 3 of 4) – 'within a general clinic run by an organ-based consultant or paediatrician'.	Noted. A general clinic run by an organ-based consultant or paediatrician will be included within children's services.
SH	Royal College of Pathologists	17.10	3.2c), page 4, bullet pt 4	Add 'complex allergy with potential cross-reactive or hidden allergen complications' to list of conditions in which referral should be considered	Noted, however this is intended to reflect current practice.
SH	Royal College of Pathologists	17.11	4.1.1a), page 5	Add 'angioedema' and 'those in whom allergen immunotherapy might be considered' to list of conditions	Your comments are acknowledged, however this list of symptoms is not exhaustive.
SH	Royal College of Pathologists	17.12	4.1.2a), page 6	The diagnoses listed are frequently confused with or mistaken for allergic conditions in respect of symptomatology. Although the guideline will not cover management of these non-allergic conditions some thought should be given as to mechanisms by which by which they will be differentiated from allergy in Primary Care. One function of specialist allergy clinics is to make that differentiation but separating allergy and non-allergy in a community setting (even if only to inform decisions on referral) will not be straightforward.	Thank you. These groups fall outside the scope and no guidance will be produced for the diagnosis of these conditions, however we will consider them in the context of diagnosing food allergy.

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SH	Royal College of Pathologists	17.13	4.3.1c), pages 6-7	It is not clear, even in general terms, how the diagnostic tool evaluation process will be undertaken. Methodology for this should be clearly defined. It might be assumed, but is not explicit, that this will be undertaken jointly with specialist input in light of the potential clinical dangers of some of these listed procedures, their operational requirements and practicalities and the expertise required to optimally and correctly interpret the results of (all of) these procedures. The tool(s) must enable effective risk assessment to allow effective triage of referrals. The guideline could usefully consider minimum quality assurance measures for ensuring proper performance and interpretation of relevant tests in the clinic/practice, diagnostic laboratory and point-of-care setting.	This is acknowledged, however detailed information regarding evaluation and quality assurance processes fall outside the scope. All evidence will be reviewed and critically appraised following the NICE methodology. Guidance will be produced with the Guideline Development Group, which will include members from the relevant fields. For more information on processes and methodology please see the guidelines manual (link below): http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp We would also anticipate that issues such as interpretation of results will be part of the detailed deliberations.
SH	Royal College of Pathologists	17.14	4.3.1c), page 7, bullet pt 5 at top	'Atopy patch test' is not a term, or a technique, which is commonly used in the UK and its inclusion in the document may require some explanation/clarification as to its performance, purpose and provision within the NHS (? Delivered through allergy services or dermatology). In the context of the latter (dermatology), those comments for 14 as above apply. Note that patch testing is not standard or routine practice in the UK and would generally have a minor place only in the investigation and diagnosis of food allergy.	Noted. Evidence relating to all possible diagnostic tools including the atopy patch test will be considered and will be reviewed before decisions are made.
SH	Royal College of Pathologists	17.15	4.3.1f), page 7	The ethos of comments as in 14 above also applies here. Evaluation of those tools listed requires properly constructed and controlled scientific trials or analysis/meta-analysis of existing evidence. As with all diagnostic tools, their use is not suitable for any ad hoc evaluation based on unblended, anecdotal	Noted. All evidence will be reviewed and critically appraised following the NICE methodology. Guidance will be produced with the Guideline Development Group, which will include members from the relevant fields. For more information on processes and methodology please see the

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				individual patient experiences or analysis of small numbers of patients in either primary or secondary/tertiary care. Involvement of Primary Care/community services in such proper evaluation is supported. These tools should not at present be recommended for, or used in, the investigation or monitoring of known or suspected food allergy.	guidelines manual (link below): http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp Also the GDG will be providing 'content specific' interpretation and consideration of the evidence.
SH	Royal College of Pathologists	17.16	4.3.2a), page 7	As for comment 13 above, food intolerance is part of the differential diagnosis of food-related allergic disease. Although the guideline will not encompass management of food intolerance it should provide guidance on such differential diagnosis and on differentiating food allergy and intolerance.	Noted. Although no guidance will be produced for the diagnosis of food intolerance, it will be considered in the context of food allergy.
SH	Royal College of Pathologists	17.17	4.5, page 8	The 2006 DoH review of services for allergy encompasses an appendix document (An evidence review on the interventions and services available for the treatment and diagnosis of allergies) which contains some relevant (incomplete) economic information.	Thank you. Your comment is acknowledged.
SH	Royal College of Pathologists	17.18	General	Ensuring the promulgation of/support for effective, practical operational links between Primary/Community care and specialist services is an essential component of optimising the investigation, diagnosis and referral of children with food allergies and for ensuring a consistency of approach to high quality care across the country.	Thank you. Your comments are acknowledged. We also anticipate that such operational issues will be part of the issues considered by the Implementation team at NICE later in the development process.
SH	Royal College of Pathologists	17.19	General	Note that DoH and the Royal College of Paediatrics & Child Health are currently collaborating in the development of a national care pathway for children with food allergy. This might usefully be considered/alluded to in the workings of this NICE guideline development process.	Thank you. The development of this guidance has been referenced (see section 5.1) and we have been aware of this work during the development of the Scope.

These stakeholder organisations were approached but did not respond

Action Against Allergy
ALK Abello
Allergy UK
Anaphylaxis Campaign, The
Association of Paediatric Emergency Medicine
BMJ
Breastfeeding Network, The
Brighton and Sussex University Hospitals Trust
British National Formulary (BNF)
British Society for Allergy & Clinical Immunology (BSACI)
British Society of Gastroenterology
British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)
Calderdale and Huddersfield NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Care Quality Commission (CQC)
Citizens Commission on Human Rights
Cleft Lip and Palate Association
Coeliac UK
Commission for Social Care Inspection
Connecting for Health
County Durham PCT
Department for Communities and Local Government
Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)
Diagnostic Innovations Limited
Dudley Group of Hospitals NHS Trust
East Kent Coastal PCT
Education for Health
Gloucestershire Hospitals NHS Trust
Infant and Dietetic Foods Association
Institute of biomedical Science
James Paget University Hospitals NHS Foundation Trust
La Leche League GB
Leeds PCT
Liverpool PCT Provider Services
Luton & Dunstable Hospital NHS Foundation Trust
Medicines and Healthcare Products Regulatory Agency (MHRA)
Menarini Diagnostics

MIDIRS (Midwives Information & Resource Service)
Ministry of Defence (MoD)
National Allergy Strategy Group
National Childbirth Trust
National Patient Safety Agency (NPSA)
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
National Working Group on Food Allergy
NeuroDiversity International(NDI)/NeuroDiversity Self-Advocacy Network(NESAN)
NHS Clinical Knowledge Summaries Service (SCHIN)
NHS Islington
NHS Plus
NHS Quality Improvement Scotland
NHS Sheffield
Nutricia Advanced Medical Nutricion
Nutricia Ltd (UK)
Nutrition Society
Parents Protecting Children UK
PERIGON Healthcare Ltd
Public Health North East
Royal Brompton & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners Wales
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal college of Paediatric and Child Health - National care pathways project - children with allergies
Royal College of Paediatrics and Child Health
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Pathologists
Royal College of Physicians London
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of Edinburgh
Royal College of Surgeons of England
Royal Free Hospital NHS Trust
Royal Society of Medicine

Royal United Hospital Bath NHS Trust
Salford Royal Hospitals Foundation NHS Trust
Sandwell PCT
Scottish Intercollegiate Guidelines Network (SIGN)
Sheffield Children's NHS Foundation Trust
Skin Care Campaign
Social Care Institute for Excellence (SCIE)
Social Exclusion Task Force
South London Healthcare Trust
South Tees Hospitals NHS Trust
St George's Healthcare NHS Trust
UCLH NHS Foundation Trust
UK National Screening Committee
United Kingdom Association for Milk Banking
University of Southampton
Wellfoods Ltd
Welsh Assembly Government
Welsh Scientific Advisory Committee (WSAC)
Western Health and Social Care Trust
Wirral University Teaching Hospital NHS Foundation Trust
York NHS Foundation Trust