National Institute for Health and Clinical Excellence

Food allergy in children & young people
Guideline Consultation Comments Table
9 August - 6 September 2010

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Anaphylaxis Campaign, The	2.00	Full	General		The guidelines will be an invaluable, clear and comprehensive tool for health professionals and anyone working or living with children and young people with food allergy or suspected food allergy and their families.	Thank you for your comment.
SH	Anaphylaxis Campaign, The	2.01	Full	General		Evidence from the study reviews add weight to the document and will be useful for health professionals who wish to pursue further study.	Thank you for your comment.
SH	British Dietetic Association	16.00	Full	9	1.1.5 1.1.5 1.1.5 1.1.15	Would suggest that elimination trial is extended to 4-6 weeks as it takes at least 1 week for parents to familiarise themselves with a diet. Can the "if appropriate" be taken out re advice from a dietitian? – dietetic advice is important to ensure elimination is carried out correctly and appropriate alternative is suggested. However, if referral to dietetics is not thought appropriate in every case, then it needs defining the circumstances under which a dietitian should or must be seen. Referral to dietitian if appropriate – suggest define what is appropriate eg for multiple exclusions, infants weaning onto solids. Please also add "protein" to cows milk (protein) allergy. Suspected cows milk allergy. What is	Thank you for your comments. The length of the elimination trial has not changed to 4-6 weeks as the results of the elimination diet may be clear after 2 weeks. As there was a lack of evidence this was based on GDG expertise and consensus, which included input from 2 dietitians who were members of the GDG. Section 1.1.5 has been re-worded following GDG discussions to remove the word 'if appropriate. We have added the word 'protein' as suggested. Recommendation 1.1.15 relates to the providing information and support question. The GDG discussed the evidence relating to children with suspected cow's milk protein allergy in detail (see table 5 in 2.5.1). They felt that young children who were breastfeeding and were allergic to cow's milk

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						the evidence for removing cows milk from breastfeeding Mums in all cases? Why is cows milk the only one mentioned? What about other allergens?	protein would need special attention.
SH	British Dietetic Association	16.01	Full	10	1.1.14	Food exclusion. Should have referral to a dietitian.	Thank you. This recommendation focuses on the provision of information and support. Recommendation 1.1.5 indicates dietitian involvement in food elimination and reintroduction.
SH	British Dietetic Association	16.02	Full	10-11	24-28, 1-8	Most GP's would need a dietitian to give this information, especially for children, and in the evidence most studies quoted mention a dietitian giving the advice.	Thank you. This section does not specify which healthcare professional should deliver the information but suggests which elements should be included.
SH	British Dietetic Association	16.03	Full	11	1.1.14	Parents should also be advised on the nutritional implications of unwarranted dietary exclusion, to deter from them from excluding foods they have not been advised to do so. Should refer to a dietitian.	Thank you. The guideline has been amended to include the hazards of exclusion diets
SH	British Dietetic Association	16.04	Full	11	1.1.15 1.1.15	As before, it would be useful to state when a dietitians help would be needed. Advise on nutritional supplements for mother and baby and dietary exclusion advice, not just change of formula. Seek advice from dietitian (infants are at high risk of nutritional compromise and feeding problems if weaning progress is delayed even over 6 weeks).	Thank you. The guideline has been amended when referring to input from the dietitian. It is anticipated that more detailed information relating to nutritional supplements would be provided by the dietitian when their advice is sought.
SH	British Dietetic Association	16.05	Full	11	1.1.16	Babies/young children with suspected cows milk allergy should always be referred to a paediatric dietitian.	Thank you. The GDG discussed this issue and agreed that a referral would not always be necessary, however, advice from a dietitian should always be sought. The wording has been changed, in the guideline to remove the words 'if needed'.
SH	British Dietetic Association	16.06	Full	11	1.1.17	First bullet point, please insert infant in front of the word child.	Thank you, thorough editorial changes have been made.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	British Dietetic Association	16.07	Full	35	2.3.5 (6)	See first point above on duration of elimination diet. This should read "with a dietitian". NOT "with a dietitian if appropriate". It is always appropriate for children to be seen by a dietitian, if on a restricted diet.	Thank you, the wording has been changed in the guideline to remove the words 'if appropriate'
SH	British Dietetic Association	16.08	Full	48	2.4.2.1 and 2.4.2.2.	*".... three test for hens egg allergy in children under 8 years ranged from 58% to 100%, 32% to 100% and 5% to 84% for skin patch test, specific IgE antibody test and atopy patch test respectively"* This sentence does not make sense – would patch have a better sensitivity? See also 2.4.2.2, 2.4.2.4. Section 2.4.2.3 is correct. Suspect other sections should be in similar format.	Thank you, these are ranges of sensitivities and specificities and not average values, the unusual values may be outliers.
SH	British Dietetic Association	16.09	Full	60	3	Second sentence has a "T" in the middle of the sentence.	Thank you, thorough editorial checks will be made.
SH	British Dietetic Association	16.10	Full	61	1.2.14 1.2.14 ultimate	As this type of advice can be quite complex in cases where other nutritional exist, would it not be good to suggest a referral to a dietitian, to ensure adequate nutritional intake. Primary care challenges/re-introduction may need support from local allergy unit (secondary or tertiary). Add bullet point – to offer advice on recipes and how to cook with alternative ingredients and whereto get them.	Thank you, This section relates to the provision of information. Where an elimination diet is recommended (see recommendation 1.1.5), dietetic input should be sought when appropriate.
SH	British Dietetic Association	16.11	Full	62	1.2.15	When is dietetic advice needed? It is important similarly to when children should be referred to specialist allergy services, that it is specified when a dietetic review is warranted.	Thank you, following further GDG discussions the wording has been changed in the guideline**.**
SH	British Dietetic	16.12	Full	67	2.6.4	Recommendation 1.2.17 – severe aversive	Thank you. There was no evidence found in

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Association					feeding should be added to the list for requirements to referral to secondary services.	the literature searched to support severe aversive feeding as a reason for referral. This was not raised as an issue during development of the guideline.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.00	full	3	introduction	food allergy is defined as an adverse, immune mediated response to food allergens – this needs to be stuck to throughout the recommendations	Thank you. The recommendations have been split into IgE and non-IgE mediated food allergy, however the main definition in the introduction can still be applied here.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.01	full	6	Section1.1.1	The list of GI symptoms and signs are a nonsense. The GDG have used as a reference for this list a review in a supplement in a low quality journal (Bahna 2003). This is not evidence and most if not all of this list needs to be removed and certainly rewritten • most are very vague and should not be in that list at all (eg pallor and tiredness, 'perianal redness'). • Outwith either IgE mediated reactions and coeliac disease We would argue that in very few of those is there any good evidence of 'immune mediated response to food allergens'? In some there is low quality evidence, largely anecdotal, of a response to a diet, this is not the same as a food allergy and should not be regarded as such. We would suggest would removing dysphagia, food refusal/aversion, colic, pain, constipation as well • Ones which would be reasonable to keep in but need referring to secondary and tertiary care would be vomiting (? IgE mediated), severe reflux not responding to standard management, diarrhoea and blood or mucus	Thank you for your comment. Following GDG discussions, this section has been amended in the guideline and has now been split into whether an IgE or non-IgE mediated allergy is most likely. There was also agreement that some symptoms in isolation may not be indicative of food allergy. As the evidence base was weak this list is also based on GDG expertise and consensus and this is made clear in the evidence to recommendations section (2.2.3). We acknowledge that there are a large number of risk factors but anticipate that clinical judgement and the allergy-focused clinical history would help to focus further testing in those groups who have a higher risk of having an allergy.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						in the stool. Keeping this list as it is runs the risk of the very large number of children who come under that banner of symptoms and signs being inappropriately investigated and put on unsuitable diets. It is correct to point out that food allergy may be worth considering in the face of unexplained GI symptoms that do not respond to standard management in the community (but is only likely to be a cause in a small proportion of patients). If the Sx are bad or persistent enough referral to secondary or tertiary care for further investigation and management (not necessarily food allergy related) should be recommended. Probably ties in with section 1.1.17(page 11)	
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.02	full	7	Section 1.1.2	repetition of some of the Sx in 1.1.	Thank you for your comment. Although these conditions have also been mentioned previously in section 1.1.2, the GDG felt that children with these conditions who were not responding to treatment were specifically more likely to have a food allergy.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.03	full	11	Section 1.1.15	what competencies are required to be able to advise on suitable formulae?	Thank you. Specific input from a dietitian is recommended when using substitute formulas.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.04	Full	13	Section 1.2.1	• IgE conditions – Needs to say acute urticaria, chronic urticaria is not food related • Non-IgE - Food allergy is only rarely proven in the non-IgE conditions, other conditions must be excluded first. Enteropathy, proctocolitis, enterocolitis and eosinophillic oesophagitis cannot be diagnosed in	Thank you. This section provides a general overview of food allergy and has been amended in the guideline.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						primary care and so should be removed. If suspected they should be referred on.	
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.05	Full		Section 1.2.1 b	this is mainly IgE mediated	Thank you. This section has been taken directly from the scope and provides a general overview of food allergy.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.06	Full		Section 1.2.2	Target population – I think should say severe or persistent GI symptoms not responding to standard management	Thank you. This section has been taken directly from the scope and sets out the original aims of the guideline.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.07	Full	General		In considering this document, we wonder whether non Ig-E mediated reactions should be excluded from the document completely due to the lack of evidence and the ability to give clarity to management in primary care.	Thank you, The remit was to address diagnosis of food allergy. Because there is also variation in current practice, possibly due to lack of good quality evidence, we think it is important for it to be included within the guideline.
SH	British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)	15.08	Full	22	Section2.2.4	See comments under 2 and 3	Thank you for your comment. Following GDG discussions, this section has been amended in the guideline and has now been split into whether an IgE or non-IgE mediated allergy is most likely. There was also agreement that some symptoms in isolation may not be indicative of food allergy and this is reflected in the recommendation. As the evidence base was weak this list is also based on GDG expertise and consensus and this is made clear in the evidence to recommendations section (2.2.3).
SH	BSACI Primary Care Group	8.00	full	General		The main concerns are about service provision , and communication between primary and	Thank you and while we understand the importance of education and training, this is

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						secondary care. This guideline highlights that there would need to be a significant input of training and education in primary care to provide this level of care . There is the concern that if this does not happen primary care may not assess correctly , test correctly or know how to interpret the results .	outside the remit for this guideline. However, we feel this is an important point and will forward this for consideration by the implementation team.
SH	BSACI Primary Care Group	8.01	full	General		There is no mention of the well trained specialist nurse's role in primary care and Allergy	Thank you, this guideline is applicable to all healthcare professionals who work within primary or community care including the specialist nurse.
SH	BSACI Primary Care Group	8.02	full	General		To address the communication gaps , you could suggest a network between all primary care outlets and allergy expertise- preferably with nearest allergy centre of excellence ,and a movement between the two of individuals such as specialist nurses or gps (GPWSI) who should then remain updated and able to convey their knowledge.Until this happens the BSACI would be willing to help via their website which has guidelines and leaflets and can respond to questions from members- though not immediately .	Thank you, this is a service delivery issue and does not fall within the remit for this guideline.
SH	BSACI Primary Care Group	8.03	full	10	1.1.10	In addition to this guideline it may be helpful to provide an algorithm for gps to follow ,about history taking and when to test etc.	Thank you, a diagnostic pathway will be available in the NICE Quick Reference Guide.
SH	BSACI Primary Care Group	8.04	full	7	1.1.3	Time constraints of taking a good history in primary care were raised although this could be addressed by longer appointment times , and also the fact that it should be about competency based ,not professional role base So could be gp ,practice nurse ,specialist nurse ,GPWSI ,etc Skills for Health link	Thank you for your comment. Although we appreciate the importance of training and education to ensure service delivery, these issues are outside the scope of this guideline. However, we feel this is an important point and will forward this for consideration by the implementation team. The health economic analysis considered

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							variation around the appointment time and the accuracy of the tests (an equivalent for competencies).
SH	BSACI Primary Care Group	8.05	full	10	1.1.10	As above educational input required here to take good allergy history	Thank you. The issue of education and training is outside the remit for this guideline.
SH	BSACI Primary Care Group	8.06	Full	10	1.1.9	Who will be interpreting the results ?and how will this be organised, who will do the tests and where ,and how will the results be given ,	Thank you, this guideline is aimed at healthcare professionals within primary and community care who have the appropriate competencies to carry out and interpret allergy focused clinical history and allergy tests. Although we appreciate the importance of training and education to ensure service delivery, these issues are outside the scope of this guideline. However, we feel this is an important point and will forward this for consideration by the implementation team.
SH	BSACI Primary Care Group	8.07	Full	65	2.6.3	Would the gp know where to refer ,and the different services available	Thank you. Referrals to secondary and/or specialist care would include paediatric gastroenterology, dermatology, specialist allergy centres and other similar adult services as appropriate. We anticipate that healthcare professionals would also use their clinical experience and knowledge when referring children for further investigation.
SH	BSACI Primary Care Group	8.08	Full	66	2.6.3	Some of these patients are seen in casualty and not admitted , and then discharged with a note to see their gp for follow up or onward referral , so they do come to see gps and are an important group to consider ,	Thank you for your comment. Although most children with anaphylactic reactions will present directly to secondary care, it is anticipated that children and young people who are referred back to the GP will go through the diagnostic process as set out in the guideline.
SH	BSACI Primary Care Group	8.09	Full	9	1.1.7	What would the GDG consider the basic facilities to be in general practice, to be able to deal with an anaphylactic reaction,	Thank you. Facilities similar to those available for vaccination were considered appropriate (see section 2.4.4) as there is also a risk of anaphylaxis in this situation.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	BSACI Primary Care Group	8.10	Full	General		There was the impression that some gps not familiar with Allergy reading this guideline may not find it immediately user friendly, and would need more educational input , practical information ,and resources to refer to ,for it to be put into practice.	Thank you for your comment, the guideline will also be accompanied by a Quick Reference Guide and tools to help organisations implement this guideline.
SH	BSACI Primary Care Group	8.11	Full	Section 1.2.1		Eczema as a marker for the presence of food allergy should be emphasised more, so that practitioners are aware of the very strong relationship between eczema and food allergy, and see that the presence of eczema is an indicator to think about/investigate for food allergy	Thank you. We acknowledge the importance of eczema as a marker for the presence of food allergy and following GDG discussions this has also been included in the allergy focused clinical history. The initial signs and symptoms and section 1.2.1 in the guideline have also been amended.
SH	BSACI Primary Care Group	8.12	Full	1.2.2		An example here is the phrase 'don't respond adequately to treatment for eczema'. Eczema is a marker for increased risk of food allergy, whether or not the eczema responds to topical treatment. Therefore think that this phrase should refer to all eczema rather than just that which responds poorly to treatment. The rationale for investigating for food allergy in someone with eczema does not just relate to controlling the eczema, it relates to identifying unrecognised IgE mediated food allergy which has the potential to lead to systemic allergic reactions if the relevant foods are not avoided.	Thank you. Please see recommendation 1.1.1. We acknowledge the importance of eczema as a marker for the presence of food allergy and following GDG discussions this has also been included in the allergy focused clinical history. The initial signs and symptoms in the guideline have also been amended.
SH	BSACI Primary Care Group	8.12	Full	p.13	Final sentence	Would add in '.. or a paediatric allergist'.	Thank you. This section of the guideline has been amended following GDG discussions.
SH	Coeliac UK	18.00	Full	9	1.1.5	Recommend screening for coeliac disease (cross-reference with NICE guideline 86) if problems relate to foods containing wheat or meet the guideline criteria.	Thank you, we will insert cross-reference to other NICE guidelines as appropriate.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Department of Health	10.00		General		In our view, the recommendations look clear and represent what we would currently consider good practice.	Thank you for your comment.
SH	Department of Health	10.01		General		We are not aware of the NHS offering kinesiology, vega tests or hair analysis. We feel however that it is helpful to know that NICE advises not to use these to diagnose food allergy.	Thank you.
SH	Education for Health	3.00	Full	9	1.1.6	There is considerable confusion in practice about the interpretation of positive SPT/sIgE tests where there is no history of symptoms on exposure, an approach that is in increasingly being advocated by those who seek to sell 'panels' of allergens for testing. A good example is the child sIgE testing panel (Phadia Ltd) for rhinitis and asthma which includes egg; a positive egg test in the absence of a history is un-interpretable and misleading (and in taking a history of rhinitis/asthma the clinician is unlikely to ask about egg sensitivity as egg is rarely a trigger of either). Although the guideline does say that test results should be interpreted alongside a good allergy history, it is not in my view strong enough on this point. I recommend that these sections need to be clear that neither SPT or sIgE tests can be used to 'screen' for allergy because of their poor positive and negative predictive values, and that the NICE guidelines team develop some form of algorithm that says, for example, if the history is positive then a test may be useful to confirm sensitivity, if the history is negative then there is no value in performing a test. Much of the marketing of	Thank you for your comment. The GDG discussed the issue of screening for allergies using panels of allergens and this has been documented in the evidence to recommendations. It was agreed that only allergens that are suspected from the allergy focused clinical history and possible cross reactive allergens should be tested for by a competent healthcare practitioner.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						these diagnostic products is based on identifying 'hidden' allergens that the patient has no history of symptoms to; this is nonsense - confusing and potentially damaging to patients - and clinicians and patients alike would benefit from a strong message in this document to prevent misinterpretation.	
SH	Education for Health	3.01	Full	General		There are likely to be significant training requirements to enable non-specialist clinicians to deliver high quality food allergy services as outlined in this guideline. It is important that this document links to the work done by Skills for Health in developing competencies that underpin the performance of key tasks within allergy consultations to enable the right NHS staff to be delivering services within their capabilities.	Thank you. Although we appreciate the importance of training and education to ensure service delivery, these issues are outside the scope of this guideline. However, we feel this is an important point and will forward this for consideration by the Implementation team.
SH	Food Standards Agency	4.00	Full	General		The Food Standards Agency welcomes the opportunity to comment on this important Guideline and in general considers that the draft is a well constructed, well informed and evidence based Guideline that is clear and relatively straightforward to follow. We have a number of relatively minor suggestions for its improvement/refinement, as set out below.	Thank you for your comments.
SH	Food Standards Agency	4.01	Full	General		"cows' milk" and "practices" are spelt wrongly or inconsistently in a number of places in the document (e.g. p4 2nd para 'practised', p.62 recommendation 1.2.15 'cow's milk'.	Thank you. Final editorial changes have been made and these have been amended.
SH	Food Standards Agency	4.02	Full	5	9	This early section of text in the Guideline could benefit by being clearer about what age range the guideline is covering, since the current text 'If the child or young person is under 16' is not clear and could be interpreted as implying that the guideline covers adults as well as children	Thank you. For detailed information about who the guideline is for please see section 1.2.2. This section clarifies the age range that is being covered by this guideline and states 'children and young people up to their 19th birthday'.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						and young people unless it has already been made clear that this document covers children and young people up until their 19th birthday. Suggest a new sentence is added before this sentence to make clear what age range the guideline covers.	
SH	Food Standards Agency	4.03	Full	7	15	Recommendation 1.1.3, first bullet sets out that an allergy focused clinical history should include "any family history of atopic disease (such as asthma, eczema, allergic rhinitis, in parents or siblings" but should this particular list not also include "food allergy" in the list of examples of family atopic disease in brackets? We think this should read "any family history of atopic disease (such as asthma, eczema, allergic rhinitis or a food allergy) in parents or siblings".	Thank you for your comment. This has been amended in the guideline to reflect your suggestion.
SH	Food Standards Agency	4.04	Full	8	7	Was there any evidence to suggest that how the food was prepared (e.g. raw versus cooked allergens) should also be something that is considered when taking the clinical history, since this often has a bearing on the manifestation/severity of a reaction?	Thank you, however we did not evaluate the use of raw versus cooked allergens and therefore this was not raised as an issue during the development of the guideline.
SH	Food Standards Agency	4.05	Full	9	10	The recommendation 1.1.6 does not specify any preference between selecting a skin prick test versus an IgE test to confirm IgE mediated food allergy although some guidance on this is given in recommendation 1.1.8. I just question whether recommendation 1.1.6 should read "...skin prick test **and/**or blood tests for..." if there are circumstances in which a health professional may wish to carry out both types of test (if they are available)? Given that the sensitivities and specificities of either of these tests on their own for the various foods are quite variable, is there evidence to suggest any	Thank you for your comment. The GDG discussed the issue of testing using both IgE and SPT and felt that there may be some situations in which the healthcare practitioner may wish to carry out both tests and this decision would be based on their competencies. The recommendation has been changed to reflect your suggestion.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						benefit in carrying out (or at least not precluding carrying out) BOTH types of test in certain circumstances?	
SH	Food Standards Agency	4.06	Full	10	17	The text "an exclusion diet and oral food challenge or food reintroduction procedure" is a little confusing given that in the immediately preceding recommendation (1.1.11) it says not to use oral food challenges to diagnose IgE-mediated allergy in primary care or community settings. See also 1.1.14 on page 11, line 5.	Thank you. This has been amended in the guideline to remove 'oral food challenges' from the recommendation
SH	Food Standards Agency	4.07	Full	10	28	There is much information on how to follow a food exclusion diet (and other aspects of food allergy management) on evidence based web sources of information such as the Food Standards Agency website, but these are not mentioned here. The existence of web based resources such as this could be mentioned either in the recommendation itself or in the detailed text of the relevant Guideline section 5.2.	Thank you. While we acknowledge that there may be evidence based web sources of information, we are unable to cite them within the guideline. We anticipate that healthcare practitioners will provide details of specific web sites and other information to patients and their carers as required.
SH	Food Standards Agency	4.08	Full	12	5	The list of scenarios given for referral to secondary care is appropriate, but what if it is not possible to make a diagnosis in the primary care setting because of for example lack of availability or access to the recommended allergy tests? (e.g. in chilcare settings these might not be easily available/accessible).	Thank you for your comment. An allergy test is only one component of the diagnostic process; assessment, an allergy-focused history and physical examinations are also important factors. These steps all require healthcare practitioners with appropriate competencies and access to allergy testing should be made available where appropriate. Recommendation 1.1.17 also states that referral is appropriate when based on symptoms or suspicion of food allergy alone.
SH	Food Standards Agency	4.09	Full	6 - 12	5	Why do the numbered recommendations in this "List of all recommendations" (these are all 1.1.x) not match the numbered recommendations in the body of the Guideline	Thank you. This has been amended and final editorial changes have been made.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						(these are all 1.2.x). It would be helpful (for cross referencing purposes and to avoid confusion) if the 2 numbers matched.	
SH	Food Standards Agency	4.10	Full	13	7	Should this sentence not end with the following additional text "...one or more of the following symptoms", since once can have more than one of the symptoms listed (but you don't have to have them all to have an IgE mediated reaction). Same applies to line 15 in relation to non-IgE mediated reactions.	Thank you this section has been amended in the guideline.
SH	Food Standards Agency	4.11	Full	13	26	This sentence currently does not make sense.	Thank you, this has been amended in the guideline
SH	Food Standards Agency	4.12	Full	14	8	This paragraph could benefit by inclusion of reference to some of the data that is also available for young people (as opposed to just children up to 3 years). There is data from the Isle of Wight (funded by the Food Standards Agency) which suggests prevalence of challenge confirmed food allergy is in the range 0.5 to 2.5% for school aged children (Venter et al., 2006; Pereira et al., 2005)	Thank you for your comment, however this section has been taken directly from the scope and with the exception of editorial changes, should remain unchanged. It is acknowledged that prevalence figures of food allergy do vary and for this reason a range has been reported.
SH	Food Standards Agency	4.13	Full	23	14	Consider adding in "food allergy" to the list of family history atopic diseases here (as per my comment number 4 above)	Thank you for your comment. This has been amended in the guideline.
SH	Food Standards Agency	4.14	Full	48	5	We believe that "skin patch test" should read "skin prick test" in this line and also in lines 11, 17 and 23, and line 7 of page 49. Currently they could be confused with atopic patch testing which is different.	Thank you for your comment. This has been amended in the guideline.
SH	Food Standards Agency	4.15	Full	54	5	Recommendation 1.2.6 Did the GDG discuss the importance (or otherwise) of ONLY conducting SPT's and IgE's to those foods clinically implicated via the clinical history (and maybe also related foods such as tree-nuts if the suspected allergy is to peanuts), rather than	Thank you for your comment. The GDG discussed the issue of screening for allergies using panels of allergens and the guideline has been changed to reflect these discussions. It was agreed that only allergens that are suspected from the allergy focused

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						to a standard panel of food allergens? Our understanding is that the latter can lead to false diagnoses of food allergies for which there is no clinical basis and consequently to a child/young person needlessly cutting foods out of their diet, so maybe it is worth covering this in the recommendation/guideline if there is evidence to support this? Limiting the panel of foods tested may also help reduce costs.	clinical history and possible cross reactive allergens should be tested for by a competent healthcare practitioner.
SH	Food Standards Agency	4.16	Full	54	5	Recommendation 1.2.6. What if such tests (specific IgE/skin prick tests) are not routinely available e.g. for unusual foods or fresh fruits (e.g. kiwi). Did the GDG discuss whether/how to give guidance on how to diagnose food allergies other than those for which there are SPT and IgE tests readily available and fairly well validated (ie. The foods for which the evidence is presented on pages 48 and 49). We think that the Guideline should give health professionals some guidance on what to do in these scenarios. For example, would the GDG recommend prick to prick testing for suspected allergy to fresh fruits/vegetables where no standard SPT/IgE tests are routinely available and where the allergens degrade quickly, and would the GDG recommend using an exclusion diet for diagnosis of suspected IgE mediated food allergy to foods where SPT tests and/or IgE tests are not routinely available?. It would be helpful to have something on this covered in the guideline if there is any evidence to enable it, not least since allergy to fresh fruits is relatively common and food allergy is not just limited to the 8 foods listed in the evidence on p. 48 and 49.	Thank you for your comment. The evidence reviewed was limited to the most common food allergens and the GDG did not discuss unusual foods, although the principle in an allergy-focused clinical history taking would be the same. Similarly the evidence for prick-prick tests were not reviewed therefore specific recommendations cannot be made here.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Food Standards Agency	4.17	Full	General		Whilst the guideline has reviewed the evidence for the various available types of diagnostic test and made clear and useful recommendations about which tests to use, in what circumstances, and the importance of interpreting them in the context of the clinical history, it does not provide any further insight into how the results should be interpreted into a positive diagnosis. Is there any further guidance that can be given? In particular, if I was a primary care professional and the clinical history was not very indicative and yet the allergy test was positive, not sure you'd know what diagnosis to make given that the predictive value of a 'positive' result from these tests is not always that strong. Also, my understanding is that there are very few data relating to the predictive value of these tests in the very young childhood age range, so perhaps particular care needs to be taken when diagnosing food allergies in the very young. We note the research recommendation relating to establishing cut off points for SPT/IGE diagnosis of food allergy so perhaps it is simply a lack of evidence that means it is not possible to go further than the current text of the guideline.	Thank you. As mentioned, it is difficult to be more prescriptive in the interpretation of allergy test results given the lack of evidence relating to the predictive values of SPT and IgE tests. The decision to perform tests and the interpretation of results should be based on the allergy-focused clinical history and should be carried out by a practitioner with the appropriate competencies for the suspected allergen and likely cross reactive allergens. The GDG also discussed the issue of screening for allergies using food panels and it was agreed that this should not be recommended. In the example of a history that is not indicative of an allergy, healthcare professionals should exercise their professional judgement based on individual cases. However, in the case of a positive allergy focused history and a negative allergy test result it would be recommended to refer the child to secondary or specialist care (see recommendation 1.1.17).
PR	NETSCC, Health Technology Assessment (Ref 1)	7.00	Full	General		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope)** No	Thank you for your comment.
PR	NETSCC, Health Technology Assessment (Ref 1)	7.02	Full	General		**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guideli**	Thank you for your comment.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						nesmanual). This appears to be a thorough and comprehensive review following the methods prescribed.	
PR	NETSCC, Health Technology Assessment (Ref 1)	7.03	Full	general	general	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** In recognition of the poor quality of the selected papers and also methodological limitations the opportunity for statistical analysis is limited. The group appropriately considered reported values for Sensitivity and Specificity of diagnostic tests for allergy and considered performing a Meta-Analysis of study results, concluding that this was not justified due to the overall poor quality of papers.	Thank you for your comment.
PR	NETSCC, Health Technology Assessment (Ref 1)	7.05	Full	General		**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** Wide ranges were observed for estimated levels of both Sensitivity and Specificity leading to cautious interpretations. In the absence of a justified Meta Analysis, somewhat subjective conclusions and recommendations were based on a consensus view. This seems a reasonable approach.	Thank you for your comment, the variation in the estimates of point accuracy have been reinforced in the evidence to recommendations section.
PR	NETSCC, Health Technology Assessment (Ref 1)	7.07	Full	General		**3.2 Are any important limitations of the evidence clearly described and discussed?** Yes, footnotes to grade profiles documented limitations, inconsistencies, poor precision and other issues of reviewed articles subsequently	Thank you for your comment.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						discussed in the text.	
PR	NETSCC, Health Technology Assessment (Ref 1)	7.09	Full	General		**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** I found the report to be both readable and well presented.	Thank you.
PR	NETSCC, Health Technology Assessment (Ref 1)	7.13	Full	General		**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** The group identifies 5 potential areas for further research each supported by suitable justification. I feel that two in particular have merit: (1) A study of the prevalence and natural history of non-IgE mediated allergy and (4) Investigation of SPT results to predict specific IgE reactions.	Thank you.
PR	NETSCC, Health Technology Assessment (Ref 2)	7.01	Full	Sections 2.3.1 and 2.4.1		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope)** The most important dilemma in the diagnosis of food allergies in childhood is which tests should be used. Clarification of this issue is requested in the DH Scope, Section 4.3.1 c. However, the guideline does not issue this issue well. More under Recommendations, Section 3.	Thank you. The evidence was searched for for all the tests as outlined in the scope However, the evidence was of very low quality, and the GDG made the recommendations based on this evidence available and GDG expertise and consensus.
PR	NETSCC, Health Technology Assessment (Ref 2)	7.04	Full	general	general	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The health economic analyses all seem	Thank you for your comment.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						satisfactory and not too much can be expected from them as the evidence-based data used for the models is quite variable and the evidence is not of the highest quality for most questions.	
PR	NETSCC, Health Technology Assessment (Ref 2)	7.06	Full	25ff and 37 ff		**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** The specificity and sensitivity of the different diagnostic tests for each specific antigen should have been summarized in table format in the evidence statements (1.4.2 and 2.4.2) for easy comparison. The interpretation by the GDG is very broad-brush. It seems that for the majority of antigens the skin prick test has higher sensitivity and specificity than the IgE antibody test. This also seems the key driver in the economic model where skin prick test is slightly more cost-effective than specific IgE antibody testing. This is not well reflected in the interpretation and in the recommendations. As it stands, recommendations 1.1.8 and 1.2.8 are not very helpful for GPs in choosing the best test and in my view do not clearly follow SH from the evidence presented. Also, the possible value of combining the two tests is not discussed. The guideline should be very clear about this issue.	Thank you for your comment. The points about key drivers in the economic model have been expanded in the evidence to recommendations section. The overall diagnostic performance of the tests were similar, therefore the decision to use one test over the other should be dependent on the results of the allergy-focused clinical history, the acceptability/suitability for the specific child being assessed and the competencies of the healthcare professional. Following GDG discussions it was also decided that both tests may be carried out in certain circumstances and this would be dependent on the competencies of the healthcare professional. Thorough editorial changes have been made.
PR	NETSCC, Health Technology Assessment (Ref 2)	7.08	Full	67 to 69		**3.2 Are any important limitations of the evidence clearly described and discussed?** Section 2.7: The summary of the evidence for this section is very cursory. It is not clear whether the ensuing recommendations (2.7.4)	Thank you for your comment. The evidence to recommendation section (2.7.3) has been amended to make this clear.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						are based on the evidence reviewed or the lack of evidence (in particular as recommendations 1.2.18 and 1.2.19 are handled separately).	
PR	NETSCC, Health Technology Assessment (Ref 2)	7.10	Full	48 and 49		**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** In each of the paragraphs in Section 2.4.2 the skin prick test is erroneously called "skin patch test"	Thank you; this has been amended in the guideline.
PR	NETSCC, Health Technology Assessment (Ref 2)	7.11	Full	3	2nd from bottom	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** "the" missing in front of, non-IgE mediated.	Thank you. Thorough editorial changes have been made.
PR	NETSCC, Health Technology Assessment (Ref 2)	7.12	Full	7	7 and 9	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Bullet point for "chronic constipation", line 9: the missing behind the parenthesis	Thank you. Thorough editorial changes have been made.
PR	NETSCC, Health Technology Assessment (Ref 2)	7.14	Full	34	Last paragraph	**4.2 Please comment on whether the research recommendations, if included, are clear and justified. Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.** The information on anaphylaxis occurring only rarely and mostly in cases of cow's milk and	Thank you, the GDG did discuss the risks of anaphylactic reactions and this has been documented in the evidence to recommendations (2.3.4). However it was acknowledged that these may be rare. Safety issues are also addressed in recommendation 1.1.14.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						hens' egg allergy should be included as a safety warning in recommendation 1.2.5	
NICE	NICE PPIP (Sarah Chalmers)	17.00	Full		All	PPIP thank you for the opportunity to comment on the document, which we think is very patient focussed and will have a positive effect on the care of children with food allergies	Thank you for your comment.
NICE	NICE PPIP (Sarah Chalmers)	17.01	Full	5-6		Could the section on patient centred care be amended to acknowledge the needs of parents and families, following the pattern of the idiopathic constipation in children guideline? For example: This guideline offers best practice advice on the care of children and young people with suspected food allergies. Treatment and care should take into account patients' needs and preferences. Children and young people with suspected food allergies and their parents and carers should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If children do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent (available from www.dh.gov.uk/consent) and the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk). In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent). If the patient is under 16, healthcare	Thank you for your comment. This section has been changed using your suggested text.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						professionals should follow the guidelines in 'Seeking consent: working with children' (available from www.dh.gov.uk). Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's and family's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. Families and carers should have the opportunity to be involved in decisions about treatment and care. Where appropriate, for example for older children, this should be with the child's agreement. Families and carers should also be given the information and support they need. Care of young people in transition between paediatric and adult services should be planned and managed according to the best practice guidance NICE clinical guideline 99 – constipation in children and young people 8 described in 'Transition: getting it right for young people' (available from www.dh.gov.uk).	
NICE	NICE PPIP (Sarah Chalmers)	17.02	Full		1.2.13 and 1.2.14	Thank you for including these recommendations	Thank you for your comment.
NICE	NICE PPIP (Sarah Chalmers)	17.03	Full		1.2.15	Thank you for focusing on the information needs of patients. However, have the group considered the potential impact of ethnicity and	Thank you, cultural and health beliefs have now been included in the guideline, in recommendation 1.1.15.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						religion on the information needs of patients and their parents and families? Many ethnic groups and religious groups have specific foods that they avoid or consume more of than other groups, and this may affect the acceptability of diets and their ability to get enough nutrients if foods are excluded. Although I know that there may not be evidence to make specific recommendations in this area, could the group consider adding a line about "information should be sensitive to the cultural or religious needs of the individual" or something like that?	
SH	Nottingham Support Group for Carers of Children with Eczema	9.00	Full	3	32	"Food allergy is an adverse immune response to food allergens. It can be classified into IgE mediated, non-IgE mediated." Replace the comma with "and"	Thank you, final editorial changes have been made.
SH	Nottingham Support Group for Carers of Children with Eczema	9.01	Full	7	28	"Who suspects the food allergy" makes this document sound as if it is passing some kind of judgement on the person who suspects the allergy	Thank you for your comment, this section of the guideline has been rephrased.
SH	Nottingham Support Group for Carers of Children with Eczema	9.02	Full	8	3	The weaning history may not always be recalled Should the first part of section 1.1.3 indicate "as much as possible " ?	Thank you, we appreciate that weaning history will not always be accurately recalled especially in older children. The GDG felt that this recommendation was appropriate especially for children and infants in whom weaning has taken place in the not too distant past.
SH	Nottingham Support Group for Carers of Children with Eczema	9.03	Full	10	10	"Information should be offered to the child or young person, or their parent or carer". Information should be given to both the patient themselves and the carer, in appropriate formats, as appropriate rather than only one set of information needing to be given, as the present wording implies..	Thank you for your comment; this has been changed in the guideline.
SH	Nottingham Support	9.07	Full	66	1	Not sure what "certain some" conveys	Thank you; this has been changed in the

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Group for Carers of Children with Eczema						guideline, and removed the word 'certain'.
SH	Nottingham Support Group for Carers of Children with Eczema	9.08	Full	79	23	Please include in the glossary an explanation for the terms: food allergy, anaphylaxis, asthma, eczema, pruritis, angiodema, erythema, urticaria, laryngeal stridor, rhino conjunctivitis, gastro-oesophageal reflux, dysphagia, vega test, kinesiology, enteropathy, enterocolitis, eosinophilic oesophagitis, proctitis, proctocolitis, oral allergy syndrome, IgE and non IgE mediated reactions	Thank you. In addition to the full version of the guideline we will produce an Understanding NICE Guidance (UNG) version which is a translation of the recommendations into plain English. Many of these terms have been explained in the UNG, which will be developed in collaboration with the GDG professional and patient/carer members. A glossary has also been added to the guideline.
SH	Phadia Ltd	6.00	Full	9	10	Phadia believe that the advice given to GPs – that they consider offering a child / young person a skin prick test – needs more clarification. Since it is being recommended that skin prick tests only be undertaken by healthcare professionals with the appropriate competencies and where there are facilities to deal with an anaphylactic reaction, NICE may, in effect, be recommending a referral to secondary/tertiary care, as this is the setting in which nearly all SPT is currently being carried out by competent professionals, with the appropriate safety procedures. Moreover, when NICE go on to recommend that GPs choose between a skin prick test or a specific IgE blood test **"*based on which tests are available locally"*,** it should be recognised that this, in reality, represents a choice between a specialist hospital referral – for SPT, (*with*	Thank you for your comments. The recommendation relating to the use of SPT is based on the evidence review. Although some testing may take place within a secondary care setting, the GDG felt that the use of SPT within primary care was feasible provided safety and competency issues were taken into consideration. Therefore this recommendation will remain unchanged. The issue of competencies is outside the scope of this guideline, however, the guideline acknowledges the RCPCH document, in the section 5.1. The guideline has been amended and the decision to use an SPT or IgE test will not depend on which tests are available locally, but will focus on results of the allergy-focused clinical history, competencies of the healthcare professional and the suitability/acceptability of the test for the child being assessed.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						potentially lengthy waiting times, travel expense and time off work/school for the patient, plus significant costs to the PCT), or a routine blood test. Specific IgE testing is readily available to *every* GP and covered, in most cases, by their pathology block contracts. If the intention of these guidelines, is to ***improve*** the availability of accurate allergy diagnosis in Primary Care, then the comprehensive, nationwide network of specific IgE (RAST) facilities, should be actively highlighted, as GPs may not be aware that their local pathology contract provides this service. Phadia believe that NICE should reconsider their recommendation that GPs offer SPT within their own practice. We acknowledge the caveats relating to competencies and safety, but since no guidance is given regarding how such competencies should either be acquired or assessed, we believe that GPs and/or their practice nurses should be advised *against* its use until they have attended/passed some form of accredited training. Moreover, due to the potential risks of anaphylaxis and the precautions needed, the **MHRA** require all allergen SPT extracts for in-vivo diagnosis to be licensed. However, Phadia are only aware of three approved food extracts, namely Wheat, Whole Egg and Milk. So if NICE do recommend this specialist in-vivo diagnostic technique for use in a primary care setting, their advice should specify that only licensed extracts be used, and especially, discourage testing with	In addition, as we did not look at the evidence for standardised extracts, raw extracts and the use of prick-prick testing in any detail, specific recommendations cannot be made. Although we recognise the importance of training and education issues, unfortunately this is outside the remit and so comments cannot be made. It should be noted that both tests are cost effective for use in the community depending on local arrangements. The GDG considered that SPT tests could be provided safely within community setting and not require referral to secondary care.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						fresh foods (prick-prick tests). Phadia would also like to suggest that reference is made to the availability of allergy training courses, such as those run by the Allergy Academy and Education for Health, as well as the Allergy MSc programmes at Imperial and Southampton.	
SH	Phadia Ltd	6.01	Full	9	14	In a recent review **(*Arch Dis Child* 2005 90: 826-831),** Professors Holgate and Lack comment: Skin prick testing provides a rapid form of assessing allergies in a clinical context… However, the technique suffers from several drawbacks. Patients (particularly children) will only tolerate a limited number of tests, and numerous children who are receiving antihistamine treatment cannot be tested. Furthermore, patients with dermatographism give false positive results to skin prick tests, and food allergen extracts are not standardised, therefore different product batches may give different results. In contrast, their comments on specific IgE include: The advantages of specific IgE testing are that multiple tests can be performed on the same blood sample and that the technique is not influenced by use of antihistamines or the presence of dermatographism. In addition, blood samples can be stored and reanalysed should further allergic symptoms present. Patients with a very high total IgE level may exhibit multiple positive specific IgE tests with a	Thank you. As the diagnostic performance of both tests is similar, the decision to test using SPT and/or IgE should be based on the results of the allergy-focused clinical history, the suitability/acceptability of the test for the specific child being diagnosed and the competencies of the healthcare professional. The aim of the guideline was to assess the diagnostic accuracy of SPT and specific IgE. The evidence review focused on the specific IgE test in general and we did not look at specific forms of IgE tests. As we did not review the evidence on component IgE tests we are unable to make a specific recommendation, however following GDG discussions, a research recommendation has been made.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						high chance of false positive results. However, the increasing use of the new generation of invitro tests with greater sensitivity and specificity means that this effect is now infrequent. In this last paragraph, Phadia believe that Profs Holgate and Lack are referring to the latest "component" or "Molecular Allergology" IgE tests, further described in sections 3-6 below. Phadia believe these tests deserve some mention in the Guidelines, due to their unique diagnostic advantages in managing the food allergic child.	
SH	Phadia Ltd	6.02	Full	9	15	Specific IgE tests (often called RAST) considered for diagnostic evaluation of IgE mediated allergy should also include the new generation of Molecular Allergology specific IgE tests available from the local pathology/immunology laboratory The new generation of tests provide improved clinical resolution and serve as immunological indicators for patients at risk to severe allergy reactions (IgE mediated allergy). Supporting evidence and further information is provided as a separate document with this proforma regarding specific IgE Molecular Allergology diagnostic tests.	Thank you. Our aim was to review whole foods rather than components of foods and specific IgE test in general rather than specific forms of the test. The reason for this is that the main utility of the component resolved diagnostics are to assess cross reactivity and be able to determine suitable specific immunotherapy. These are outside the scope. Following GDG discussions, a research recommendation has also been made to address this issue.
SH	Phadia Ltd	6.03	Full	38	2	Specific IgE levels to hen's egg white, Ovomucoid allergen component should be considered when performing an allergy risk assessment. The Ovomucoid tests should be used in conjunction with the egg white test. Increased levels of Specific IgE to Ovomucoid	Thank you for your comment. The evidence review aimed to look at the performance of diagnostic tests as a whole for the main allergens. We did not review evidence relating to specific egg allergens therefore we do not make recommendations specific to egg

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						protein indicate persistent egg allergy or if cooked egg can be reintroduced into a child's diet. Supporting evidence and further information has been sent in a separate document with this proforma concerning specific IgE Molecular Allergology tests.	allergy. Following GDG discussions, a research recommendation has also been made to address this issue.
SH	Phadia Ltd	6.04	Full	41	9	Specific IgE levels to peanut allergen component Ara h 2 should be considered when performing a peanut allergy risk assessment. The Ara h 2 test should be used in conjunction with the whole peanut allergen specific IgE test. Increased levels of Specific IgE to Ara h 2 allergen protein indicate a patient who is more at risk to severe peanut allergy symptoms such as asthma, eczema or anaphylaxis. Supporting evidence and further information has been sent in a separate document with this proforma concerning specific IgE Molecular Allergology tests.	Thank you for your comment. The evidence review aimed to look at the performance of diagnostic tests as a whole for the main allergens. As we did not review evidence relating to specific peanut allergens we are unable to make a specific recommendation. Following GDG discussions, a research recommendation has also been made relating to the component resolved diagnostic test. We have also not reviewed the evidence evaluating the association of specific allergens to various allergy symptoms. This was outside the scope.
SH	Phadia Ltd	6.05	Full	42	14	Specific IgE levels to the wheat allergen component Tri a 19 (Omega-5 gliadin) should be considered when performing a wheat allergy risk assessment. Tri a 19 should be used in tandom with the whole wheat specific IgE test. Increased levels of Specific IgE to Tri a 19 (omega-5 gliadin) indicate that a patient could be more at risk to wheat-dependent exercise-induced anaphylaxis (WDEIA) or at risk to immediate reaction to wheat. Supporting evidence and further information has been sent in a separate document with this proforma concerning specific IgE Molecular Allergology tests.	Thank you for your comment. The evidence review aimed to look at the performance of diagnostic tests as a whole for the main allergens. As we did not review evidence relating to specific wheat allergens we are unable to make a specific recommendation. Following GDG discussions, a research recommendation has also been made relating to the component resolved diagnostic test.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Phadia Ltd	6.06	Full	71	14	It is more likely that the different cut off points, published in the USA, Australia and Europe result from studying different *patient* populations, as opposed to any *geographical* effect. One of the most important factors affecting the cut off points is age. It has been shown in several studies that cut off points differ depending on the age of the patient, and this is now well established knowledge **(Komata 2007).** In addition, other factors such as exposure patterns, previous symptoms, severity of reactions and triggering factors other than allergens, may influence cut off points. Phadia believe that the use of cut off points derived from other geographical populations, would be equally valid in predicting the risk of reaction in UK patients. We are unaware of any UK specialists who do not accept the current cut off data points and can find no publications to support the assertion that such data should not be used in the UK. On the contrary, Phadia believe that UK doctors find the cut-off data, derived from different patient populations, to be extremely useful, so long as any differences (such as age) are taken into account **(Roberts & Lack 2005).** References: Komata T et al. The predictive relationship of food-specific serum IgE concentrations to challenge outcomes for egg and milk varies by patient age. J Allergy Clin Immunol 2007; 119(5): 1272-4	Thank you for your comments. This section relates to the GDG suggestion for areas of research.. The evidence review did not exclude on geography but found that invalidated cut off points were commonly used and these cut off points varied across research papers. The validation of cut off points for SPT and IgE tests was therefore proposed as a research recommendation. While we acknowledge that there may be some published research in this area we found the evidence in this area insufficient for the GDG to make recommendations, and as such recognise that more research in required in this area.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Roberts G, Lack G. Diagnosign peanut allergy with skin prick and specific IgE testing J Allergy Clin Immunol 2005; 115: 1291-1296.	
SH	Phadia Ltd	6.07	Full	49	30	For the clinical data on sensitivity and specificity, Youden's Index was used to measure the quality of the studies and to choose the appropriate study. The use of such a single index is "not generally to be recommended". **Ref: Everitt B.S. (2002) The Cambridge Dictionary of Statistics**. The high sensitivity compared to specificity of SPT may lead to higher false positives then an alternative with moderate sensitivity and specificity. The high false positive leads to unnecessary medical costs, such as adrenaline auto-injectors and a lower quality of life, equivalent to those who are true positives.	Thank you for your comment. Although we acknowledge the drawbacks of using the Youden Index as a summary statistic, we felt its use was appropriate given the limitations of the study designs and the fact that pooling the sensitivities and specificities would have been inappropriate. The health economic analysis considered the cost of false positives see appendix 3 page 25.
SH	Phadia Ltd	6.08	Appendix 3	11	26	The specificity at base value for the lgE test was 62,4 %. The value is lower than the base value that was chosen for SPT. This is questionable as the midpoint, lower value and upper value of the lgE test were higher than the value for SPT. Using only Rancé 2002 et al as basis for test accuracy, is questioned because the cut off for SPT for 66,1% accuracy is >-3mm, which does not equate to the >-0,35kUA/L for 62,4%. According to **Bousquet: Assessing skin prick tests reliability in ECRHS-I Allergy 2008 63:341-346,** the more accurate comparison would have been to compare with a SPT of >0mm and not 3 mm.	Thank you for your comments, the base estimate was based on the clinical review and its midpoint. However, for sensitivity analysis the same range was used for both. This resulted in both tests being associated with similar probabilities of being cost effective.
SH	Phadia Ltd	6.09	Appendix 3	17	2	For SPT to be performed by untrained nurses is not an alternative comparison for lgE. The training costs and capital costs should be	The addition of training costs to cost effectiveness analysis is associated with several technical issues. This is because it

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						incorporated for the model to be valid. Else, SPT without training should be excluded on clinical grounds. As mentioned above, NICE already suggests SPT should be only undertaken by healthcare professionals with appropriate competences.	represents an investment but an investment which does not depreciate and has a very long working life span. Estimates of the potential cost of training varied from £500 to £1000 per health care professional. It is considered that this addition is unlikely to have an impact on the cost effectiveness results. This is because the annualised cost is expected to be very small due to the time nurses remained employed by the NHS and the numbers treated per year. For example at £500 if a nurse remained employed for 15 years.
SH	Phadia Ltd	6.10	Appendix 3	17	20	Nurse time (Table 9) for IgE has a stated lower limit of 20 minutes but a base level of 2 minutes. The upper limit of 90 minutes, to take a blood test is highly questionable. **Borghesan et. al,** evaluated the cost for blood collection at 2 EURs and results evaluation by physician, 1EUR. This is to be compared with 17 EURs for a physician to consult, test and interpret SPT. REF: Borghesan et. Al.: Costs of in vivo and in vitro allergy diagnostics Clin Chem Lab Med 2007;45(3):391-395	Thank you for this comment, this was a typographical error and has been corrected to 10 minutes.
SH	Phadia Ltd	6.11	Full	General		Phadia has recognised the value of perfect information and is committed to the research in allergy and health economics	Thank you for your comment.
SH	Royal College of General Practitioners	19.00	General	General		1. Cultural issues will be important here as ethnic minorty groups may well be less aware of the dianosis of food allergy. If a diagnosis is made then this could cause problems in the diet of such individuals where nuts, chick peas and	1. Thank you, cultural issues have now been included in the guideline. 2. The guideline aims to provide a thorough assessment of food allergy and it is

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						sesame seeds may form the basis of their diet 2. Parents may already have decided that food allergy is the likely dignosis and it is important to stress that at times it will be important excluding food allergy as a diagnosis 3. The guidelines stress the importance of food exclusions dietary advice. This will not be necessarily familiar to service gps and access to paediatic dieticians may not be readliy available 4. Eosinophilic oesophagitis could also be IGE mediated. Please define Oral allergy syndrome 5. In the parent information setion there should be reference to prognosis as most parents would want to know this and healthcare professionals should have an insight into this 6. The recommendations generally are straightforward taking the above into account and are targeted at the relevant groups. The recommendations around taking an allergy focussed history are useful but can be complicated in multiple possible allergies and requres a good amount of time 7. How does one predict a higher risk. What is the absolute risk of having a fisrt degree relative affected with a food allergy and risk to offspring? 8. In the alternative diagnostic section there are many alternative practitioners who advocate treatments or interventions that are non	anticipated that healthcare professionals will emphasise exclusion of food allergy when appropriate. 3. Where elimination diets have been recommended, it is also recommended to seek input from a dietitian. Issues relating to access to services are beyond the scope of this guideline. 4. Thank you for your comment. Although it is possible for eosinophil oesophagitis to be IgE mediated, a large number of cases are non-IgE mediated and are associated with delayed reactions. Oral allergy syndrome has been taken out of the guideline. 5. Thank you, the providing information section focuses on the diagnostic process and it is anticipated that more detailed information relating to prognosis may be given when a decision regarding management is made and management is outside the scope of this guideline. 6. Thank you, the allergy focused history was discussed in detail at the GDG meetings and all the components were considered important in order to conduct a thorough assessment. 7. These groups were defined using the evidence review of risk factors for food allergy (see section 2.2) and GDG consensus and expertise. 8. Thank you for your comment. Unfortunately

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						evidence based. Could you expand on this as it would be of value in informing GPs. 9. Who should secondary care services be - what skillset should they have and what determines their expertise with the lack of allergy services	due to the poor quality of evidence there were a limited number of studies that were included in this section. The inclusion criteria were restricted to those tests stated in the original scope. 9. Referral to the appropriate secondary care service is largely dependent on the nature of the food allergy. For instance referrals may be made to paediatric gastroenterology, general paediatrics, dermatology, specialist allergy clinics or other appropriate adult services. Unfortunately the definition of competencies and skills are outside the scope of this guideline.
SH	Royal College of Nursing	14.00	General			The Royal College of Nursing welcomes this document. It is comprehensive.	Thank you for the comment.
SH	Royal College of Nursing	14.01	9	1.1.5		The wording in this section does not seem to guide health professionals firmly enough to the importance of the dietetic services input in cases where elimination of a food for a period of time is to be trialed. "Advice from a dietician is advised" may be more appropriate. We are aware of a number of cases where well meaning professionals and non professionally employed parents eliminate foods with no dietetic advice leading to undernourished children…and clear guidance from the dietician in what is a specialist area is vital. Some health professionals do not always appreciate this and we, therefore consider that more emphasis is required in this particular sentence.	Thank you, this section has been re-worded following GDG discussions to emphasise the importance of the role of the dietitian and as such have removed the words 'if appropriate' from the recommendation.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Below are some appropriate references: Grimshaw Kate E. C. 2006 Dietary management of food allergy in children. Proceedings of the Nutrition society. 65: 412-417 Grimshaw Kate E. C. 2009 Dietary exclusion and nutritional supplements Food Allergy Module 2009/2010 University of Southampton Christie L, Hine J, Parker J. G, Burks W. 2002 Food allergies in children affect nutrient intake and growth. J Amm Diet Assoc. 76: 675-80 Skypala, I., Venter,C. (2009) Food Hypersensitivity Diagnosing and Managing Food Allergies and Intolerance. Wiley-Blackwell. 243-264.	
SH	Royal College of Nursing	14.02	full	21	9	Parental suspicion of food allergy – the experience of some respiratory nurses is that it is common for parents from some ethnic groups/cultures, to believe that various food allergies cause their children's asthma (with no confirmed evidence). Ice cream, fried foods and cold drinks are commonly mentioned by these parents. Cultural factors should be included as part of the guideline.	Thank you. Following GDG discussions cultural and health beliefs have been incorporated into the recommendations.
SH	Royal College of Nursing	14.03	full	21	21	Growth and nutrition stated to be important – might be helpful to give an idea of frequency of monitoring – or suggest 'regularly' at discretion of clinician.	Thank you. The frequency of monitoring for growth and nutrition is a management issue and does not form part of the initial assessment and diagnosis.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Nursing	14.04	full	23	25	Reproducibility of symptoms – as per earlier comment, caution is advised, re anecdotal description and interpretation of child's symptoms by parents whose beliefs are that particular food cause asthma (but have no evidence to confirm it).	Thank you. While we recognise that suspicion of allergy may not be predictive of confirmed allergy the GDG strongly felt that it was still an important factor and the allergy focused history is bound to give HCPs a lot of information. We also anticipate that clinical judgement would be used in these situations.
SH	Royal College of Nursing	14.05	full	33	16	Acknowledged that services of community nurses (presumably including school nurses) may have been excluded due to GP focus. However, the potential for closer team working by nurses and GPs exists and needs to be encouraged.	Thank you for your comments. This was a review of a cost effectiveness paper, and therefore not meant to be interpreted as a recommendation. We agree that collaborative working should be encouraged.
SH	Royal College of Nursing	14.06	full	34	15	Competencies of health staff – costs of training needs addressing if implementation in community is to be successful (and cheaper than hospital).	Thank you for your comment. Competencies were outside the remit of this guideline. Consideration was made of the potential additional costs of training, however, the GDG considered it would not be a significant addition.
SH	Royal College of Nursing	14.07	full	52	23	Competence of health professionals and safety issues – (similar to point 7 above). Would be good to include school nurse representative in the GDG members to inform re role and potential contribution to childhood allergy.	Thank you for your comment. We had a GDG member who was representing Practice Nurses and Health Visitors on the GDG but worked from 2001-2008 in a duel HV/School Nursing role and was also able to consider the role of the school nurse.
SH	Royal College of Nursing	14.08	full	55	8	The review says that it did not include educational needs of healthcare professionals. But in Health Economic Modelling, page 49, surely all costs and savings should be included in overall costs.	Thank you. The clinical review did not include the educational needs of healthcare professionals and these were not included in the health economic since technically it is an investment, but given the service time of nurses in the NHS and the numbers treated per year would represent a negligible additional cost.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Nursing	14.09	GCG members list	80		Good to see the presence of a Practice Nurse. It would have been better balanced in having more than one GP as they are first in line for diagnosis. Also the group should have included a school nurse – who may be first point of contact for some parents. Good to have two patient/carers included as part of the group.	Thank you for your comment.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.00	Full	General		Well done. This is a mammoth task.	Thank you for your comment.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.01	Full	9 + 13		1.1.5: It is unclear how the GP is meant to differentiate IgE and non-IgE mediated allergy on the basis of clinical history. This is partially discussed in 1.2.1, but this section doesn't describe symptoms, but clinical syndromes such as 'enteropathy' etc.	Thank you. We appreciate the difficulties involved in differentiating between IgE and non-IgE food allergy within clinical settings. Following GDG discussions this has been clarified in section 1.1.1 of the guideline.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.02	Full	9		Section on IgE mediated food allergy: Most allergy testing in primary care will be by measuring specific IgE Please mention that the person requesting the test must be competent in it's interpretation. This also applies to skin prick testing (section 1.1.7).	Thank you; this has been amended in the guideline.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.03	Full	9 + 13		There is a discrepancy between the statement1.1.5 – non-IgE mediated food allergy; advice to try elimination of the allergen at home for 4-6 weeks, and 1.2.1: Non IgE mediated food allergy is frequently delayed onset and may need the opinion of a paediatrician or paed gastroenterologist. Does this second statement need re-wording or further advice given about conditions which need referral?	Thank you. The statement in 1.2.1 has been taken directly from the scope and is a general statement relating to non-IgE allergy. The recommendation in 1.1.5 is specific to elimination diets. For more details of when to refer to secondary or specialist care please refer to 1.1.17.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.04	Full	11	5	Refers to oral food challenge at home. To make things clearer, would it be possible to keep references to oral food challenges to procedures performed in a hospital setting and 'a trial of re-introduction' to refer to the procedure performed at home?	Thank you. This guideline focuses on primary care and therefore the recommendations reflect what should be done in primary care.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.05	Full	11	19	Section 1.1.17: By implication, the rest of the document refers to children who have suspected reactions to a single food – could this be explicit earlier in the document?	Thank you for your comment. There hasn't been any pre defined assumption, however the GDG felt a suspected reaction to more than one food could imply more underlying problems and hence the consideration for referral.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.06	Full	10	9	Patient information and support. This is a lot to do in the context of a GP consultation. For IgE mediated food allergies, the healthcare provider will need to discuss the provision of rescue medication and information about how to manage reactions due to accidental ingestion in the community.	Thank you. The recommendations concerning the provision of information and support were based on the evidence review and GDG consensus. All the included recommendations were considered important. The provision of rescue medicine and management of reactions are management issues and are outside of the remit of this guideline.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.07	Full	60	3	Omit 'T'	Thank you, thorough editorial checks will be made.
SH	Royal College of Paediatric and Child Health - National care pathways project - children with allergies	13.08	Full	49		2.4.3 Cost effectiveness of tests is fundamentally based on competence. For example: a protocol on SPT BSACI Protocol for "Skin Prick Testing" compiled by Rosemary King (Southampton University Hospitals NHS Trust) - reviewed by the Standards of Care Committee (SOCC).	Thank you for your comment, variation in the accuracy of the tests was modelled using probabilistic sensitivity analysis.
SH	Royal College of	12.00	Full	General		This guideline is most welcome. However, as	Thank you for your comment. The issue of

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Paediatrics and Child Health		guideline			has been clearly identified by the review team there is a paucity of evidence base for making recommendations and the competence that exists in the community to handle food allergy is rudimentary. It is therefore an absolute imperative that competence is defined very carefully. We would strongly recommend that there is cross referencing to the food allergy care pathways document being produced by the RCPCH. This will very clearly define the competence required to handle food allergy at various levels including primary and community care. The project team developing the care pathways would be very happy to release the draft which is close to completion. Indeed Dr Adam Fox who is on the GDG was the Chair of the working group specifically developing the food allergy pathways and hopefully will be able to communicate these directly.	competencies is outside the scope of this guideline; however, the guideline acknowledges the RCPCH document, in the section 5.1.
SH	Royal College of Paediatrics and Child Health	12.01	Full guideline	General		We note that the guideline reflects the current and rather weak evidence for the management of allergies.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	12.02	Full guideline	General		Overall this looks a balanced review.	Thank you.
SH	Royal College of Paediatrics and Child Health	12.03	Full guideline	General		We are concerned that there is no mention of suspected food allergy in disorders such as autism and chronic fatigue syndrome. Parents often seek advice and, though there is no good evidence of food allergy being involved in such conditions, parents often want to try exclusion diets.	Thank you. The evidence reviewed did not find any links of autism or chronic fatigue syndrome with food allergy and so these conditions have not been mentioned within the guideline. If any child with these conditions was suspected having an allergy, they would follow the pathway as would other children.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Mention of the hazards of multiple elimination diets, and of the need for support for parents and children embarking on such diets that one would not in the first place recommend, is important. We note that there are children with associated problems for whom exclusion diets pose a particular risk, for example children with autism who eat limited foods.	
SH	Royal College of Paediatrics and Child Health	12.04	Full guideline	General		We think the guideline should cover the potential hazards of elimination diets for very poor families without the resources to provide a balanced affordable diet when common food stuffs, e.g. milk, are eliminated, and the potential for supplementation of calcium, vitamins and substitute milk on subscription.	Thank you. We feel this is a very important point and as such have amended the recommendation (1.1.15) to include the socio economic status of the families.
SH	Royal College of Paediatrics and Child Health	12.05	Full guideline	General		We think the guideline should cover the lack of evidence for food faddism being an indication of food allergy.	Thank you, however psychological reactions to foods were excluded from the scope.
SH	Royal College of Paediatrics and Child Health	12.06	Full guideline	General		There is no mention of alerts, e.g. bracelets, alerts on records for those with potential anaphylaxis. There is also no mention of epi pens (auto injectors).	Thank you. The use of bracelets and epi pens are management issues and are outside of this remit.
SH	Royal College of Paediatrics and Child Health	12.07	Full guideline	General		There is no mention of information targeted at schools and other carers than parents, which is essential as often food allergy is dismissed as faddism.	Thank you for your comment. NICE guidelines are developed for use in the NHS but could be applicable to other settings.
SH	Royal College of Paediatrics and Child Health	12.08	Full guideline	General		There is an area of referral to specialist services which takes up an inordinate amount of time in relation to food allergy. This relates to conditions where the relationship between reaction to food and the problem is dubious or totally spurious. This particularly relates to a range of psychological disorders and incurable	Thank you. One of the aims of this guideline is to ensure that thorough initial assessments and diagnoses are carried out including a detailed allergy-focused clinical history. This should assist to reduce the number of referrals to specialist services where the likelihood of food allergy is low.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						or intractable conditions. Anecdotal evidence supports that there are many referrals with so-called ME, autism, etc. There are other conditions where there is the potential that food might aggravate the problem and indeed, as reported by one College member conducting research in this topic, this may be the case for Attention Deficit Hyperactivity Disorder.	The evidence reviewed did not support a link with food allergy and Attention Deficit Hyperactivity Disorder and this topic did not form part of the GDG discussions.
SH	Royal College of Paediatrics and Child Health	12.09	Full guideline	General		We suggest that community awareness leaflets or video presentations in GP clinics about food allergies and their possible modes of presentation would be helpful.	Thank you for your comment, NICE are willing to let organisations use the information in the UNG version of the guideline to develop their own patient information leaflets.
SH	Royal College of Paediatrics and Child Health	12.10	Full guideline	Disclaimer	3	Our understanding of guidelines is that these are by no means mandatory requirements but merely provide guidance to clinicians in ways they might manage patients. In this respect requiring commissioners and providers to implement the guidance seems rather strong and conflicting with the statement that there is an individual responsibility of healthcare professionals to make decisions appropriate to circumstances. Guidelines cannot account for all circumstances.	NICE clinical guidelines are recommendations. Trusts are required to demonstrate adherence with NICE guidelines or provide reasons why they are not doing so. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. Implementation of this guidance is the responsibility of local commissioners and/or providers.
SH	Royal College of Paediatrics and Child Health	12.11	Full guideline	Introduction	3	The first sentence of the introduction defines food allergy as an adverse immune response to food allergens. An appreciable percentage of children and young people presenting with adverse reactions to foods cannot be	Thank you, following GDG discussions a definition of food intolerance has now been added to the guideline although there are no specific recommendations relating to this issue as this was specifically excluded from

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						demonstrated to have an immune response underlying the problem. Under such circumstances this is termed food intolerance. This therefore appears to fall outside the remit of the guideline. However, as one reads through the document it becomes very apparent that the focus is on the patient presenting with an adverse reaction to foods which may or may not be allergic (i.e. immunologically based that can be IgE or non IgE mediated) or some other mechanism such as a subtle metabolic error. Focused on the patients the imperative is that the primary care and community physician is able to recognise that there is a genuine adverse reaction to foods irrespective of whether it is immunologically based or not. Presentations can sometimes be indistinguishable. This is particularly the case for gastrointestinal manifestations. Thus there is an imperative in the introduction to define food intolerance as falling within the remit of this document as well as defining food allergy.	the scope of this document**.**
SH	Royal College of Paediatrics and Child Health	12.12	Full guideline	Patient centred care	5	The statements in the patient centred care are most welcome and indeed excellent.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	12.13	Full guideline	1.1.1	6	We are concerned that this guideline will lead to a further expansion in concerns about the possibility of food allergy, causing a whole range of problems for which the evidence base is weak. From a paediatric respiratory perspective, we think the general statement that food allergy should be considered in all children with cough,	Thank you. This section of the guideline aims to guide the healthcare practitioner to think about the possibility of food allergy when the listed symptoms are present. Following GDG discussions, this section has been amended in the guideline and has now been split into whether an IgE or non-IgE mediated allergy is most likely. There was also agreement that some symptoms in isolation may not be

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						wheeze or shortness of breath is unhelpful. Clearly some immediate IgE mediated food allergies can produce bronchospasm and cough. These are obvious and infrequent discrete episodes. They are very different from more persistent cough and wheeze. Throughout the guideline there seems to be an emphasis on identification of at risk groups and investigation, but a dearth of evidence on the effectiveness of interventions. We think this should be the crux of the guideline – what benefit can be expected by diagnosing and treating food allergy. The evidence for asthma is very weak to non-existent. We suspect that this is also the case for several of the other groups of conditions listed (such as chronic constipation). We would like to see evidence of benefit stated clearly at the beginning of the document (we could not find it anywhere in the guideline). If this evidence is lacking, then why is this document promoting widespread screening for allergy identification?	indicative of food allergy. As the evidence base was weak this list is also based on GDG expertise and consensus and this is made clear in the evidence to recommendations section (2.2.3) In addition, the remit does not include treatment. The benefit of diagnosing food allergy lies in the improvement of quality of life in children who would otherwise be wrongly or misdiagnosed as having food allergy and subsequently being denied certain foods when there would be no reason to do so. Although there is lack of evidence in some areas the GDG used their expertise in this subject, and consensus of opinion, to agree the symptoms and risk factors that may trigger taking an allergy focused clinical history. Asthma was considered a risk factor, to be considered when taking an allergy focused clinical history.
SH	Royal College of Paediatrics and Child Health	12.14	Full guideline	1.1.1	6	This section is pivotal to the whole document and lists the wide range of potential manifestations of food allergy in children and young people. However, it fails to rank these in terms of probability. If this guideline is followed in its current form then vast numbers of children with upper respiratory tract symptoms, cough and wheeze will be inappropriately investigated for food allergy. There is a need for some ranking of probability.	Thank you, following GDG discussions this section of the guideline has been amended and has now been split into whether an IgE or non-IgE mediated allergy is most likely. There was also agreement that some symptoms in isolation may not be indicative of food allergy. As the evidence base is weak in this area, formal ranking of signs and symptoms would be inappropriate. We acknowledge that there are a large number of risk factors but anticipate that

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Respiratory symptoms in the absence of any other manifestations of atopic disease are unlikely to be associated with food allergy whereas manifestations in the skin and gastrointestinal tract as listed are far more likely to be due to food allergy. The respiratory symptoms listed are far more likely to be associated with inhalant allergy which may mandate allergy investigations or even onward referral but all outside the remit of food allergy. Food allergy occurs progressively more commonly in more severe and brittle asthma. Indeed, children who have been admitted to paediatric intensive care with an acute attack of asthma have a very high frequency of associated food allergy which may well have been the trigger for the acute episode. This perhaps should be more clearly highlighted. Food allergy is a rare cause of upper airway respiratory symptoms (rhinitis) without associated gastrointestinal, dermatologic, or systemic manifestations. **Reference**: Wallace D, Dykewicz M, Berstein D, Blessing-Moore J, Cox L, Khan D et al. The diagnosis and management of rhinitis. An updated practice parameter. J Allergy Clin Immunol 2008; 122:S1-S84 (41)	clinical judgement and the allergy focused clinical history would help to focus further testing in those groups who have a higher risk of having an allergy.
SH	Royal College of Paediatrics and Child Health	12.15	Full guideline	1.1.1	6	Pruritis should be spelt pruritus (also in 2.2.4, p22)	Thank you, thorough editorial changes have been made.
SH	Royal College of Paediatrics and Child	12.16	Full guide	1.1.3	7	We think that the history taking should include asking whether the child tolerates the foods that	Thank you. The aim of allergy focused clinical history is that is it specific to the individual

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Health		line			commonly cause reactions separately, e.g. cows milk, hens egg, peanut, tree nuts, shellfish, fish, kiwi fruit, wheat, soya. We think history taking should also include asking whether reactions occur by touch or inhalation of foods. We note that parents do not always volunteer this information unless asked specifically.	child being assessed and we would expect the principle to be the same for all foods. Please see 1.1.3 bullet 3.
SH	Royal College of Paediatrics and Child Health	12.17	Full guideline	1.1.3	7	We would like clarification on what is meant by "dose responsiveness" in this context. We believe this indicates that the severity of response needs to be interpreted in the context of the allergen load. This is important in terms of management decisions regarding auto injectors as well as the need for food challenges in later life.	Thank you. To clarify dose responsiveness refers to an increasingly severe reaction which is linked to increased exposure to the suspected allergen. This has been changed in the guideline.
SH	Royal College of Paediatrics and Child Health	12.18	Full guideline	1.1.3	7	If the mother is still breastfeeding then it is important to take a dietary history from the mother to establish what might be producing the problem in the infant.	Thank you, following discussions with the GDG this has been added to the guideline.
SH	Royal College of Paediatrics and Child Health	12.19	Full guideline	1.1.3	7	We think an allergy questionnaire would be useful, and help GPs and other doctors orient for proper history taking.	Thank you. NICE will also be producing tools to help organisations to implement the guideline in practice. We will pass your suggestion onto them.
SH	Royal College of Paediatrics and Child Health	12.20	Full guideline	1.1.11	10	Atopy patch tests are not utilised to diagnose IgE mediated allergy but more to identify non-IgE mediated allergic phenomena.	Thank you. While it is acknowledged that the Atopy Patch Test may not be standard practice, the evidence reviewed did assess its potential in the diagnosis of IgE mediated food allergy. As a result this evidence was presented to the GDG and its applicability was discussed (see sections 2.3.4 and 2.4.4).
SH	Royal College of Paediatrics and Child Health	12.21	Full guideline	1.1.14	10	Regarding the statement that the child or young person, or their parent or carer, be offered information on how to interpret food labels. We	Thank you. We anticipate that healthcare professionals will tailor this information to the child being assessed (see recommendation

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						suggest this information include the most common food labels on allergen contents, e.g. gluten, nuts, egg, peanut, etc.	1.1.15)
SH	Royal College of Paediatrics and Child Health	12.22	Full guideline	1.1.14	10	Whenever dietary avoidance is recommended irrespective of age it is mandatory that a dietician should be available to be consulted by the family. Even elimination of a single simple food which is non essential in the diet is not easy and there are frequent accidents. Most important in relation to the dietetic input is the recommendation of which foods are safe to eat. Thus, having a positive approach to what can be eaten rather than what cannot be eaten can improve overall outcomes.	Thank you for your comment. Following GDG discussions, recommendations relating to advice from the dietitian have been re-worded within the guideline.
SH	Royal College of Paediatrics and Child Health	12.23	Full guideline	1.1.15	11	We think this needs to specify the "most appropriate hypoallergenic formula or milk substitute to mothers of formula-fed babies". It should specify which formulas can be given, e.g. extensively hydrolysed amino acid formulas as well as when can soya milk be used. Anecdotal evidence supports that there is confusion about this among GPs and health visitors. The above can also avoid a dietician visit.	Thank you, the GDG discussed this issue and it was felt that more specific advice may be provided following dietetic input. The recommendation of a specific formula is outside the scope of this remit.
SH	Royal College of Paediatrics and Child Health	12.24	Full guideline	1.1.17	11	We agree that healthcare professionals undertaking assessment of allergy in the primary care or community setting should consider referral if the child or young person has had "acute systemic reactions or severe delayed reaction". These are children likely to be prescribed adrenaline devices. The guideline does not, however, discuss the prescription of these devices in any detail but	Thank you for your comment, however the prescription of adrenaline devices is a management issue and this is outside of the remit for this topic.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						healthcare professionals who undertake assessments of allergy need to also be competent in determining the need for adrenalin devices. Otherwise there will result a significant postcode lottery for their prescription.	
SH	Royal College of Paediatrics and Child Health	12.25	Full guideline	1.1.18	12	The very dogmatic statements about the lack of value of alternative diagnostic tools is most welcome. There are of course a very large number of alternative diagnostic approaches, none of which have any proven value. We suggest adding the whole live blood analysis to the list as it is employed by some people in the UK.	Thank you for your comment, however as we have not specifically looked at the evidence for whole live blood analysis we cannot make specific recommendations.
SH	Royal College of Paediatrics and Child Health	12.26	Full guideline	1.2.1	13	Regarding the statement, "Non-IgE mediated reactions are generally characterised by: … chronic pulmonary disease". We note that chronic pulmonary disease is a very vague term and potentially can be misinterpreted to mean a lot of things, including poorly controlled asthma. We are not aware of any evidence of non IgE mediated food allergy as a cause of "chronic pulmonary disease" per se.	Thank you; this has been altered in the guideline.
SH	Royal College of Paediatrics and Child Health	12.27	Full guideline	1.2.1	13	This is an area again where there is a need to define food intolerance as well as food allergy.	Thank you; following GDG discussions a definition of food intolerance has now been included in the guideline**.**
SH	Royal College of Paediatrics and Child Health	12.28	Full guideline	1.2.1	13	We note that many conditions are given, e.g. atopic dermatitis ,GORD, proctitis, etc. in which food allergies are to be suspected. However, it would be more helpful to see more data about the percentage of people affected with food allergies in these conditions.	Thank you, this section has been amended following GDG discussions.
SH	Royal College of Paediatrics and Child	12.29	Full guide	2.2 2.3	16 25	We are concerned that the way in which the literature review has been conducted will miss	Thank you for your comment. As food intolerance is outside the remit it was not

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Health		line			many important studies if food intolerance is not included at search. In the end the most important information required by clinicians in assessing the relative value of clinical history and tests is the sensitivity, specificity, positive and negative predictive values. There are a number of publications that do not appear in the listing that have investigated these particularly in relation to specific IgE antibody testing and comparing the outcomes in relation to food challenge. While these studies have been conducted in a hospital based service the information is important for primary care and can allow extrapolation. As mentioned above the key is competence in relation to history taking and interpretation of the results of tests.	included within the search strategy. While we understand that adding food intolerance as an additional search term may increase the number of studies picked up, we suggest that these are not likely to meet the inclusion criteria which include the use of a food challenge to confirm a food allergy. The evidence was not excluded based on applicability to primary care although this issue was discussed at the GDG meeting and is referred to in the evidence to recommendations (see section 2.3.4). For further details on excluded studies please see appendix 2.There are also studies which would have combined diagnosis with management. These studies would be excluded.
SH	Royal College of Paediatrics and Child Health	12.30	Full guideline	2.3.3	32	A key issue in assessing the health economy is that there is a very considerable increase in cost to families of the diagnosis of even a single food allergy. This has been well researched by the Food Standards Agency. It is associated with a significant increase in cost of the average supermarket food basket even if the allergy is just to nuts. Furthermore there is a considerable increase in investment in time in identifying safe food products. Thus the health economic modelling should identify the cost to families, which is exceedingly important in paediatric practice. It is also important to cost in false diagnosis of food allergy and to understand the costs either of missing a diagnosis or misappropriately applying a diagnosis. Thus even if a patient has an improvement on elimination of food there is	Thank you for your comments, NICE's reference case states that only costs to the NHS and personal social security services should be considered. The costs of misdiagnosis including quality of life impact, further GP visits, and the potential for serious events were considered.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						still a need to conduct a challenge to establish whether the diet is really required long term. Anecdotal evidence supports that many patients are seen in whom the primary care has colluded with a parent in the diagnosis of the food allergy or intolerance without proper testing and this has progressively escalated with parents identifying more and more foods as causing a problem thereby leading into serious nutritional and other adverse consequences.	
SH	Royal College of Paediatrics and Child Health	12.31	Full guideline	1.2.1 a)	47	Regarding the statement, "Food allergy in the population is amongst the most common of the allergic disorders". This is somewhat misleading because inhalant allergy is very considerably more common than food allergy.	Thank you. This has been taken directly from the scope and while we acknowledge that inhalant allergies may be more common, we suggest that food allergy can still be considered among the most common allergy disorders.
SH	Royal College of Paediatrics and Child Health	12.32	Full guideline	2.4.2.1	48	Regarding the statement, "Low quality evidence from 18 quality studies of 3165 children". Repeat use of the word quality does not make sense.	Thank you, thorough editorial changes have been made.
SH	Royal College of Paediatrics and Child Health	12.33	Full guideline	2.4.3	49	Cost effectiveness of tests is fundamentally based on competence. With respect of skin prick tests, storage of the solutions and incorrect application allowing for the effects of cryomedications, etc. is critical. Many errors are made in using skin prick tests which means that their sensitivity and specificity is very much lower than perhaps indicated from specialised clinics. There is therefore a need to assess health economics based on specificity as well as sensitivity of tests.	The specificity and sensitivity of the tests was included in the economic model. Variation around the accuracy of the tests was modelled using probabilistic sensitivity analysis. This was used to model potential variation in competencies. In addition, consideration was given to false positive costs in term of repeat appointments, quality of life impacts and allergy management. Please see pg 25 of Appendix 3.
SH	Royal College of	12.34	Full	2.4.5	54	We note that the major departure from current	Thank you**.** The issue of competencies is

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Paediatrics and Child Health		guideline			practice is that diagnosis and assessment of food allergy in children and young people is recommended in primary care and community settings. It is recommended that skin prick tests are undertaken by healthcare professionals with the appropriate competencies. However, we note that there is no definition of competency or how this is to be determined. There is little comment on competencies required to undertake the assessments in general.	outside the scope of this guideline, however, the guideline acknowledges the RCPCH document, in the section 5.1.
SH	Royal College of Paediatrics and Child Health	12.35	Full guideline	2.6.2.2	65	Cross referencing to the RCPCH national care pathways on asthma and rhinitis would be sensible in making recommendations of who to refer for further allergy investigation.	Thank you, it is expected that in cases for referral, healthcare professionals would also exercise their professional judgement.
SH	Royal College of Paediatrics and Child Health	12.36	Full guideline	2.6.4	67	We note that parents often suspect food allergy in the context of urticaria. This can be perplexing especially when the allergy-focused history fails to identify a food product in its aetiology. Anecdotal experience is that specialist assessment of such cases is not fruitful. We would recommend a specific case for **not** referring cases of urticaria.	Thank you, the GDG did discuss referrals for urticaria and it was felt that acute cases may be indicative of food allergy.
SH	Royal College of Paediatrics and Child Health	12.37	Full guideline	2.7	67	A diagnostic test not featured in this guideline is component resolved diagnostics. This is something that is now being heavily marketed by Phadia particularly in relation to predicting cross-reactivity between foods and pollens and potentially in predicting severity of food allergy. However, the evidence base is relatively weak. Given that this is a guidance for primary care, we think it is important to make some comment about this as it will be increasingly publicised over the next year or two and from a health economic perspective could be very costly. This	Thank you. As we did not review the evidence on component resolved diagnostic tests we are unable to make any specific recommendations.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						is most certainly an area where more research is required.	
SH	Royal College of Paediatrics and Child Health	12.38	Full guideline	3.1	69	There is a very large European funded study investigating the prevalence of IgE and non-IgE mediated food allergy, which perhaps means that this is a recommendation need not be quite so strong in terms of further research.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	12.39	Full guideline	3.1	69	It would be helpful to have more information on the approximate age at which each type of food allergy is expected to appear or disappear, as well as the conditions in which the food allergy disappears or wanes off with time will be useful, e.g. cows milk.	Thank you for your comment, however we feel this has been covered in research recommendation 3.1.
SH	Royal College of Paediatrics and Child Health	12.40	Full guideline	3.4	71	There are some very reasonable studies of the predictive values of specific allergy testing for individual allergens. However, this is restricted to relatively few and certainly requires extension to a much wider range of foods.	Thank you for your comment. The recommendation has not restricted the research question to a specific number of foods.
SH	Royal College of Pathologists	5.00	Full	3		Introduction, line 2: remove comma between '..IgE mediated' and 'non-IgE mediated..', replace with 'and'. Start following sentence with 'Many' (Many non-IgE reactions, which..').	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.01	Full	4	2	Replace 'are' with 'may be' ('..responses and may be..').	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.02	Full	4	2	After line 2, add 'Food allergies (IgE and non-IgE mediated) may coexist with non-immune adverse reactions to specific foods (food intolerances)').	Thank you for your comment, following GDG discussions a definition of food intolerance has been added to the guideline.
SH	Royal College of Pathologists	5.03	Full	7	1.1.3	Line 2: insert 'a' between '..young person)' and 'healthcare..'.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.04	Full	7	1.1.3	Bullet point 1: re-phrase to 'any individual and family history of atopic disease'.	Thank you, this section of the guideline has been amended as suggested.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Royal College of Pathologists	5.05	Full	7	1.1.3	Bullet point 3, hyphen 2: re-phrase to 'speed of onset following food contact'	Thank you, the guideline has been amended as suggested.
SH	Royal College of Pathologists	5.06	Full	8	1.1.4	Bullet point 2: it may be of practical value to the reader to list, or give examples of, relevant co-morbidities.	Thank you, the guideline has been amended as suggested.
SH	Royal College of Pathologists	5.07	Full	8		Diagnosis: it may be of value to try to broadly define what is meant by 'rapid'. In many cases symptoms will arise within minutes but in some there may be significant delay in onset.	Thank you, the definitions given here are broad and although there may be some delay in symptom onset for some cases of IgE-mediated food allergy, symptoms are generally experienced quicker in comparison to non-IgE-mediated allergies.
SH	Royal College of Pathologists	5.08	Full	9	1.1.8	Bullet point 2: insert ',safe for' between '..suitable for' and 'and acceptable to..'.	Thank you. This has been changed in the guideline.
SH	Royal College of Pathologists	5.09	Full	13	1.2.1	3rd line from bottom of page: line needs re-phrasing (? to 'Non-IgE mediated food allergy can be difficult to diagnose with any certainty, particularly because of a frequent delay between food ingestion and symptom onset..' or similar).	Thank you, the guideline has been amended as suggested.
SH	Royal College of Pathologists	5.10	Full	23	1.2.3	Recommendation 1.2.3, line 2: insert 'a' between '..young person' and 'healthcare..'.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.11	Full	31	2.3.2.1	The direct applicability of this evidence is uncertain. It is not anticipated that the majority of these test modalities are relevant to a primary care environment.	Thank you for your comment. The evidence statement referred to here is a summary of the evidence reviewed. We felt it was important to highlight the difficulties in making a differential diagnoses and the test modalities were included for more information. The evidence was not excluded based on test modality or applicability to primary care, although this issue was discussed at the GDG

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							meeting and is referred to in the evidence to recommendations (see section 2.3.4).
SH	Royal College of Pathologists	5.12	Full	31	2.3.2.1	The direct applicability of this evidence is uncertain. It is not anticipated that the majority of these test modalities are relevant to a primary care environment.	Thank you for your comment. The evidence statement referred to here is a summary of the evidence reviewed. We felt it was important to highlight the difficulties in making differential diagnoses and the test modalities were included for more information. The evidence was not excluded based on test modality or applicability to primary care although this issue was discussed at the GDG meeting and is referred to in the evidence to recommendations (see section 2.3.4).
SH	Royal College of Pathologists	5.13	Full	31	2.3.2.1	Line 7: 'Esophagitis' mis-spelt.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.14	Full	32	2.3.3	Paragraph 2, sentence 3: This statement requires a substantial mechanistic leap of faith (in the use of the word 'allergy') as symptom improvement on food elimination does not in itself identify a causative immunological mechanism and does not differentiate between allergy and non-immune intolerance.	Thank you for your comment. The relevant section has been removed as it was not necessary for this section.
SH	Royal College of Pathologists	5.15	Full	33-34	2.3.4	The SAC agrees with the GDG's comments on the utility of atopy patch testing (see General comments below).	Thank you for your comments.
SH	Royal College of Pathologists	5.16	Full	34	2.3.4	The SAC notes the comments of the GDG on the risks of food reintroduction following a period of dietary elimination. No contrary view is offered from the SAC but it is anticipated that other stakeholder groups with greater expertise and experience in this specific area may offer useful, informed support/challenge to the GDG consensus view.	Thank you for your comments.
SH	Royal College of	5.17	Full	51		Paragraph below Table 4: In addition to simple	Thank you for your comment, the GDG

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Pathologists					economic evaluation of tests, additional relevant factors to be considered are risks associated with tests (and the costs of those risks) and accessibility of specific tests (particularly skin tests) in primary care. Available data would indicate that the latter is vestigial, at best (Levy ML et al. Clin Exp Allergy 2004; 34: 518-9).	considered that adverse events associated with the tests were not significant and should not be included. Accessibility is only considered in terms of potential capital costs which, in this case, were not considered applicable.
SH	Royal College of Pathologists	5.18	Full	52	2.4.4	Paragraph 3: The ethos of the GDG view on allergy testing is strongly supported by the SAC, although its practical implementation is problematic. In line 2 of this paragraph, suggest slight re-phrasing long the lines of '..needed to perform, read and interpret..' might be appropriate.	Thank you, the guideline has been amended to reflect your comment.
SH	Royal College of Pathologists	5.19	Full	52	2.4.4	Bottom line: amend 'of' to 'or'	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.20	Full	53	1.2.8	Bullet point 2: insert ',safe for' between '..suitable for' and 'and acceptable to..'.	Thank you. This has been changed.
SH	Royal College of Pathologists	5.21	Full	60	3	Delete 'T' from between '..what to do' and ' while..'.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.22	Full	62	2.6	Bold print below heading: insert 'children' between '..should' and 'and young..'.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.23	Full	66	1	Re-wording needed.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.24	Full	66		Bullet point 2: re-phrase to 'clinical suspicion of multiple or cross-reactive food allergies'	Thank you for your comment. This section has been changed in the guideline as suggested.
SH	Royal College of Pathologists	5.25	Full	67	1.2.17	Bullet point 2, hyphen 3: re-phrase to 'clinical suspicion of multiple or cross-reactive food allergies'	Thank you for your comment. This has been changed in the guideline as suggested.
SH	Royal College of	5.26	Full	67	1.2.1	Symptoms arising through non-allergic	Thank you for the comment. The

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Pathologists				7	mechanisms are frequently confused with, or mistaken for, allergic conditions and differentiating allergy from pseudo-allergy is frequently challenging. One function of specialist allergy clinics is to make that differentiation but separating the two in a community setting (even if only to inform decisions on referral) will not be straight-forward, and, in many cases, may be very challenging. The GDG might usefully consider/satisfy itself whether this circumstance is adequately/already catered for in the recommendation on referral to secondary or specialist care.	recommendations were made after careful consideration of the evidence, the complexity of what food allergy is and GDG expertise and consensus. There were extensive discussions regarding the allergy focused history and what information and feedback HCPs were expected to get from patients before making a diagnosis. Following GDG discussions, a definition of food intolerance has been added to the guideline.
SH	Royal College of Pathologists	5.27	Full	69	3	The proposed research recommendations might usefully encompass processes for robust evaluation of allergy diagnostic tools (such as those encompassed in the guideline) in a primary care setting.	Thank you for your comment. The robust evaluation of diagnostic tools is addressed in the research recommendation in section 3.4 which focuses on the predictive values of SPT and IgE.
SH	Royal College of Pathologists	5.28	Full	General		Inconsistent spelling of 'focused' and 'focussed'.	Thank you, thorough editorial changes have been made.
SH	Royal College of Pathologists	5.29	Full	General		Atopy patch test is not a term, or a technique, which is commonly used in allergy (IgE mediated) diagnosis in the UK and its inclusion in the document (even if only to recommend that it is not used) may require some explanation/clarification as to its performance, purpose and provision in the context of food allergy. Patch testing (as performed by Dermatologists for Type IV hypersensitivity) is not standard, routine practice in the investigation and diagnosis of food allergy in the UK.	Thank you. While it is acknowledged that the Atopy Patch Test may not be standard practice, the evidence reviewed did assess its potential in the diagnosis of IgE mediated food allergy. As a result this evidence was presented to the GDG and its applicability was discussed (see sections 2.3.4 and 2.4.4).
SH	Royal College of	5.30	Full	General		It may be useful to stress the importance of	Thank you for your comment. Throughout the

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Pathologists					robust diagnosis, not only for exclusion of problematic foods but also in preventing unnecessary dietary exclusion of suspect foods which are safe and which should be eaten as part of a normal, healthy, balanced diet.	guideline, emphasis has been put on the importance of an allergy-focused clinical history. The guideline has been amended to include the hazards of exclusion diets.
SH	Royal College of Pathologists	5.31	Full	General		As in the SAC response to the previous scoping document it is unclear, and an issue of concern, how the various competencies used to diagnose and assess food allergy such as focused-history taking, skin prick testing and other tools (dietary manipulations) will be acquired and deployed in primary care. These skills are significantly and generally lacking at present (Levy et al). It is accepted that this is an underlying structural problem which may not be relevant to the direct remit of this guideline. However, it remains an issue which is likely to impinge substantially on the prospect of this guideline being widely and effectively implemented.	Thank you for your comment. The GDG discussed the issue of competencies in detail and acknowledges the RCPCH document on core competencies.
SH	Welsh Assembly Government	21.00	General			This organisation responded and said they had no comments to make.	Thank you.

These organisations were approached but did not respond:

Action Against Allergy
Alder Hey Children's NHS Foundation Trust
ALK Abello
Allergy UK
Association of Breastfeeding Mothers
Association of Paediatric Anaesthetists of Great Britain and Ireland
Association of Paediatric Emergency Medicine
Barnsley Hospital NHS Foundation Trust
BMJ
Breastfeeding Network, The

Brighton and Sussex University Hospitals Trust
British Association for Community Child Health
British Dietetic Association
British National Formulary (BNF)
British Paediatric Allergy, Immunity & Infection Group
British Society of Gastroenterology
Calderdale and Huddersfield NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Care Quality Commission (CQC)
Cerebra
Citizens Commission on Human Rights
Cleft Lip and Palate Association
Commission for Social Care Inspection
Connecting for Health
County Durham PCT
Department for Communities and Local Government
Department for Education
Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)
Diagnostic Innovations Limited
Dudley Group of Hospitals NHS Trust
East Cheshire NHS Trust
East Kent Coastal PCT
Food and Drink Federation
Gloucestershire Hospitals NHS Trust
Imperial College Healthcare NHS Trust
Institute of biomedical Science
James Paget University Hospitals NHS Foundation Trust
La Leche League GB
Lambeth Community Health
Leeds PCT
Liverpool Community Health
Liverpool PCT Provider Services
Luton & Dunstable Hospital NHS Foundation Trust
Manchester Community Health
Mead Johnson Nutrition
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 Direct
NHS Direct
NHS Islington
NHS Knowsley
NHS Plus
NHS Quality Improvement Scotland
NHS Sheffield
NHS Western Cheshire
North West Allergy and Clinical Immunology Network
Nottingham Community Nutrition and Dietetic Department
Nutricia Advanced Medical Nutricion
Nutricia Ltd (UK)
Nutrition Society
Parents Protecting Children UK
PERIGON Healthcare Ltd
Poole and Bournemouth PCT
Public Health North East
Royal Brompton & Harefield NHS Foundation Trust
Royal College of Anaesthetists
Royal College of General Practitioners Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Physicians London
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)
Scottish Paediatric Allergy Group

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
Southampton University 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 Scientific Advisory Committee (WSAC)
Western Health and Social Care Trust
Wirral University Teaching Hospital NHS Foundation Trust
Worcestershire PCT
York NHS Foundation Trust