NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2018 surveillance of Food allergy in under 19s: assessment and diagnosis (2011)

Consultation dates: 1 to 14 August 2018

Do you agree with the proposal to not to update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Coeliac UK	No	We suggest the addition of cross referencing to the NICE guideline for recognition, assessment and management of coeliac disease (NG20). The gastrointestinal system symptoms listed in Table 1 are similar to the symptoms of coeliac disease which should trigger investigations for coeliac disease. This is particularly relevant in light of recommendation 1.1.11 which recommends trialling elimination of the suspected allergen. Coeliac disease should be eliminated before gluten and/or wheat are eliminated from the diet as testing for coeliac disease is only accurate if gluten is present in the diet.	Thank you for your comments. Based on your feedback, we will make editorial amendments to include cross-references from NICE guideline CG116 to coeliac disease: recognition, assessment and management (2015) NICE guideline NG20. The following editorial amendments will be made: Recommendation 1.1.2, bullet point 3: A cross-reference to Coeliac disease: recognition, assessment and management (2015) NICE guideline NG20 will be included for information. The text will state: For information about coeliac disease see NICE's guideline on Coeliac disease: recognition, assessment and management (2015) NICE guideline NG20.

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			Recommendation 1.1.11: A cross-reference from CG116, 1.1.11 (non-IgE-mediated food allergy) to Coeliac disease: recognition, assessment and management (2015) NICE guideline NG20 will be included. The text will state: For people undergoing investigation for coeliac disease see NICE's guideline on Coeliac disease: recognition, assessment and management (2015) NICE guideline NG20.
Royal College of Pathologists	Yes	No comment provided	Thank you for your response.
Public Health England	Yes	The Scientific Advisory Committee on Nutrition recently published the following publications which may be of interest: Feeding in the first year of life (2018) https://www.gov.uk/government/publications/feeding-in-the-first-year-of-life-sacn-report SACN-COT statement on the introduction of peanut and hen's egg into the infant diet (2017) https://www.gov.uk/government/publications/sacn-cot-statement-on-the-introduction-of-peanut-and-hens-egg-into-the-infant-diet	Thank you for your response. The SACN report, *Feeding in the first year of life* (2018), will be considered during a planned update of Maternal and child nutrition NICE guideline [PH11]. Please refer to the guideline surveillance report for more information: Surveillance report 2017 – Maternal and child nutrition (2008) NICE guideline PH11. The SACN-COT statement on the introduction of peanut and hen's egg into the infant diet (2017) is outside of the remit for the current guideline as the statement covers prevention of food allergy.
Allergy UK	No	I think an update would be recommended as information such as patch testing that is referenced to needs to be corrected with statements such as 'patch testing has no place in the diagnosis of either IgE or Non-IgE food allergy' so that non-allergy specialists do not consider this as a validated test for food allergy, also so that the child or	Thank you for your comments. During development of the guideline the committee concluded that the test was of little value in diagnosing non-IgE-mediated food allergy in primary care settings; they also concluded that the test in primary care was inappropriate for IgE-mediated food allergy.

		young person does not get referred to a paediatric dermatologist for patch testing rather than a paediatric allergist to diagnose and manage their suspected food allergy.	The guideline does not recommend the use of atopy patch testing for either IgE or Non-IgE food allergy. Recommendation 1.1.10 states: Do not use atopy patch testing or oral food challenges to diagnose IgE-mediated food allergy in primary care or community settings. Furthermore, we have not received any implementation data to indicate that professionals are using atopy patch testing to diagnose non-IgE-mediated food allergy in primary care and community settings, as a result of misunderstanding the guideline. We have not identified evidence that would merit changes to the guideline regarding atopy patch testing at this time.
Anaphylaxis Campaign	Yes	Given the current evidence and intelligence available at this time we would agree that the proposal does not need to be updated at present	Thank you for your response.
British Society for Allergy & Clinical Immunology BSACI	Yes	**BSACI Response** CG116 for primary care and community use was the 1st food allergy-related both UK and NICE publication and remains the definitive one. In being the 1st such guideline, its scope correctly focuses on the initial diagnosis and assessment of food allergy in primary care and community settings where suspected cases mostly first present. Since its publication 7 years ago NICE have very properly responded to the growing and continuing UK evidence that food allergy continues to be sub-optimally assessed, diagnosed, and managed in primary care and community settings by producing a number of further supporting documents: **CKS** on cow's milk protein allergy in children	Thank you for your comments.

		Anaphylaxis guideline – where food allergy is the trigger in over 90% of cases in children in primary care and community settings **Quality Standards** for both food allergy in children and anaphylaxis in all age groups **E-learning programme** for food allergy in children and anaphylaxis in all age groups Further NICE accredited British Society for Allergy and Clinical Immunology (BSACI) individual food allergy guidelines have also been published for egg, cow's milk and nuts. These more recent publications contain some newer factual details at odds with CG116 with regards to these foundational elements of assessment and diagnosis. Therefore, if CG116 is still to remain as the definitive NICE and UK guideline on food allergy, some further simple but key in house NICE editorial and factual corrections are definitely required. Otherwise we believe it will be considered by the key food allergy topic experts and stakeholders in the UK as now very dated. The following further editorial (e.g. presentation of symptoms and signs) and factual corrections are still strongly advised: **Guidance** **1.1 List of all recommendations** **Assessment and allergy-focused history**	Thank you. We considered these documents when preparing the surveillance proposal. We noted the NICE accredited BSACI guidelines are considered partially relevant to NICE guideline CG116, but were primarily developed for secondary and tertiary care audiences and were broader in their scope as they covered management of food allergies. We also noted a discrepancy between the NICE quality standard food allergy (March 2016) QS118, statement 3; this has been addressed in our review decision (further details are outlined below). In addition, NICE Clinical Knowledge Summaries: Cows' milk protein allergy in children (2015), is a practical resource for primary care professionals (it is not formal NICE guidance). It includes a section on the management of children with confirmed cows' milk protein allergy, an area that experts indicated could be included within NICE guideline CG116. However, this area is beyond the remit of NICE guideline CG116 which is limited to diagnosis and assessment. To trigger any update beyond minor editorial corrections, new evidence would be required in most instances. No evidence was identified through intelligence gathering for this surveillance review that would impact the recommendations.

		1.1.1 Consider the possibility of food allergy in children and young people who have one or more of the signs and symptoms in Table 1, below. Pay particular attention to persistent symptoms that involve different organ systems. It remains fundamentally important that within CG116, a list of possible signs and symptoms of possible food allergy should remain. However this Table 1 was actually hurriedly developed between the completion of the full guideline (Dec 2010) and the then production of its accompanying Quick Reference Guide. NICE commissioned 2 of the expert advisors to carry this out but given the very short time frame of a few weeks, it essentially adapted the existing relevant Table from the Dec 2010 published **'Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel'.** Subsequently over the last 8 years both the experience of our USA colleagues and locally that, whilst the concept of such a Table has been clearly welcomed, it could have been much more practically and helpfully set out for primary care use. In time I expect our USA colleagues will address this but currently NICE now have the opportunity to editorially do so for more optimal UK healthcare professionals' use. The main criticism of the original Table 1 has been that it is simply a list and has not set out and highlighted in a practical enough way the distinctive patterns of signs and symptoms between suspected IgE and non-IgE food allergy. If this original Table 1 is not better presented following this review	Thank you for your comments on recommendation 1.1.1 and the associated table. No evidence was identified to indicate the table was factually incorrect or that this table was not appropriate for supporting local practice. To trigger an update of the guideline we would require clear evidence to support changes to the

		process, then it will simply increasingly confirm that CG116 has become dated for guiding ongoing UK best practice. **1.1.4** **Diagnosis** **IgE-mediated food allergy** **1.1.8** Choose between a skin-prick test and a specific IgE antibody blood test based on: •the results of the allergy-focused history and •whether the test is suitable for, safe for and acceptable to the child or young person (or their parent or carer) and •the available competencies of the healthcare professional to undertake the test and interpret the results. It would be helpful to signpost here to the 3 more recently published NICE accredited BSACI guidelines on cow's milk allergy, egg allergy and nut allergy. Much helpful and practical guidance is given here, building on the general points made in the above 3 bullet points. **Non-IgE-mediated food allergy** **1.1.11** Based on the results of the allergy-focused clinical history, if non-IgE-mediated food allergy is suspected, trial elimination of the suspected allergen (normally for between 4 and 6 weeks) and reintroduce after the trial. Seek advice from a dietitian with appropriate competencies, about nutritional adequacies, timings of elimination and reintroduction, and follow-up.	recommendation and table; furthermore the footnote acknowledges that the list is not exhaustive. However, we will monitor this area and consider again at the next surveillance review of the guideline. As noted above, the NICE accredited BSACI guidelines are considered partially relevant to NICE guideline CG116, but they are primarily intended for secondary and tertiary care audiences and broader in their scope as they cover management of food allergies. We do not feel they are relevant resources for the intended primary and community setting audiences. A potential discrepancy was noted by a topic expert between the NICE quality standard food allergy (March 2016) QS118, statement 3, and NICE guideline CG116 - the source guideline for this quality

		This wording must be revised as it is now unsafe due to the more recent NICE Quality Standard for food allergy more correctly saying that this only applies to suspected 'mild-to-moderate' cases. Suspected 'severe' cases should be seen by a specialist allergy service and any required diagnostic open food challenge should be under their direct care and observation. 'Seek advice from a dietitian with appropriate competencies, about nutritional adequacies, timings of elimination and reintroduction, and follow-up.' This clearly suggests in all suspected cases. Whilst this is true for example in an infant where the food to be eliminated makes up a major part of the diet, it is clearly not necessary if a minor single food is to be eliminated from the diet for a short trial period particularly in an older child or young person. Therefore some qualification to this statement is now needed as wide-spread negative UK clinical feedback relating to unnecessary dietetic referrals to a much pressurised service would strongly further indicate. Elsewhere in the Recommendations, this important	standard. We acknowledged this issue in the consultation proposal and responded accordingly: The quality statement 3 says: 'Children and young people whose allergy-focused clinical history suggests a non-IgE-mediated food allergy, and who have not had a severe delayed reaction, are offered a trial elimination of the suspected allergen and subsequent reintroduction'. One expert was concerned that this statement provided additional information about severe delayed reaction that was not, and should be, present in NICE guideline CG116 recommendation 1.1.11. We have checked the guideline content and have identified that this statement is based on NICE guideline CG116 recommendations 1.1.11 and 1.1.17. Recommendation 1.1.17 recommends consideration of referral to secondary care where the child or young person has had one or more severe delayed reactions. The quality statement will be updated to clarify that it was based on 2 recommendations, 1.1.11 and 1.1.17. We believe that the issue is addressed by revising the NICE quality standard. Recommendation 1.1.17 covers children with severe delayed reactions. During development of the guideline the committee discussed the duration of food elimination diets and the competencies needed by healthcare professionals to oversee them. It was agreed that, although a referral would not always be necessary, advice should be sought from a dietitian and this should include follow-up and nutritional issues. Information should be sought and local arrangements should be in place to ensure that support is available for local practitioners. The nature and extent of the support would

		qualification regarding more selective referrals is actually covered: **Providing information and support to the child or young person and their parent or carer** **1.1.15 For** babies and young children with suspected allergy to cow's milk protein, offer: • food avoidance advice to breastfeeding mothers • information on the most appropriate hypoallergenic formula or milk substitute to mothers of formula fed babies. Seek advice from a dietitian with appropriate competencies **A suggested additional point under this Non-IgE-mediated food allergy section** Within the IgE-mediated food allergy section; 1.1.10 addresses the role of both atopy patch testing and food challenges in food allergy diagnosis in primary care and community settings. It emphasises that atopy patch testing should not be used: Do not use atopy patch testing or oral food challenges to diagnose IgE-mediated food allergy in primary care or community settings. This non-IgE section just addresses food challenges/reintroduction in the diagnosis, emphasising its positive place. It does not address atopy patch testing. This has led to the possible interpretation that atopy patch	be a local matter, and advice may come via local protocols or other resources for practitioners.

		testing could also have a positive role in the diagnosis of non-IgE food allergy in primary care and community settings. The last international guideline to mention atopy patch testing specifically in the possible diagnosis of suspected non-IgE food allergy was published as long ago as 2007 – **'Guidelines for the diagnosis of cow's milk protein allergy in infants'** (Y. Vandenplas et al, *Arch Dis Child*, 2007; 92: 90-908) It states on page 906: 'Patch testing in the investigation of CMPA is still a subject of on-going research and can aid the diagnosis of non-IgE associated reactions. … However, the patch test method needs to be standardised.' Subsequently over the past 11 years all attempts to standardise atopy patch testing in suspected non-IgE food allergy have failed. Subsequently all the post-2007 national and international guidelines do not include it as a possible tool in diagnosing suspected non-IgE mediated food allergy. The 2 most relevant such guidelines from NICE's perspective would be the NICE CKS on CMA (2015) and the BSACI guideline on CMA (2014). This should be sufficient evidence to now exclude the role of patch testing therefore this requires updating to a further recommendation: **'Do not use atopy patch testing to diagnose non-IgE-mediated food allergy in primary care and community settings.'** **Referral to secondary or specialist care**	During development of the guideline the committee concluded that the atopy patch test was of little value in diagnosing non-IgE-mediated food allergy in primary care settings; they also concluded that the test in primary care was inappropriate for IgE-mediated food allergy. There is no place in the guideline where atopy patch testing is recommended. Furthermore, we have not received any implementation data to indicate that professionals are using atopy

		1.1.17 'Based on the allergy-focused history, consider referral to secondary or specialist care in any of the following circumstances • The child or young person has: • confirmed IgE-mediated food allergy and concurrent asthma' Since the 2011 publication of CG116, NICE have correctly identified the very real lack of progress in primary care developing skills and competencies in diagnosing and confirming suspected IgE-mediated food allergy from any cause. Consequently in the 2015 NICE CKS on cow's milk allergy in young children, they have helpfully made the following statements: Pg. 16 'Children with immunoglobulin E (IgE)-mediated cow's milk allergy are usually managed in secondary care.' Then later in the text: Pgs. 19, 20 '...diagnostic tests for suspected IgE-mediated cow's milk protein allergy "should only be undertaken by healthcare professionals with the appropriate competencies to select, perform and interpret them". CKS recognises that the expertise to choose, perform and interpret these tests may not be readily available in primary care: therefore, the diagnosis and subsequent management of cow's milk protein allergy is more likely to be done in secondary care. ...	patch testing to diagnose non-IgE-mediated food allergy in primary care and community settings. We have not identified evidence that would merit changes to the guideline regarding atopy patch testing at this time. The recommendations 1.1.5 to 1.1.10 in the IgE-mediated food allergy section of the guideline clarify that tests should only be undertaken by healthcare professionals with the appropriate competencies to select, perform and interpret them (see recommendation 1.1.16). In circumstances where a practitioner does not have the relevant skills and competencies it would be necessary to adopt local arrangements for referral to available competent professionals. We acknowledge that local primary care and community services may vary and have a wide-range of

		In addition, children and young people with confirmed IgE-mediated cow's milk protein allergy are more likely to have an anaphylactic reaction (especially if they also have asthma). It is therefore safer that these children are managed in secondary care.' • confirmed IgE-mediated food allergy and concurrent asthma' This would now read more correctly in keeping with NICE CKS CMA as: ….consider referral to secondary or specialist care in any of the following circumstances. • **Suspected IgE-mediated food allergy, especially in presence of concurrent asthma** NICE have a unique place in catalysing improved medical practice within the UK. BSACI is confident that they would wish to continue to lead on and support the foundational need for the better diagnosis and management of all expressions of suspected food allergy in children and young people presenting in primary care and community settings. Therefore, it is imperative that this 2011 foundational and definitive NICE food allergy guideline is brought up to date by these further suggested editorial and factual corrections in-house NICE amendments. In so doing, it will now become compatible with the numerous further NICE and NICE accredited publications that have followed on from it. The above suggested amendments are not major – mostly addressing a better overall editorial presentation and up-dated terminology.Should such changes not be made, then CG116 will now simply be seen as becoming increasingly	arrangements with secondary care, but the guideline is not able to specify how those relationships are managed. The recommendation 1.1.17 states to consider referral to secondary or specialist care in certain circumstances including when the child has confirmed IgE-mediated food allergy and concurrent asthma. As mentioned above, arrangements for local tests should be in place and performed to confirm IgE-mediated food allergy. Referral to secondary care for tests is a separate issue, and it would be necessary to adopt local protocols for referral to available competent professionals.

		dated and we believe both key UK food allergy topic experts and stakeholders will no longer be able to continue to signpost to it as the definitive UK guideline on suspected food allergy in UK children and young people.	NICE is committed to keeping guidelines current. During this surveillance review no new evidence was identified which suggested NICE guideline CG116 should be updated.
Food Allergy Specialist Group of the British Dietetic Association	No response provided	Agree with proposal that a full update is not required at present. Suggest alongside the proposed editorial changes an addition to the section 1.1.18 Alternative diagnostic tools. To the following text: 'Do not use the following alternative diagnostic tests in the diagnosis of food allergy: • vega test • applied kinesiology • hair analysis' add: • Bioresonance testing • Bioelectric impedance measurement (BIM) • Supermarket, health food shop or chemist allergy testing kits • Home IgE test kits in the absence of an assessment by a qualified healthcare professional (test results have no meaning in the absence of interpretation by trained medical professional).	Thank you for your comments. We have not identified any evidence that would impact recommendations 1.1.18 or 1.1.19 at this time. The use of home test kits would be outside the scope of the current guideline.
Royal College of Nursing	No response provided	Nurses caring for people with food allergies have reviewed the proposal and have no comments to submit at this stage.	Thank you.
Royal College of Paediatrics and Child Health	No response provided	Royal College of Paediatrics and Child Health have reviewed the proposal and have no comments to submit at this stage.	Thank you.

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Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Coeliac UK	Yes	As noted above, NICE guideline NG20 should be cross referenced due to similarities in gastrointestinal symptoms.	Thank you for your comments.
Royal College of Pathologists	No	No comment provided	Thank you for your response.
Public Health England	No	No comment provided	Thank you for your response.
Allergy UK	Yes	There are a few studies published since CG116 was written, which look at preventative pathways such as LEAP and EAT study, also research evidence has now emerged that protecting the skin barrier is important and targeting eczema(getting that diagnosis early with prompt treatment of the impaired skin barrier essential) Assessment by Health Visitor and/or GP as we now know that infants can be sensitised to allergens through the impaired skin barrier	Thank you for your comments and these suggestions. The EAT and LEAP studies consider interventions for the prevention of food allergy. These interventions are beyond the scope of the current guideline. Studies on the protecting the skin barrier would also be outside of the scope of the current guideline, which focuses on assessment and diagnosis. Please note that there is a NICE guideline on Atopic eczema in under 12s: diagnosis and management (CG57).
Anaphylaxis Campaign	Yes	We would agree with experts that the guidance could include the management and treatment of food allergy in primary care and cross-references be made to guidelines that cover management of food allergies	Thank you for your comments. There are currently no new NICE guidelines or quality standards planned on the management and treatment of food allergy for any population. A list of proposed quality standards can be found at this link: guidance and advice list. As mentioned in our proposal for this consultation: NICE uses cross-references to external sources or guidelines sparingly, and rarely

			where the products are not NICE accredited. In addition, cross-references to external sources are difficult to manage when changes occurs. The 2 NICE accredited BSACI guidelines are considered partially relevant to NICE guideline CG116, but were primarily developed for secondary and tertiary care audiences and were broader in their scope as they covered management of food allergies. It is proposed that new cross-references to external guidelines are not included at this time.
British Society for Allergy & Clinical Immunology BSACI	No	No comment provided	Thank you for your response.
Food Allergy Specialist Group of the British Dietetic Association	No	No comment provided	Thank you for your response.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response
Coeliac UK	No	No comment provided	Thank you for your response.
Royal College of Pathologists	No	No comment provided	Thank you for your response.
Public Health England	No	No comment provided	Thank you for your response.
Allergy UK	No	No comment provided	Thank you for your response.

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Anaphylaxis Campaign	No	No comment provided	Thank you for your response.
British Society for Allergy & Clinical Immunology BSACI	No	No comment provided	Thank you for your response.
Food Allergy Specialist Group of the British Dietetic Association	No	No comment provided	Thank you for your response.

Do you agree with the proposal to make an editorial amendment to the text preceding Recommendation 1.1.5?

We propose to change the section headed 'Diagnosis' where it says: 'Food allergy can be classified into IgE-mediated and non-IgE-mediated allergy. IgE-mediated reactions are acute and frequently have a rapid onset. Non-IgE-mediated reactions are generally characterised by delayed and non-acute reactions'.

Reference to the term 'acute' and 'non-acute' in the context of food reactions will be replaced with 'immediate' to describe IgE-mediated reactions and 'delayed' for non-IgE-mediated. The revised text will state: 'Food allergy can be classified into IgE-mediated and non-IgE-mediated allergy. IgE-mediated reactions are frequently immediate and have a rapid onset. Non-IgE-mediated reactions are generally characterised by delayed reactions'.

Stakeholder	Overall response	Comments	NICE response
Coeliac UK	Yes	No comment provided	Thank you for your response.
Royal College of Pathologists	Yes	No comment provided	Thank you for your response.
Public Health England	No response provided	No comment provided	Thank you.

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Allergy UK	Yes	No comment provided	Thank you for your response.
Anaphylaxis Campaign	Yes	No comment provided	Thank you for your response.
British Society for Allergy & Clinical Immunology BSACI	No response provided		Thank you.
Food Allergy Specialist Group of the British Dietetic Association	Yes	Agree with this proposal	Thank you for your response.