NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE HEALTH AND SOCIAL CARE DIRECTORATE QUALITY STANDARD CONSULTATION SUMMARY REPORT

1 Quality standard title

Food allergy and anaphylaxis due to any cause

Date of Quality Standards Advisory Committee post-consultation meeting: 18 December 2015

2 Introduction

The draft quality standard for food allergy and anaphylaxis due to any cause was made available on the NICE website for a 4-week public consultation period between 5 October and 2 November 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 8 organisations, which included national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in the appendix.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the <u>NICE local</u> <u>practice collection</u> on the NICE website. Examples of using NICE quality standards can also be submitted.

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft placeholder statement 7: Do you know of any evidence-based guidance that could be used to develop this placeholder statement? If so, please provide details. If not, would new evidence-based guidance relating to the diagnosis of food allergy in adults have the potential to improve practice? If so, please provide details.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Several stakeholders welcomed the quality standard, commenting that it was much needed and highlighted the increasing incidence of food allergy and anaphylaxis.
- Primary care is often not geared towards dealing with allergies.
- Several stakeholders highlighted the need to improve competencies in dealing with allergy, and hoped that this quality standard would help with this. Several stakeholders mentioned how important education would be to implementing this quality standard. A stakeholder questioned how front line primary care staff will gain the competencies needed to deliver the statements.
- Stakeholders suggested that combining food allergy and anaphylaxis into a single quality standard would reduce impact.
- Anaphylaxis was suggested to be underrepresented and should have more than two statements.
- Stakeholders suggested that there was no mention of important causes of anaphylaxis (e.g. drugs, venom, food allergy in adults).
- Stakeholders expressed concern that venom allergy is not included in this quality standard, particularly as this is a major cause of adult anaphylactic reactions. In particular, there should be mention of venom immunotherapy which is not well known among GPs (despite a NICE Technology Appraisal on this subject) and is not available for all patients.
- Several stakeholders questioned why statements 1-4 are limited to children and young people and suggested the scope should be expanded to adults.
- The quality standard should include the fact that food allergy management needs specialist dietetic input.
- The quality standard should clearly specify expectations at primary, secondary and tertiary levels.

Consultation comments on data collection

- Good clinical history taking was suggested to be hard to measure as it can become a tick box exercise.
- The important thing to measure (for statement 1) is when an allergy goes undiagnosed because symptoms are not recognised – however it is very difficult to measure when this had occurred.
- There needs to be exemptions from offering a trial elimination and reintroduction of a suspected allergen (statement 3) for people who, for example, have severe reactions.
- Accurate coding of anaphylaxis in A&E and primary care will be needed to measure the statements concerning anaphylaxis.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Children and young people with suspected food allergy have an allergy-focused clinical history taken.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- This statement should also include adults.
- Concern was raised that primary care practitioners will not have time to take the clinical history as described in this statement (this would be more appropriate for a specialist). The use of a shorter allergy history was suggested.
- Stakeholders also commented that education would be needed on how to carry out an allergy-focussed clinical history and also on how to interpret what the likely mechanism of the allergic reaction is from this history.
- The statement needs to specify what commissioners should do. Many commissioners do not specifically commission for allergy (often assuming that other service providers can provide these services).
- The allergy focussed clinical history should include a growth assessment and also nutritional assessment. Co-factors (e.g. illness, alcohol, tiredness, exercise) that can affect reactiveness should also be recorded.
- The statement contains no mention of patient input or education regarding how to recognise the symptoms of food allergy.
- A stakeholder questioned how front line primary care staff would gain the competencies necessary to carry out an allergy-focussed clinical history.
- Are there any tools we could highlight to help carry out an allergy-focused clinical history?

5.2 Draft statement 2

Children and young people whose allergy-focused clinical history indicates an IgEmediated food allergy are offered a skin prick test or blood test for specific IgE antibodies to the suspected foods and likely co-allergens.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- The statement needs to make clear that tests are carried out and interpreted by a healthcare professional with appropriate competencies.
- Interpretation of allergy tests is difficult (as many people with positive tests will not in fact be allergic) and many healthcare practitioners are not able to make an accurate diagnosis.
- The statement should make it clear that results of tests should be interpreted only in light of an allergy-focussed clinical history. A stakeholder commented that 50% of those with a positive test are not allergic. However, this statement does not make the implications of interpreting tests without a clinical history clear. A stakeholder suggested specifying that interpretation of tests must include awareness that positive tests results may not indicate presence of an allergy.
- The term 'co-allergen' should be clarified as it will not be understood by all primary care practitioners.
- The statement should be clear on how such testing is accessed. Some primary care doctors will be unable to access blood tests for diagnosis of IgE-mediated allergy.
- A stakeholder questioned how front line primary care staff would gain the competencies necessary to perform these tests.

5.3 Draft statement 3

Children and young people whose allergy-focused clinical history suggests a non-IgE-mediated food allergy are offered a trial elimination and reintroduction of the suspected allergen.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- The statement should acknowledge that reintroducing problem foods to diet might be difficult for patients or carers, and that better support needs to be provided for this part of the process.
- Reference should be made to detailed food and symptom diaries (which are important for the diagnosis of non-IgE mediated food allergy)
- Trial elimination diets should be defined as being 4-6 weeks (rather than 2-6 weeks; taken from NICE CG116 recommendation 1.1.11) because 2 weeks is too short to establish non-IgE mediated food allergy in children
- There is a need for education for primary care professionals regarding non-IgE mediated food allergy. The statement also needs to clarify whether this should be done by primary care clinicians or dietitians.

5.4 Draft statement 4

Children and young people are referred to secondary or specialist allergy care if indicated by their allergy-focused clinical history or subsequent diagnostic testing.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Stakeholder suggested that the term 'indicated' needs clarifying. It is not specific enough and this statement can therefore be disregarded.
- There is a need to educate primary care professionals regarding who should be referred. There is also a need to ensure that services in secondary care where referrals are made to have the competencies to manage patients appropriately. A stakeholder commented that paediatric or dermatology departments who provide allergy services often do not have the training to provide appropriate care.
- People are less likely to attend services if they are a long way off. There may therefore be a need to drive improvement in local services.
- It was suggested to add severe feeding difficulties and nutritional deficiencies as indicators for referral to secondary/tertiary care.
- It will be difficult to measure this statement because the list of circumstances that a referral should occur under is broad.

5.5 Draft statement 5

People who have emergency treatment for suspected anaphylaxis due to any cause are referred to a specialist allergy service.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- It should be made clear that anaphylaxis is due to any cause, such as drugs latex or venom allergy. It was suggested that drug and venom allergy are overlooked in this quality standard.
- Measures for this statement should be focussed on referral from A&E. Moving the site of action of this statement further from the place where people with suspected anaphylaxis present will lead to cases being missed.

5.6 Draft statement 6

People who are prescribed an adrenaline auto-injector after emergency treatment for suspected anaphylaxis due to any cause are given training in how and when to use it.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- The statement should state that adrenaline auto-injectors (AAIs) are prescribed after emergency treatment for suspected anaphylaxis.
- The problem of retraining in AAI use was also raised. Retraining was suggested to be necessary at every opportunity (for example, at re-prescription) and does not currently occur.
- Should devices be given at A&E or later by a GP? Training and prescription on site of presentation would be ideal, but would require local negotiation and understanding. A potential problem would be if training occurs in one device and then another is prescribed. Pharmacists demonstrating use at the point of dispensing could help with this.

5.7 Draft statement 7 (placeholder)

Improvements in recognising symptoms of food allergy in adults will help to determine which diagnostic tests should be used and how the condition should be managed. Food allergy can be more complex in adults than in children and young people, and often involves multiple foods, allergic co-morbidities and also reactions to food that happen only in the presence of a co-factor (for example, with alcohol). Distinguishing food allergy from food intolerance and conditions such as irritable bowel syndrome in adults can be difficult; misdiagnosis results in inappropriate referrals to secondary care. Improved diagnosis of food allergy (both IgE- and non-IgE-mediated) in adults can greatly reduce healthcare burden, save NHS resources and improve quality of life.

Consultation comments

Stakeholders made the following comments in relation to draft statement 7:

- Several stakeholders highlighted that this is an important area and should be developed as soon as possible.
- A stakeholder commented that there is little guidance available in this area and that allergy services for adults can involve many different specialties. It is also important to look at possible multi organ/systemic symptoms from allergy – not just the immediately obvious acute reactions.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- It was suggested to add a statement concerning venom allergy: "Patients with venom allergy should be referred to a specialist in allergy for consideration for bee or wasp venom immunotherapy." Venom was highlighted as a major cause of anaphylactic reactions in adults and venom immunotherapy (despite being recommended in a NICE technology Appraisal) is not well known among GPs.
- The availability of a dietitian with training in allergy was highlighted as essential and lacking in this quality standard. Several stakeholders suggested a separate statement should cover this.
- A statement should also be included to specify that people should receive advice for nutritional issues (such as growth faltering, weight loss, vitamin and mineral deficiencies) that may occur as a result of an elimination diet.
- A statement should cover the provision of information and support for families affected by food allergy; high quality advice and support should be provided at the point of care after diagnosis.
- A statement regarding commissioning was suggested: "Commissioners should be aware of the allergy needs of the population they serve, understand what different allergy services can deliver and have a commissioning plan for anaphylaxis and food allergy". A stakeholder commented that commissioning of allergy services is poor and there is no incentive for primary care practitioners to improve their allergy knowledge.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments ¹
Gen	eral comments on the q		
	The Anaphylaxis Campaign	General	The Anaphylaxis Campaign welcomes these QS in the hope that it will improve competencies across all levels of health care including primary care which in some cases needs improving in order for patients to receive an appropriate care pathway.
	The Anaphylaxis Campaign	General	We feel however that this should have been produced as two separate quality standards, one for food allergy and one for anaphylaxis particularly as the food allergy QS applies to children and the anaphylaxis one covers adults as well. Anaphylaxis needs more than just the two statements.
	The Anaphylaxis Campaign	General	We are concerned that venom allergy is missing despite it being the cause of anaphylaxis is about 25% of adults. We also feel mention should be made of venom immunotherapy which is very effective but not well known by GPs and if there is no specialist centre local to the patient very little will be offered for this condition which can prove fatal.
	The Anaphylaxis Campaign	General	Due to lack of commissioning allergy services are patchy and often inadequate. These QS are an opportunity to highlight the importance of a good commissioning plan which will in turn lead to improvements in GP knowledge. QS 1 could be tightened to be more specific.
	British Society for Allergy and Clinical Immunology	General	There is an enormous burden of disease from both food allergy and separately anaphylaxis, poorly dealt with in the NHS and with wide variations in equality of care. Areas in the north and south west have poorly developed allergy services and consequently in such areas primary care generally is much less geared to dealing with allergy. Many sectors of health care are unable to meet the needs of these patients, so improved competencies are required. This document is therefore welcomed and much needed.
	British Society for Allergy and Clinical Immunology	General	We are concerned to see that two guidelines on food allergy and anaphylaxis have been combined into one QS. Each subject alone encompasses a major health need and the Quality Standards required are different. Putting both together weakens each. There is a strong argument to separate these. The food allergy QS apply only to children but anaphylaxis statements apply to adults as well but there is no mention

¹PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments ¹
			of important causes of anaphylaxis in adults eg drugs and venom. Food allergy in adults, an important cause of anaphylaxis accounting for ¼ to 1/3 rd of cases is also ignored. Anaphylaxis is thus under represented - yet there has been a substantial increase in the incidence over the last 2 decades, with repeated anaphylaxis (eg in up to 1 in 12 patients per year) and avoidable cost to the NHS and to patients if standards were improved. Severe, near fatal and fatal anaphylaxis occur yet there are only 2 statements on anaphylaxis. More attention should be given to this topic.
	Food Allergy Specialist Group of the British Dietetic Association	General (Page 1)	When reactions to foods are not classified as a food allergy these are referred to as a food intolerance in the draft. Should we be calling the reactions 'adverse reactions to foods' instead of 'food intolerance'?
	Food Allergy Specialist Group of the British Dietetic Association	General (Page 3- Domain 1, page 4 – Table 2, Domain 4)	Why only refer to infant mortality and not children mortality per say?
	Food Allergy Specialist Group of the British Dietetic Association	General	All of the food allergy QS only relates to children and young people - we acknowledge that there are limited guidelines, but in essence statement 1-4 are also applicable to adults. This is what should occur in management
	Food Allergy Specialist Group of the British Dietetic Association	General Page 6 – List of quality statements	Why are the quality statements paediatric focused only? With EAACI publication on allergy focused history in both paediatrics and adults these statements need to include also adults. Although data may be limited in adults, we consider that there there is sufficient information to warrant similar statements for adults. It would improve clinical care hugely and with the availability of QoL questionnaires and mortality data you can have measureable outcomes. See following publications that may help: <u>http://www.ncbi.nlm.nih.gov/pubmed/8521176</u> <u>http://www.ncbi.nlm.nih.gov/pubmed/7884702</u> http://www.ncbi.nlm.nih.gov/pubmed/15080800
	Food Allergy Specialist Group of the British Dietetic Association	General	The BDA considers that it would be reasonable to add that food allergy management needs specialist dietetic input. Where there is no local specialist dietetic services for allergy patients should be referred to their nearest specialist dietetic service. This is particularly lacking in adult food allergy. We propose that there are named specialist dietetic allergy adult services in the country where patients can be specifically referred as required when there is no local specialist dietetic allergy services.

ID	Stakeholder	Statement number	Comments ¹
	National Allergy Strategy Group	General	The NASG welcomes these QS in the hope that it will improve competencies across all levels of health care including primary care which in some cases needs improving in order for patients to receive an appropriate care pathway.
	National Allergy Strategy Group	General	We feel however that this should have been produced as two separate quality standards, one for food allergy and one for anaphylaxis particularly as the food allergy QS applies to children and the anaphylaxis one covers adults as well. Anaphylaxis needs more than just the two statements.
	National Allergy Strategy Group	General	We are concerned that venom allergy is missing despite it being the cause of anaphylaxis is about 25% of adults. We also feel mention should be made of venom immunotherapy which is very effective but not well known by GPs and if there is no specialist centre local to the patient very little will be offered for this condition which can prove fatal.
	National Allergy Strategy Group	General	Due to lack of commissioning allergy services are patchy and often inadequate. These QS are an opportunity to highlight the importance of a good commissioning plan which will in turn lead to improvements in GP knowledge. QS 1 could be tightened to be more specific.
	Nottingham Support Group for Carers of Children with Eczema	General	We congratulate the team for producing such clear and cogent standards.
	The Royal College of General Practitioners	General	A helpful document in a difficult area where "cure" may not be possible and a child/family have to make long term changes to life style, diet and also be always prepared for an acute and life threatening event. (PS)
	The Royal College of General Practitioners	General	The need to provide support, counselling, training and reassurance is vital if the family can be helped to cope and flourish. (PS)
	The Royal College of General Practitioners	General	Occasional "cure" by desensitisation may be possible. (PS)
	The Royal College of General Practitioners	General	The changing incidence, duration and prevalence, and the difference between rich and poor societies world-wide suggest that prevention may be possible. Presently this is secondary prevention by avoidance having proven allergy rather than by primary prevention. (PS)
	Royal College of Paediatrics and Child Health	General	There appears to be no differentiation between the expectations at primary, secondary or tertiary level. Should the standards not be different in these different settings?
	Royal College of Paediatrics and Child	General	There is no detail about the mechanism by which front line staff in primary care can be expected to gain the competencies to deliver these standards. Taking an allergy focussed history and interpreting allergy

ID	Stakeholder	Statement number	Comments ¹
	Health		tests requires training and experience and there is little facility currently for these. The danger is that in order to comply with the standard people will indeed interpret the allergy tests but without the competence to do so.
	Royal College of Paediatrics and Child Health	General (page 1)	Use of word "drug" in foods is confusing - ? use chemicals and give an example eg salicylate?
	Royal College of Paediatrics and Child Health	General (page 6)	Talks about education – this will be very important as education is needed to correctly determine what is meant / understood by the wording of the standards.
	Royal College of Physicians	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our experts in allergy medicine and would like to make the following comments based on the consultation questions:
			Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement?
			Question 2 If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?
			Question 3 Do you have an example from practice of implementing the NICE guidelines that underpin this quality standard? If so, please submit your example to the NICE local practice collection here. Examples of using NICE quality standards can also be submitted.
			Questions about the individual quality statements Question 4 For draft placeholder statement 7: Do you know of any evidence-based guidance that could be used to develop this placeholder statement? If so, please provide details. If not, would new evidence- based guidance relating to the diagnosis of food allergy in adults have the potential to improve practice? If so, please provide details.
	Royal College of Physicians	General	Our experts believe that the increasing incidence of food allergy and anaphylaxis seen in both primary and secondary care contributes to loss of quality of life and considerable anxiety in patients and carers. We welcome this QS which is much-needed and are hopeful that it fulfils the aims stated.
	Royal College of	General	Our experts expressed concerned that the attempted combining of the two guidelines on food allergy and
			Page 16 of 25

ID	Stakeholder	Statement number	Comments ¹
	Physicians		anaphylaxis risks a watering-down of each statement and should be reconsidered. For example the food allergy statement apply only to children but anaphylaxis statements apply to adults as well but there is no mention of important causes of anaphylaxis in adults, for example drugs and venom.
Con	sultation question 1		
	The Anaphylaxis Campaign	Consultation question 1	The importance of a dietitian with training is allergy is essential but is not highlighted in the document. There should be a separate QS on this topic.
	British Society for Allergy and Clinical Immunology	Consultation question 1	Availability of dieticians with training in allergy is important and essential for children. This aspect is not given sufficient prominence. This is mentioned in QS3 under commissioning. A separate QS on the need for access to dieticians in primary and specialist allergy care should be included.
	British Society for Allergy and Clinical Immunology	Consultation question 1	Commissioning for allergy services is poor and there is no incentive for primary care practitioners to improve their knowledge of allergy (which is generally minimal, as no training in clinical allergy is provided at most medical schools and allergy is not specified in the GP curriculum). Suggests adding a separate QS as follows: 'Commissioners should be aware of the allergy needs of the population they serve, understand what different allergy services can deliver and have a commissioning plan for anaphylaxis and food allergy. ' NHS England should be aware of the population needs for specialist commissioning and have systems in place to deliver quality specialist care. In general the statements on implications for commissioners are too general and should be made tighter.
	British Society for Allergy and Clinical Immunology	Consultation question 1	Venom anaphylaxis is serious and can be life threatening. It accounts for about 25% of anaphylaxis in adults. Despite the availability of a highly effective treatment (venom immunotherapy) the majority of GPs are unaware of this. Similarly patients. So in patients referred to a specialist, there are commonly long delays of many years; and of course larger numbers are never referred. This lack of awareness in GPs persists despite the NICE TA on venom immunotherapy, 2012. There is inequality of care as patients who do not live near a specialist allergy centre, have little chance of this treatment, because of lack of awareness of it. Fatal bee or wasp sting anaphylaxis occurs in people who have not been referred. Patients in large parts of the country are disadvantaged and a specific QS would go some way to redressing this. It would be important to make this treatment known by a QS to state: 'Patients with venom allergy should be referred to a specialist in allergy <i>for consideration for bee or wasp venom immunotherapy</i> .'
	National Allergy	Consultation	The importance of a dietitian with training is allergy is essential but is not highlighted in the document.
	Strategy Group Royal College of	question 1 Consultation	There should be a separate QS on this topic. Qu 1 – does look at key areas although perhaps input from a dietitian important in many cases too. Also
		Consultation	Qu'T – does look at key areas although perhaps input from a dietitian important in many cases too. Also

Paediatrics and Child Health Royal College of Paediatrics and Child Health Food Allergy Specialist Group of the British Dietetic Association Iltation question 2 Royal College of Paediatrics and Child Health	question 1Consultation question 1Consultation question 1Consultation question 2	 management of the allergic child in the community eg at school – but accept not really part of original guidance. There is no quality statement about provision of information and support for families affected by food allergy. Making the diagnosis is only the first step and if simple FA is to be managed effectively in primary care then high quality advice and support should be available at point of care. There is a quality statement missing on nutritional issues. For example: People with food allergies receive specific advice for nutritional issues that may arise as a result from the elimination diet, including growth faltering, weight loss, vitamin and mineral deficiencies Qu 2 – templates may help in history taking but it is easy to tick a box to say something is done without actually doing it properly so good / effective history taking not that easy to measure.
Paediatrics and Child Health Food Allergy Specialist Group of the British Dietetic Association Iltation question 2 Royal College of Paediatrics and Child	question 1 Consultation question 1 Consultation	 allergy. Making the diagnosis is only the first step and if simple FA is to be managed effectively in primary care then high quality advice and support should be available at point of care. There is a quality statement missing on nutritional issues. For example: People with food allergies receive specific advice for nutritional issues that may arise as a result from the elimination diet, including growth faltering, weight loss, vitamin and mineral deficiencies Qu 2 – templates may help in history taking but it is easy to tick a box to say something is done without
Group of the British Dietetic Association Itation question 2 Royal College of Paediatrics and Child	question 1 Consultation	specific advice for nutritional issues that may arise as a result from the elimination diet, including growth faltering, weight loss, vitamin and mineral deficiencies Qu 2 – templates may help in history taking but it is easy to tick a box to say something is done without
Royal College of Paediatrics and Child		
Paediatrics and Child		
		It is the non recognition and the unidentified allergy which is important but this is very difficult to measure. By improving education on symptoms though, this should indirectly improve. Recording of "offered a home challenge " in non ige to prove diagnosis will also need education and it needs to be accepted / appropriate to also " tick a box" to say home challenge not appropriate eg severe reactions but these should have been referred on to secondary care anyway. Need to be able to appropriately exclude this group. Are dietitians to have the competences to decide on the likely mechanism eg non ige or ige and advise on the type of testing er challenge or blood / spt? Accurate coding eg what is anaphylaxis and needs referral from a and e dept will be paramount. Need good communication from primary care to secondary care and in order to measure this, as well as good /accurate coding in primary care.
y statement 1	•	
The Anaphylaxis Campaign	Quality statement 1	We would expect to see adults included in this as it is not just children who have food allergies
British Society for Allergy and Clinical Immunology	Quality statement 1	The standards are focused only on children and yet should apply equally to adults. Food allergy affects more adults than children and is an important cause of anaphylaxis in adults. A full guideline on food allergy is needed and should be developed for adults as stated in QS 7. This would be important to address inequalities of care.
British Society for Allergy and Clinical Immunology	Quality statement 1	Commissioners. This statement needs to be strengthened with more specifics. A survey showed that many commissioners are unaware of allergy, do not specifically commission for allergy, or assume another service provider eg dermatology, respiratory or immunology can provide allergy services. On the whole this is not the case. Primary care will not have the time to take this history as given (this would be more Page 18 of 25
	The Anaphylaxis Campaign British Society for Allergy and Clinical mmunology British Society for Allergy and Clinical	The AnaphylaxisQuality statement 1Campaignstatement 1British Society for Allergy and Clinical mmunologyQuality statement 1British Society for Allergy and ClinicalQuality statement 1

ID	Stakeholder	Statement number	Comments ¹
			appropriate for the specialist) in a 10minute consultation, and perhaps a shorter version, a quick allergy history, could be advised, to initiate improvement of standards.
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 1	Statement 1 – would include "Children and young people with suspected food allergy have an allergy-focused clinical history taken, <i>including a growth assessment</i> ". This is often not done as part of the allergy focused history and is crucial in paediatrics. This is also an easy outcome measure.
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 1	(Page 9) Allergy focussed history and what this should include – would suggest adding nutritional assessment – weight/height as a basis.
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 1	(page 10) Need some mention of recording cofactors here (as briefly mentioned on page 28) that patients have specifically founds that can affect reactivity eg illness, menstruation, alcohol. Tiredness, exercise etc
	National Allergy Strategy Group	Quality statement 1	We would expect to see adults included in this as it is not just children who have food allergies
	Nottingham Support Group for Carers of Children with Eczema	Quality statement 1	What is the rationale to restricting this statement to children and young people? This quality standard is obviously not based solely on CG116 which deals with young people. Neither is there any discussion that indicates that an allergy-focussed clinical history will be significantly different between children, young people or adults. Many patients or carers suspect food has an impact on their atopy. Does this quality standard take into account and include numerically these widespread suspicions? It appears not as the supporting information directs that "Children and young people with signs and symptoms of food allergy (and their parents or carer if appropriate) are asked about their symptoms and lifestyle" (a passive consultation) and "healthcare professionals can recognise the signs and symptoms of food allergy in children and young people" and there is no mention of patient input or patient education regarding how to recognise the signs of food allergy.
	Royal College of Paediatrics and Child Health	Quality statement 1	Statement 1 – will need education to know what an allergy focussed history is
	Royal College of Paediatrics and Child Health	Quality statement 1	Statement 1 – education needed to interpret from the history what the mechanism of reaction is likely to be. The term coallergen is likely to be poorly understood in primary care
	Royal College of Physicians	Quality statement 1	The Quality Standards are focused only on children and yet should apply equally to adults. More adults than children suffer from food allergy and therefore we are hopeful that this inequality will soon be
			Page 19 of 25

ID	Stakeholder	Statement number	Comments ¹
			addressed by NICE and a full guideline on food allergy be developed for adults as stated in QS 7.
Quali	ity statement 2		
	The Anaphylaxis Campaign	Quality statement 2	We would like to see it made clear in the statement that the tests are to be undertaken by a health care professional with the appropriate competencies. We see this is noted in the wording further on but it is so important it needs to be made clear from the start
	The Anaphylaxis Campaign	Quality statement 2	Interpreting allergy tests is essential when making an accurate diagnosis and many HCPs are not competent to do this as 50% of those with positive tests will not be allergic. Although mention is made of interpretation it should be clarified that the implications are extremely important. An extra sentence could explain this.
	British Society for Allergy and Clinical Immunology	Quality statement 2	It would be important to clarify what is meant by a co-allergen. This could be a second allergen, or a cross reacting allergen. There is also the potential to confuse with the term 'co-factor', which is not usually a food. If this refers to cross –reacting allergens, some explanation of these, with example, is required and how to test for these. This will not be understood by primary care health care professionals. It may not always be a good idea to test for these, but will depend on the clinical circumstances. Testing for these without a history, can raise problems (see below – interpretation of allergy tests). Co-allergen is not a commonly used term.
	British Society for Allergy and Clinical Immunology	Quality statement 2	'Healthcare professionals should <i>interpret the results</i> of the tests in the light of the allergy-focused clinical history.' This is a critical point in that up to 50% of those with positive tests are not clinically allergic. But the statement does not make the implications clear. This must be conveyed as this is an area of practice where standards are poor and an excellent opportunity to improve standards. Currently a positive test is usually taken to equal allergy. There are a high proportion of false positive diagnoses. This is a significant source of diagnostic error. Suggest a supplementary statement to make this clear eg Interpretation of tests must include awareness that a positive test may indicate allergy (symptoms on exposure) or may indicate sensitisation (a state where there is a positive test for specific IgE, but no symptoms on exposure).
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 2	(Page 14) Quality statement for healthcare provider: would reinforce that only healthcare professionals with appropriate competencies should interpret the SPT or specific IgE results.
	National Allergy Strategy Group	Quality statement 2	We would like to see it made clear in the statement that the tests are to be undertaken by a health care professional with the appropriate competencies. We see this is noted in the wording further on but it is so important it needs to be made clear from the start
	National Allergy	Quality	Interpreting allergy tests is essential when making an accurate diagnosis and many HCPs are not

ID	Stakeholder	Statement number	Comments ¹
	Strategy Group	statement 2	competent to do this as 50% of those with positive tests will not be allergic. Although mention is made of interpretation it should be clarified that the implications are extremely important. An extra sentence could explain this.
	Nottingham Support Group for Carers of Children with Eczema	Quality statement 2	What is the rationale to restricting this statement to children and young people? This quality standard is obviously not based solely on CG116 which deals with young people. The crucial thing about offering skin prick tests or blood tests for non IgE-mediated food allergy for specific IgE antibodies to the suspected foods and likely co-allergens is that these tests are correctly interpreted (CG116, 1.1.6). This is supported in the data covering this statement, but it should be within the quality standard itself. If the IgE allergy suspicion centres around anaphylaxis having taken place – is there any point in doing a skin test?
	Royal College of Paediatrics and Child Health	Quality statement 2	There is no indication of who such tests should be accessed. This is likely to occur in secondary care. Some primary care doctors are unable to access blood tests for diagnosis of IgE mediated allergy. Although Skin prick testing is a specialised service requiring trained staff blood tests should be more easily accessed in primary care
	Royal College of Physicians	Quality statement 2	The term co-allergen may confuse some and may be read as cross-reacting foods or co-factor which is not usually a food. It appears as though this is intended to imply related and cross-reacting foods (nuts or seeds for example). Our experts noted that this should be clarified.
Qual	ity statement 3		
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 3	(Page 17) Need to include detailed food and symptom diaries as these are the main cornerstone of diagnosis; especially in non IgE mediated food allergy
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 3	(page 18) Trial of elimination diet – please amend to indicate 4-6 weeks, as 2 weeks are too short to establish improvement in non IgE mediated cohort in paediatrics. Refer to data: http://www.ncbi.nlm.nih.gov/pubmed/25963794
	Nottingham Support Group for Carers of Children with Eczema	Quality statement 3	What is the rationale to restricting this statement to children and young people? This quality standard is obviously not based solely on CG116 which deals with young people. Food elimination trial with appropriate information and healthcare professional support is great. But it should be acknowledged that the reintroduction of the problem foodstuff can be far less acceptable to the patient or carer. Whilst the reintroduction is considered essential by professionals to confirm the diagnosis, it is equally essential that those professionals give far better empathetic support for this stage of the trial.
	Royal College of	Quality	Statement 3 – again – many primary care professionals will be unaware of non ige mediated disease. Will

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ID	Stakeholder	Statement number	Comments ¹
	Paediatrics and Child Health	statement 3	need education on formula choice and input, possibly from pharmacists in ccgs regarding guidelines. Also is this considered to be a primary care clinician role or one which dietitans should be involved in – again need improved services and education for them.
Qual	ity statement 4		
	British Society for Allergy and Clinical Immunology	Quality statement 4	The term "indicated" is non-specific and does not convey enough information and the QS as stated can be disregarded. Suggest clarification – does it mean when there is difficulty with diagnosis or when the food allergy is severe or when guidance on avoidance or reintroduction is required? Otherwise 'indicated' is unhelpful to the non-expert and to most of primary care.
	British Society for Allergy and Clinical Immunology	Quality statement 4	Equality statement: part of this (providing off site or mobile clinics) would not be applicable to allergy.
	Food Allergy Specialist Group of the British Dietetic Association	Quality statement 4	(page 19) Indicators for referral to secondary and tertiary care – please add severe feeding difficulties and nutritional deficiencies as indicators for secondary/tertiary care
	Nottingham Support Group for Carers of Children with Eczema	Quality statement 4	What is the rationale to restricting this statement to children and young people? This quality standard is obviously not based solely on CG116 which deals with young people.
	Royal College of Paediatrics and Child Health	Quality statement 4	Statement 4 – says referred to – again may need to drive improvement in local services as if the referral is made but eg 2 hours away – the patient is less likely to attend. Needs to be accessible / appropriate. No point in referring if patient does not go /want to go.
	Royal College of Paediatrics and Child Health	Quality statement 4 (Page 19)	Again prim care professionals need education as to who is appropriate to refer. Those seeing them in secondary care need training to do so and there needs to be some liason with secondary care that those to whom referral is made have the competences to manage the referrals appropriately. Consistent advice needs to be given, At present there are NICE guidelines for community care and BSACI guidelines for allergy clinics / specialists but often those seen by paediatric departments or dermatology who may claim to be providing allergy services do not have the training nor any guidance to follow to know what is appropriate, perhaps they too need encouragement to look at both lots of guidelines. This may go back to training in other specialities being appropriate and also including allergy in the gp curriculum as currently no drivers for education in allergy. Anaphylaxis does interestingly come under dermatology in the curriculum.
	Royal College of Physicians	Quality statement 4	The term 'indicated' is non-specific and does not convey enough information and the QS as stated can be disregarded. Our experts believe clarification is needed to determine whether it means when there is

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			difficulty with diagnosis, when the food allergy is severe, or when guidance on avoidance or reintroduction is required.
Qual	lity statement 5		
	The Anaphylaxis Campaign	Quality statement 5	Add "to any cause eg drug, latex and venom allergy"
	British Society for Allergy and Clinical Immunology	Quality statement 5	Suggest thatto any cause eg drug and venom allergyis added – as these important causes are overlooked in all the QS. Practitioners often do not think of these causes when dealing with anaphylaxis.
	National Allergy Strategy Group	Quality statement 5	Add "to any cause e.g. drug, latex and venom allergy"
	Royal College of Paediatrics and Child Health	Quality statement 5 (page 23)	It would be great if the measure was made from recording of anaphylaxis or suspected anaphylaxis in a and e and they could be given permission to refer and the monitoring of who was referred should be checked there too as this is likely to be the best way of checking it is done. As before, variations in coding and filing without reading thoroughly will lead to missed "suspected anaphylaxis" if moved further from the place of presentation.
	Royal College of Physicians	Quality statement 5	Our experts suggest that drug and venom allergy is added 'to any cause' as these important causes are overlooked in all the QS.
Qual	lity statement 6	-	
	British Society for Allergy and Clinical Immunology	Quality statement 6	Suggest re-word to: After emergency treatment for suspected anaphylaxis due to any cause an adrenaline auto-injector should be prescribed. Training in the correct use of the adrenaline auto-injector should be given to ensure patients know when to use it and how to use it, in an emergency. For service providers, this means that they must have competencies in this training (often done completely in adequately eg read the leaflet). Demonstration is required with a trainer pen; then the patient must be asked to use the trainer. A further problem is retraining which would come at the point of referral to an allergist; then further retraining at every opportunity thereafter eg re-prescription, should be undertaken. This does not happen for most patients, who are therefore unable to use the AAI. Vast numbers are prescribed – many to no avail.
	Royal College of Paediatrics and Child Health	Quality statement 6 (Page 26)	As above – should devices be given from a & e or wait to see the gp. Training and prescription at site of presentation would be ideal but would need local negotiation and understanding of formularies across trusts. What can happen is be shown one device and prescribed a different one – need to allow for this, pharmacists showing how to use devices at the point of dispensing would also help.

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	Royal College of Physicians	Quality statement 6	Suggest re-word to: After emergency treatment for suspected anaphylaxis due to any cause an adrenaline auto-injector should be prescribed. Training in the correct use of the adrenaline auto-injector should be provided to ensure effective use in an emergency.
Qual	lity statement 7		
	The Anaphylaxis Campaign	Quality statement 7	This is extremely important and we are keen for it to be actioned as a matter of priority
	British Society for Allergy and Clinical Immunology	Quality statement 7	NICE should ensure that this is developed as a matter of urgency, because new evidence-based guidance relating to the diagnosis of food allergy in adults has the potential to improve practice. BSACI are developing a nut allergy guideline (NICE accredited) and the BSACI cow's milk and egg guidelines although focussed on children also apply to adults.
	National Allergy Strategy Group	Quality statement 7	This is extremely important and we are keen for it to be actioned as a matter of priority
	Nottingham Support Group for Carers of Children with Eczema	Quality statement 7	It is manifestly ridiculous to have at least four quality statements for children and young people (QS 1-4) and simply placeholder one for adults.
	Royal College of Paediatrics and Child Health	Quality statement 7	Statement 7 – desparate need for work in this area. Very under resourced. Little guidance. Patients often seen by multiplespecialties. Allergy services for adults need to involve respiratory, GI, dermatology, possibly ent as well as the specialist " allergy role often taken on by immunologists. They are not trained in / have knowledge of the adult gi disorders which could be allergy related and education needed for all associated specialists as allergy often goes unrecognised and poorly managed by the individual specialties.
	Royal College of Paediatrics and Child Health	Quality statement 7 (page 28)	Great need for adult services and guideline although what is very important is looking at the possible multi organ / systemic symptoms from allergy – not just the immediately obvious acute reactions. There is lots of use of nutritionalists, and non conventional approaches sought by patients and we have in primary care very little option in where to refer those who want a secondary care opinion and who have complex symptoms. We need to look not just at the obvious ige reactions but again there isn't always a local service dealing even with suspected anaphylaxis appropriately.
	Royal College of Physicians	Quality statement 7	NICE should ensure that this is developed as a matter of urgency.
No c	omments		
	Department of Health	I wish to conf	irm that the Department of Health has no substantive comments to make, regarding this consultation.

ID	Stakeholder	Statement	Comments ¹
		number	
	NHS England	Thank you for the opportunity to comment on the above quality standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.	
	Royal College of Nursing	The Royal College of Nursing have no comments to submit to inform on the above quality standards consultation at this time	

Registered stakeholders who submitted comments at consultation

- The Anaphylaxis Campaign
- British Society for Allergy and Clinical Immunology
- Food Allergy Specialist Group of the British Dietetic Association
- National Allergy Strategy Group
- Nottingham Support Group for Carers of Children with Eczema
- The Royal College of General Practitioners
- Royal College of Paediatrics and Child Health
- Royal College of Physicians