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Trust Guideline for the Management of

Children (under 16 years of age) requiring Food Challenges in Paediatric Allergy

A Clinical Guideline recommended for use

In:	Paediatrics
By:	All staff
For:	Children and young people requiring food challenges
Key words:	Allergy, food challenge, allergic reaction
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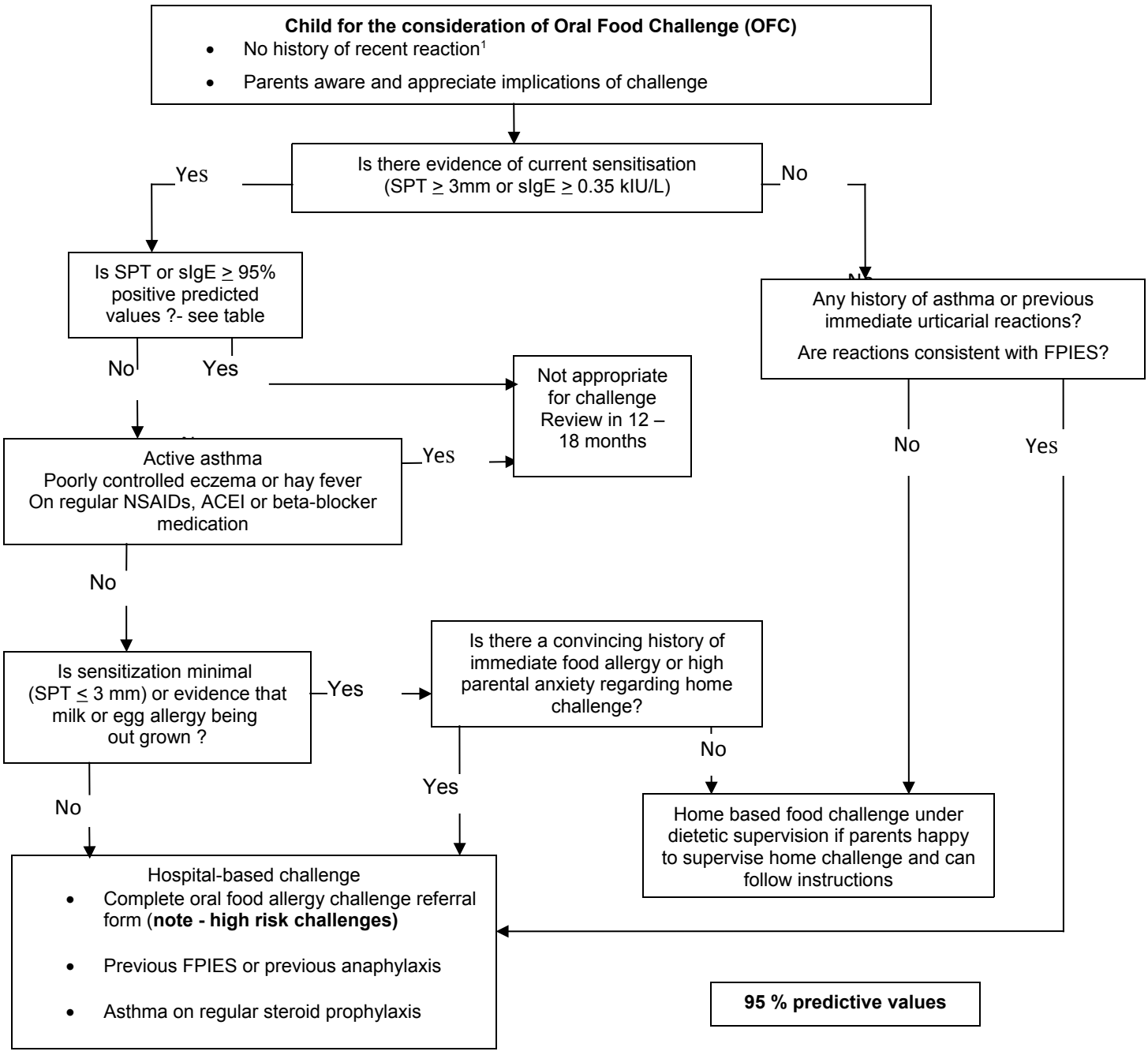
Trust *Policy / Guideline* for the Management of: *Condition or Procedure* in Adults and / or Children (title needed on every page)

Glossary	
IgE	Immunoglobulin E
OFC	Oral Food Challenge
SPT	Skin Prick Test
CAU	Children's Assessment Unit
CDW	Children's Day Ward
JLOPD	Jenny Lind Outpatients Department
FPIES	Food Protein Induced Enterocolitis Syndrome
NSAID	Non-Steroidal Anti Inflammatory Drug
ACE-I	Angiotensin Converting Enzyme Inhibitor
PPV	Positive Predictive Value

Children (under 16 years of age) requiring Food Challenges in Paediatric Allergy



[1] no reaction within the past 12 months (or 6 months if under 3 years of age)

95 % predictive values

Food	Age	Skin prick test wheal	Specific IgE (kIU/L)
Milk	< 2 years	6 mm	5
	> 2 years	8 mm	15
Egg	< 2 years	5 mm	2
	> 2 years	7 mm	7
Peanut	< 2 years	4 mm	14
	> 2 years	8 mm	14
Tree nuts	Any age		15
Fish	Any age		20

For soya and wheat, there are no 95 % predictive values.
The 73 and 74 % predictive values for soya and wheat are 30 kIU/L and 26 kIU/L, respectively.

Introduction

Food allergies are common and affect approximately 6 % of children in the United Kingdom based on history and oral food challenge (1). These reactions may be life threatening and consequently elicit high levels of parental anxiety (2). Some food allergies (i.e. milk and egg) have a good prognosis with between 40-90 % of children 'growing out' of these allergies between 1 and 5 years of age (3-5). Other food allergies (i.e. peanuts, tree nuts and sesame) have a poorer prognosis and tolerance to these foods is achieved in only the minority of children (6,7). Apart from a limited role for allergen desensitization, the mainstay of the management of food allergies is strict avoidance of antigen. Exclusion diets foster anxiety, are expensive and difficult for some families and may lead to nutritional deficiencies. It is important to establish in a timely fashion which children have outgrown their food allergies and therefore to perform food challenges when appropriate.

Food challenges

Food challenges establish whether a particular foodstuff is likely to elicit clinical reactivity in an individual patient. Oral food challenges (OFC) for children with proven or suspected food allergy are undertaken in a step-wise fashion in hospital to ensure that if severe reactions are elicited they can be quickly and effectively treated. In selected low risk cases, challenges may be undertaken at home. Food challenges aim to identify immediate food allergy signs and symptoms (Table 1), but must take into account symptoms of delayed allergy which may appear after discharge (generally eczema, gastrointestinal manifestations).

Table 1.

Clinical signs and symptoms suggestive of allergy according to time after ingestion

Early signs and symptoms (< 2 hours after ingestion)

Skin signs	Urticaria*, angioedema, flare of eczema
Respiratory symptoms	Cough, wheeze, hoarse voice, respiratory distress, rhinorrhoea, nasal congestion
Gastrointestinal	Vomiting, nausea, diarrhoea, abdominal pain
Cardiovascular	Pallor, sudden sleepiness, floppy, loss of consciousness, hypotension
Oropharyngeal	Palatal itching, throat itching, throat swelling

*Contact urticaria i.e. localised hives around the mouth where the foodstuff has inadvertently come into contact with the skin in the absence of other signs/symptoms of an allergic reaction is not an indication to stop the challenge.

Late signs and symptoms (> 2 hours after ingestion)

Skin	Eczema, angioedema
Gastrointestinal	Constipation, diarrhoea, abdominal pain
Respiratory	Respiratory distress, wheeze, cough, fall in lung function

Indications for food challenge

The decision to put a child forward for a food challenge is based on history and clinical testing and should be made by a Paediatric Consultant, Paediatric Dietitians (with consultant agreement) or Paediatric Dermatology Consultants.

Clinical testing comprises measurement of specific immunoglobulin E (IgE) circulating in blood and/or skin prick testing to food extracts or whole foods. While both these methods are useful in determining specific allergen sensitization they **do not predict clinical reactivity** in terms of thresholds for food tolerance or the severity of reaction.

Factors influencing the decision to undertake an oral food challenge

These may include:

a) Nutritional background of child
b) Wishes of child and family
c) Child's medical history
d) Trend of skin prick testing +/- specific IgE
e) Time since last reaction
f) Age of child
g) Age at which tolerance develops to particular food in question

Note: For milk in particular, infants should be assessed every 6 – 12 months from 12 months of age to assess the suitability for re-introduction based on SPT or specific IgE results. Tolerance to milk and egg develops in most children by age 5 years, whereas tolerance of peanuts, tree nuts, fish and shellfish is rarely achieved and OFC should be done only every 1-5 years. Tolerance is almost never acquired after 12 years of age.

Exclusion criteria

Exclusion criteria reduce unnecessary risks to the child and equivocal results.

a. Active chronic disease i.e. eczema, asthma BTS guideline stage 3 or above, allergic rhinitis,
b. Poorly controlled asthma,
c. Recent (< 12 months) anaphylactic reaction to a food,
d. Absence of consent,
e. Drugs which may modify or mask food-induced reactions (ACE inhibitors, beta-blockers, aspirin, NSAIDs),

f. Children with value of Skin Prick test (SPT) or specific IgE above 95% positive predictive values for a reaction **should not have OFC**. See table 2 for age and food specific values.

Table 2. **Thresholds (95 % PPV) for specific IgE and skin prick testing to commercial extracts according to age (adapted from Sampson et al, 2004; 8).**

Food	Age	Skin prick test wheal	Specific IgE
Milk	< 2 years	6 mm	5 kIU/L
	> 2 years	8 mm	15 kIU/L
Egg	< 2 years	5 mm	2 kIU/L
	> 2 years	7 mm	7 kIU/L
Peanut	< 2 years	4 mm	14 kIU/L
	> 2 years	8 mm	14 kIU/L
Tree nuts	Any age		15 kIU/L
Fish	Any age		20 kIU/L

For soya and wheat, there are no 95 % predictive values. The 73 and 74 % predictive values for soya and wheat are 30 kIU/L and 26 kIU/L, respectively.

Indications for food challenges in hospital:

1. Children who have a positive specific IgE levels or skin prick testing (skin prick test = 1-5 mm, specific IgE 0.35 - 2 kIU/L) should have OFC in hospital. This includes:
   a. Children with previous experience of an immediate clinical reaction where history now suggests tolerance or previously positive specific IgE or skin prick testing results within the above range.
   b. Children who have significantly positive test results to a particular food which has never been ingested and in whom there is a clinical suspicion of allergy to that food.
   c. In children with eczema and/or gastrointestinal symptoms **and asthma**, who have extended periods of elimination diets (>2 months) with reduction of symptoms but still have significantly elevated SPT or specific IgE.

2. In children who have negative specific IgE levels or SPT
   a. Children with a convincing clinical history of immediate food allergy to confirm the diagnosis or assess tolerance.
   b. Where the clinical history is not sufficiently convincing yet there is a high degree of child/parental anxiety regarding re-introduction of food despite negative specific IgE and/or SPT.

<u>Higher risk challenges</u>

A previous history of anaphylaxis to the food

Teenagers >12y

Moderate asthma on regular prophylaxis

Previous Food Protein Induced Enterocolitis Syndrome (FPIES)
Indications for food challenges at home

Children who have never had a reaction to ingestion of a particular food and have a negative specific IgE or SPT to it can have the food introduced at home.

Procedure for performing food challenges

A parent information leaflet is available to download here:
Food Challenges and Supervised Feeds Trustdocs Id: 14761

Requirements for performing food challenges

The oral food challenge is usually performed as a day case admission and requires the child to be monitored over a period of at least 4 hours, including 2 hours after the final dose has been given. If serious adverse reactions occur, such as anaphylaxis, then overnight admission is necessary. Children should be placed on open access for 48 hours after the food challenge and parents should be encouraged to take pictures/videos of any rashes, or to return for further evaluation if they have concerns.

a. OFC should take place in paediatric areas – CDW, JLOPD or Buxton ward
b. Appropriately trained medical and nursing staff are available to deal with severe reactions
c. Necessary level of safety, monitoring and evaluation is in place
d. Parental information has been given and Informed Consent obtained
e. The middle grade Doctor covering the clinical area is aware that a food challenge is taking place
f. Drugs and equipment for resuscitation are available
g. The guideline for managing adverse reactions is accessible
h. Appropriate medication has been prescribed

Informed Consent

All children undergoing food challenges should have written consent. Children and parents should be aware of the repercussions of a food challenge in terms of incorporating the foodstuff into the diet should the challenge be passed. The food should be eaten regularly (at least once a week) after a successful challenge starting 48 hours after passing the challenge assuming there have been no delayed reactions. In the event of a delayed reaction the parents should be advised to contact the dieticians and the food avoided in the child's diet.

Preparation of foods

Parent will be asked to bring in the food to be tested under guidance from the Paediatric Dietitians.

Patient factors

The children should be already avoiding the food they are to be challenged with (with the exception of baked egg if either cooked or raw egg is being tested in the OFC). They should be clinically stable, **off antihistamines for 5 days prior to OFC**. All other maintenance treatments for asthma, hayfever and eczema should be continued. OFC should not be undertaken if the child is taking neuroleptics, oral corticosteroids or immunosuppressants. The child should be fasted at least 2 hours before the food challenge. During the food challenge the child can eat and drink foods and fluids authorised by the nurse/dietician.

The insertion of an intravenous cannula should be considered on a case-by-case basis but is obligatory for testing children which have a history suggestive of FPIES (food protein-induced enterocolitis syndrome) or those who have previously had anaphylaxis in response to trace amounts of the allergen.

Food dosing

Detailed protocols for specific food challenges are available on Children's Day Ward. The food is given in incremental doses and the top dose should be the maximum daily dose of protein expected to be ingested. The children should initially have a lip dose of the food (this may be positive in children who subsequently pass the challenge and represent a local contact reaction). Doses are given in intervals of 20 minutes

Management of allergic reactions

A management protocol for the treatment of allergic reactions during oral food challenges is given as an appendix (Appendix 2). Reactions require prompt treatment particular when there are symptoms suggestive of anaphylaxis. Children with persistent asthma have the highest risk of an anaphylactic reaction and if there is concern over their asthma control pre-challenge then lung function testing with spirometry prior to challenge should be undertaken.

Drugs

1. All drug doses should be prescribed prior to the food challenge.
2. Adrenaline intramuscularly is the first-line drug in anaphylaxis and delayed administration is associated with a poor prognosis. Adrenaline is given via adrenaline autoinjector in a dose appropriate for age (0.01 mg/kg; maximum 0.5 mg). These doses can be repeated every 5 – 10 minutes if symptoms persist or worsen.
3. Antihistamines are indicated for the management of benign skin and GI manifestations of an allergic reaction including urticaria, angioedema, rhinoconjunctivitis and abdominal pain. They do not stop the more severe manifestations and should not delay the administration of the intramuscular adrenaline.
4. Short acting beta-agonists are given for respiratory symptoms such as wheeze, respiratory distress and cough. The dose is 10 puffs via spacer, or via nebuliser if there is severe respiratory distress requiring oxygen to be repeated as necessary every 10 – 20 mins. Unless wheeze and cough are transient and mild they should be given in conjunction with the adrenaline autoinjector.
5. Steroids are used to prevent late-onset manifestations and according to the severity of the reaction can either be given orally (1 – 2 mg/kg prednisolone; maximum 40 mg) or intravenously (4 mg/kg; maximum 100 mg hydrocortisone).

6. Oxygen 15L via face mask should be given if the child has respiratory distress or is in shock.
7. Fluid resuscitation (20mLs/kg bolus of 0.9% sodium chloride) should be given for cardiovascular shock. Children in shock should be laid flat with legs elevated unless sitting is more comfortable for their breathing.

Table 3. **Drugs to be written up with doses**

Drug	Dose	Route
Adrenaline		
< 10 kg	0.01 mL/kg of 1:1000	Intramuscular
10 – 30 kg	0.15 mg; Jext Junior	Intramuscular
30 – 50 kg	0.3 mg; Jext Adult	Intramuscular
50+ kg	0.5 mg	Intramuscular
Salbutamol		
< 5 years	2.5 mg	Nebulized
> 5 years	5 mg	Nebulized
Salbutamol	10 puffs	Via spacer device
Hydrocortisone	4 mg/kg to a maximum of 100 mg	Intravenously
Prednisolone	2 mg/kg to a maximum of 40 mg	Orally
Adrenaline	5 mL of 1:1000	Nebulised
0.9% sodium chloride	20 mL/kg aliquots	Intravenously
Cetirizine		
1 – 2 years	2.5 mg	Orally
2 – 6 years	5 mg	Orally
6 + years	10 mg	Orally
Chlorphenamine		
< 1 year	1 mg	Orally

Clinical audit standards

To ensure that this document is compliant with the above standards, the following monitoring processes will be undertaken:

a) A clinical audit of oral food challenges will be undertaken at the trust every 3 years to ensure children are not being put forward unnecessarily for challenges and that these challenges are conducted appropriately.

The audit results will be sent to Clinical Lead for paediatrics who will ensure that these are discussed at relevant governance meetings to review the results and make recommendations for further action.

Summary of development and consultation process undertaken before registration and dissemination

The authors listed above drafted this document on behalf of Dr Morris, Clinical Lead for Paediatrics) who has agreed the final content. During development it has been circulated for comment to Dr Grattan, Consultant Dermatologist, Dr Morris and Dr Briars, Consultant Paediatric Gastroenterologists, Dr Upton and Dr Kavanagh, Consultant Paediatric Respiratory Physicians, Dr Booth and Dr Dyke, Consultant Neonatologists and Paediatric Dieticians. The document was revised and recirculated following comments and presented to a multispecialty, multidisciplinary meeting following which further revisions were undertaken.This version has been endorsed by the Clinical Guidelines Assessment Panel.

Distribution list/ dissemination method

This guideline will be freely available on the intranet for all clinicians and a hard copy will be available in Children's Day Ward for the team carrying out the challenges.

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9. National Institute for Health and Care excellence. Clinical Guideline 134 Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode. December 2011.

Appendix 1

B

Patient Identifier Label

Food Challenge Protocol
(Page 1 of 2)

Nursing Assessment of child prior to commencing challenge		Tick
1)	Inform on call SpR (bleep – 0009) that food challenges are taking place	
2)	Ensure oxygen and suction are in working order at the child's bedside	
3)	Ensure all emergency drugs are prescribed	
4)	Check that the drug box is complete and that it is readily available (expiry dates of drugs should be checked at least once weekly and the stock replenished when used)	
5)	Record sats, pulse, BP, resp rate and auscultation of the chest. Do PEFR if child used to this.	
6)	Ensure that the child is fit for challenge (no intercurrent wheeze, cough, upper respiratory tract infection or other illness). The challenge should not take place within 2 weeks of any infection or acute exacerbation of asthma, eczema or rhinitis.	
7)	Ensure the child has stopped antihistamines for 5 days prior to challenge	
8)	Complete the consent form and ensure parents/child are fully aware of the procedure and risks involved.	

If the child has a latex allergy they should avoid all latex products during admission.

Low risk challenge: Proceed to challenge

High risk challenge: Child will require cannulation prior to challenge and ensure consultant on-call has been informed

The Food Challenge

The dietician will organise both the challenge foods and any carrier foods on the day of admission. The foods will be labelled and dated in the ward kitchen. Name and doses should be checked prior to administration.

In between doses perform a full set of observations and chest auscultation. Challenge in increasing doses at 20 minute intervals according to the specific food protocol.

- **Dose 1.** Lip challenge
  Place a drop of fluid or rub the food on the inner aspect of the child's lip and leave *in situ*
- **Doses 2 - 6.** Challenge in approximate 2 fold increasing amounts until the top dose attained. This should represent the cumulative maximum dose a child would be reasonably expected to eat at a single setting.

Patient Identifier Label

B

Preparation for Discharge

Successful completion of top dose	tick
Observation for 2 hours	
Discharge with 'Discharge Information Leaflet'	
Advise parents to watch for delayed reactions within the next 48 hours	
If no reaction, child should incorporate food into diet at least 3x week as advised by allergy team	
If reaction occurs advise parents to follow allergy management plan, to avoid food in diet and to contact CAU for advice.	

Reaction occurred	tick
Refer to protocol for managing allergic reactions.	
For mild reactions observe for a period of 2 hours following the last dose.	
For severe reactions, call for SpR, administer emergency medication according to enclosed algorithm and observe for a period of 4 – 24 hours according to severity of reaction	

Inconclusive challenge	tick
Occurs when either the top dose is not reached or it is uncertain whether a reaction occurred	
Advise family to continue avoiding food and consider re-booking	

All children	tick
Adrenaline auto-injector and inhaler technique checked if appropriate.	
The parents and child may need to see the dietician for dietary advice	
All paperwork and treatment plans should be given to the parents along with the discharge medication if required	
Add to CAU open access list for 48 hours post challenge and ensure parents have contact details	

Name……..

Signature……

Designation……

Date *(dd/mm/yyyy)*……

Appendix 2

Algorithm for the management of adverse events during food or drug challenges

Cardiorespiratory arrest

Treat as per APLS protocol

Evaluate
- Airway
- Breathing
- Circulation

If possible remove allergen
Call for help

Angioedema, urticaria or mild wheeze only

Oral antihistamine
If known asthmatic or mild wheeze give 10 puffs of inhaled salbutamol and oral prednisolone (2 mg/kg; max 40 mg)

If persistent vomiting or abdominal pain – consider i.m. adrenaline and i.v./i.m.

Respiratory distress, hypotension or collapse
Give i.m. adrenaline
High flow oxygen

Hypotension or collapse

Lie patient flat
Obtain intravenous/intraosseus access
0.9% sodium chloride 20 mL/kg
Give intravenous hydrocortisone
Give intravenous or intramuscular antihistamine
Give nebulised salbutamol if respiratory distress and nebulised adrenaline if stridor

If no response in 5 – 10 mins

Repeat i.m. adrenaline
Repeat fluid bolus (up to 40 mL/kg)
Consider iv adrenaline infusion, inotropes, iv magnesium and intubation
Admit to ITU/HDU

Stridor

Give nebulised adrenaline
Obtain intravenous access
Give intravenous hydrocortisone
Give intravenous antihistamine

If no response in 5 – 10 mins
Repeat nebulised adrenaline
Repeat i.m. adrenaline

Wheeze, respiratory distress, persistent cough

Give nebulised salbutamol
Obtain intravenous access
Give oral or intravenous corticosteroid
Give oral or intravenous antihistamine

If no response in 5 – 10 mins
Repeat nebulised salbutamol
Repeat i.m. adrenaline

Intramuscular Adrenaline

Dose is 0.01 mg/kg adrenaline (0.01 mL/kg of 1:1000)

or

< 10 kg	0.1 mg
10 kg – 25 kg	0.15 mg
25 kg – 50 kg	0.3 mg
Greater than 50 kg	0.5 mg

Antihistamine doses

Chlorphenamine (orally)	
1 month – 1 year	1 mg
Cetirizine (orally)	
1 year – 2 years	2.5 mg
2 – 6 years	5 mg
6 years +	10 mg
Chlorphenamine (intravenously)	
< 6 months	250 microgram/kg
6 months - 6 years	2.5 mg
6 – 12 years	5 mg
12 – 18 years	10 mg

Observations

Children with hypotension or collapse should be admitted to HDU and observed for a period of at least 24 hours

Children with respiratory signs or symptoms should be observed for a period of at least 6 – 8 hours in hospital prior to discharge

Refer as per NICE guideline CG134 (9)

Appendix 3

A

Children (under 16 years of age) requiring Food Challenges in Paediatric Allergy

Patient Identifier Label

Referral form for food challenges

Date of referral: ……

Referral made by: ……

Please tick challenge required: Oral food challenge ☐ Supervised Feed ☐

Food to be tested – multiple foods **MUST** be challenged separately:

Baked milk biscuit ☐ Baked milk muffin ☐ Fresh milk ☐

Baked egg ☐ Boiled egg ☐

Baked soya ☐ Fresh soya ☐

Peanut ☐ Almond ☐ Cashew ☐ Hazelnut ☐ as (eg biscuit, butter, nut)……..

Other ☐ Please specify……

Challenge Food supplied by: patient ☐ Hospital ☐

Results of Skin Prick Test /Specific IgE to food to be tested:

Food……. SPT……. Specific IgE……..

Food……. SPT……. Specific IgE…….

Any other food / aeroallergen allergies:
……..

Does this child have asthma? Yes ☐ No ☐

Any other co-morbidities? Yes ☐ No ☐

If yes please state:
……

Current medication:
……

Does this child require intravenous cannulation? (previous FPIES, anaphylaxis to trace exposure) Yes ☐ No ☐ **Please send to Dr Alex Brightwell, Consultant Paediatrician**

Appendix 4

Please click here for full version of the Discharge Information leaflet Discharge leaflet (Trustdocs id12262)

Discharge Information

Type of food challenge:

Your child has finished the food challenge. Once home, your child should avoid strenuous activities for the rest of the day so encourage quiet play and activities such as reading or watching TV. Some children can have a delayed reaction which can occur 6 to 48 hours after the challenge and strenuous exercise may increase the risk of this happening.

Signs of an allergic reaction include:

- Runny nose and/or eyes
- Generalised blotchy rash
- Hives (itchy raised spots like nettle rash) anywhere on the body
- Feeling sick or being sick
- Diarrhoea or constipation
- Tummy ache
- Wheezing and/or coughing
- Itching and/or swelling in the mouth
- Tightness in the throat
- Difficulty in breathing and/or swallowing
- Weakness and/or floppiness
- Flare of eczema

If a reaction does occur follow your child's allergy management plan

Mild to Moderate Reactions	Action
Swelling of lips, face, eyes Hives or itchy rash Itchy/tingling mouth or itchy throat Abdominal pain, vomiting	Stay with child Call for help if necessary Give antihistamine (cetirizine or chlorphenamine) Contact parent/carer

Watch for signs of a severe delayed allergic response

Severe Reactions	Action
Difficult or noisy breathing Persistent cough or wheeze Difficulty swallowing or tightness in throat Weakness or floppiness	**IF ANY ONE OF THESE SIGNS ARE PRESENT:** **Lie child flat.** If breathing is difficult allow to sit **Dial 999 for an ambulance stating ANAPHYLAXIS** **Stay with the child**

If any of these symptoms occur seek additional help from your GP, our Children's Admission Unit on 01603 289774, your local Accident and Emergency Department or the Emergency Services

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