NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Drug allergy: diagnosis and management

Date of Quality Standards Advisory Committee post-consultation meeting:
5 May 2015

2 Introduction

The draft quality standard for drug allergy: diagnosis and management was made available on the NICE website for a 4-week public consultation period between 12 March and 13 April 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 11 organisations, which included service providers, 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 appendices 1 and 2.

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. For each quality statement what do you think could be done to support improvement and help overcome barriers?

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

4. For each draft quality statement: Please can you confirm whether the draft quality statements apply to all populations or are there any statements for which we need to differentiate between adults and children? For example, in draft quality statement 3, does drug allergy need different management in adults and children and do we need to differentiate the services needed for the 2 groups? Please can you add as much detail on this differentiation issue as possible?

5. For draft quality statement 1: Please can you state which specific healthcare professionals would be documenting the drug allergy reaction by using a structured assessment guide for people with suspected drug allergy?

6. For draft quality statement 3: The NICE guideline on drug allergy (CG183) covered 4 drug classes, but to aid specificity and measurability please can you firstly state which 1 or 2 drug classes are the most important for quality improvement and explain why? Based on your answer, please can you also state the specific populations for whom you think may frequently need these drug classes in the future?

7. For draft developmental statement 4: Please can you confirm whether this reflects an important emerging area of service delivery or technology? If so, does it indicate outstanding performance, currently found only in a minority of providers, which will need specific, significant changes to be put in place, such as redesign of services or new equipment? Can you please provide any examples of current practice in this area?

4 General comments

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

- General support for the draft quality standard reflecting the key quality improvement areas of recognition, documentation and management of drug allergy.
- Concern raised that this quality standard will increase pressure on the already stretched allergy services with insufficient resources for NHS children drug allergy services highlighted.
- Request to state the importance of transitional co-ordination between the paediatric and adult services for complex or rare drug allergies especially from oncology drugs and anaesthetic agents which children infrequently present with.

- Query raised how this standard would directly lead to improvement in outcomes for exposure to unnecessary broad spectrum antibiotics or antimicrobial resistance rates.

Consultation comments on data collection

- Based on necessary systems and structures being in place, data collection should be possible.
- Concern raised on data collection being very difficult to collect in practice for draft quality statements 1, 2 and 3.
- This Quality Standard is pragmatic. It would be ideal to assess the use of structured templates for all potential allergic drug reactions some of which will be subsequently discounted. However, it is unlikely that an audit process could differentiate these from documented drug side-effects unless new diagnostic codes are introduced.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with suspected drug allergy have their reaction documented using a structured assessment guide based on timing of onset.

Consultation comments

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

- The detailed list of information makes sense prior to drug allergy evaluation. After clinical investigation this information can be simplified to enable decision making by future health professionals.
- Concern raised on the statement wording on ‘timing of onset’ as being insufficient. Although time of onset is important in drug reactions, it is not the sole or most important criterion. Suggestion to remove this wording as it is complete as is or alternatively change to ‘including time of onset’.

- Concern raised that the quality statement's focus appears to be new onset allergies whereas the quality statement is applicable to any person reporting a suspected drug allergy.
- One important aspect of taking a drug allergy history is routinely recording every time the patient is seen as patients can forget.
- Suggestion to include detailing the drug history of over the counter medicines as (Nonsteroidal anti-inflammatory drugs) NSAIDs are a common cause of drug allergy.
- Further clarification requested on the implementation of the structured assessment guide and whether this is only about immediate, rapidly evolving reactions or all reactions as listed in boxes 1-3. How can decisions be made if a patient has had a true allergic reaction that is life threatening or important other than the table (boxes 1-3).
- How this information is carried by patients i.e. generic 'alert' bracelets is important. A template for carrying information is required.
- NICE could consider systems to manage incorrect allergy diagnoses. The patient safety issue here is not just avoidance of allergen exposure but the administration of less effective and/or more toxic antibiotics to patients because of an inappropriate allergy diagnosis.
- Improve drug allergy education and awareness through:
  -Assessment and documentation as part of mandatory organisation training in organisations.
  -Greater emphasis on assessing and documenting suspected drug allergies based on timing of onset, as well as those who report pre-existing allergies.
  -Dissemination and promotion of NICE drug allergy algorithm (essential questions to ask) through local clinical guidelines.
  -Increase awareness of drug allergy referral processes and pathways via various routes i.e. intra-hospital, direct from GPs and other community referral pathways.
- 'De-labelling' the patient is needed. This is often difficult as each admission or healthcare contact gives another opportunity for a health professional to copy a previous erroneous note in the record therefore perpetuating the error. A robust process of documentation and change process is needed to tackle this.

- This statement's achievement is crucially dependent on doctors and other healthcare professionals having the necessary knowledge of the clinical features of allergic reactions.
- Suggestion to include community pharmacists and hospitals in the service provider audience descriptor.
- This statement applies to all populations.
- This statement will require some basic training, but at least all doctors and nurse practitioners should be responsible for documentation using a standardised structured questionnaire. A web-based resource could be made available to all NHS staff to help non-allergists to quantify the drug hypersensitivity reactions (DHR). It should then be up to the specialist service to update the information following their consultation.

Consultation question 5

Stakeholders made the following comments in relation to consultation question 5:

- The healthcare professional would be who diagnoses – commonly the GP but could be extended to nurses or pharmacists in some situations.
- The doctor responsible for the acute care following drug allergy or the first doctor to see the patient following an acute drug allergic reaction.

- **Consultation comments on data collection**
- Based on necessary systems and structures being in place, data collection should be possible.
- Concern raised on collecting number of repeat allergic drug reactions (including patient-reported episodes).
- Inclusion of dispensing drugs as an outcome measure.

5.2 Draft statement 2

People with drug allergy and their family members or carers are given advice to carry the information provided about their drug reaction at all times.

Consultation comments

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

- Standardised written information given to families of patients with a diagnosed drug allergy is vital and carrying this documentation at all times. Only through the carrying can we measure whether this standard is being properly applied.
- Empower patients to own and volunteer their drug allergy information as part of each healthcare interaction through:
  - Clear information and education about the difference between allergy and sensitivities or other intolerance.
  - Patient or family held information about allergies e.g. medic alert bracelets, phone upload the information onto their phone (photograph of discharge letter or clinic outcome) clinic outcome emailed and use of ‘Patient Passport’.
  -Information provided to patients regarding drug allergy status change on discharge or following drug allergy consultation.
- Informing the patient not just verbally but in copy letters is essential.
- Concern raised on giving advice to patients who may or may not follow it.
- This statement should be measured on advice being given to patients and family recorded in the hospital notes and GP letter (copied to the patient). The outcome would then be hard copy information handed to the patient which can also be emailed or phone uploaded by the patient.
- Children, parents, family members or carers should be advised to carry the relevant drug allergy information. When appropriate patients should carry the information but for those with cognitive disabilities, family members and carers will take responsibility.

- **Consultation comments on data collection**
- Concern raised on collecting data on ‘proportion of people with drug allergy whose family members or carers receive advice to carry information for the person about the drug reaction at all times’. This was felt to be very difficult in practice.
- Suggested process measure on ‘proportion of patients with documented allergy carrying information with denominator of patients known to have a documented allergy’.

5.3 Draft statement 3

People who have had a severe drug reaction are referred to a specialist drug allergy service for advice if they may need this class of drug in the future.

- **Consultation comments**

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

- Statement was supported as referral from a severe drug reaction is important.
- Concern raised that the majority of serious drug reactions are for patients given a drug to which they have previously had an adverse reaction. Agreement that inadequate recording of drug allergy information on patient notes, prescriptions and electronic records is a major problem.
- A severe drug reaction implies anaphylaxis. Suggestion to reword statement population to those with ‘likely Immunoglobulin E (IgE) related drug reaction’. The reaction severity is dependent on patient and drug factors
- Drugs or drug class avoidance is a surprisingly grey area. Accurate and proportionate information must be provided for GPs and pharmacists. Currently, IT system warnings are overly sensitive and highlight cross-reactivity with distant relatives. As a result there is risk of both over-avoidance and under-recognition of potential significant reactions.
- Request to strengthen the statement by stating all patients with a severe drug allergy should be assessed by a specialist service as the primary physician should not be left with the decision whether patient will need this drug class in the future.

- Definition of severe drug allergy requested.
- Concern raised that severity is one reason for referral and drug allergy and needing drugs in future is another reason. Therefore it was felt that this statement has incorrectly combined two recommendations and is misleading.
- Suggestion that this does not apply to General anaesthetic (GA) allergy as everyone who develops anaphylaxis during GA should be referred.
- There is usually no specialist drug allergy service for children in the NHS. Suggestion to change to specialist allergy service for children.
- Often patients use multiple medications simultaneously so it may not be clear which drug caused their reaction. Suggestion to reworded statement to include ‘or when it is not clear which drug has provoked their reaction’.
- In the immediate management of a severe drug reaction with cutaneous manifestations patients require urgent assessment by a dermatologist. In severe reactions especially in the early stages the diagnosis is not always clear.
- Concern raised that the lay audience descriptor which states ‘whether a reaction is due to drug allergy or not… they should investigate further’ is quite vague and should be more explicit in terms of the recommendations or include examples when further investigations may be required.
- Suggestion to list Drug Allergy Services within NICE guidance, including newly established services. Describe a clear referral pathway to all drug allergy clinics.
- Neonates may have to be differentiated from adults and children for this statement. Drug allergy is more common in adults compared to children. However, the diagnosis and management pathway applies to children and adults equally. As the population of children with drug allergy is much smaller compared to adults it might make sense for all children suspected of drug reactions to be reviewed by specialist drug allergy clinics. These children often grow up with the label of drug allergy unnecessarily.

- **Consultation question 6**

- Stakeholders made the following comments in relation to consultation question 6:

- Penicillin and beta-lactam based antibiotics as it is vital to avoid over and under diagnosis of penicillin allergy. There are significant usage limitations but occasional severe reactions.
- Antibiotics needed by those with a history of recurrent infection or those susceptible to recurrent infection.
- General anaesthetics-anaphylaxis – applicable for everyone
- Specific populations who are likely to frequently require penicillin-based antibiotics are patients with chronic chest disease, recurrent urinary infections, asplenia and immunodeficiency.
- Beta-Lactam antibiotics supported to be important for quality improvement due to a number of reasons:
  - Most frequently reported drug allergy
  - Relatively few side effects and generally well tolerated
  - Inexpensive and effective
  -Narrow spectrum (active against mostly gram positive bacteria) hence lower risk of developing resistance.
- In terms of specific populations:
  -All patients with suspected Beta-Lactam allergy aged 60 or over
  -All immunocompromised patients
  -All patients undergoing chemotherapy or planned for chemotherapy
  -All patients with underlying chronic medical condition (diabetes, asthma, cardiac problems)
  -All patients planned for complex surgery, which is likely to require antibiotics in the post op period (including orthopaedic surgery such as joint replacement)
  -Suspected drug reaction under general anaesthesia (GA)
- This is important for quality improvement because:
  -Patients likely to need to complete the surgery or require another surgery in the future
  -Multiple drugs given simultaneously hence impossible to establish the culprit without allergy testing
  -Anaphylaxis under GA is often related to drugs other than general anaesthetics and hence high likelihood patient will come across them even if no future surgery

needed

-Drugs used in GA can be cross reactive with other drugs used hence difficult to avoid unless allergy confirmed and cross reactivity established by Drug Allergy review (Vancomycin and Teicoplanin)

- In terms of specific populations, all patients who suffered anaphylaxis/drug reaction under anaesthesia.

- **Consultation comments on data collection**
- Concern raised on collecting data on the outcome of 'inappropriate avoidance of drugs' as being difficult to collect with EPR. Suggestion to make this a developmental statement instead.

5.3 Draft statement 4 (development)

Healthcare professionals document a person's drug allergy status in their electronic medical record using one code.

- **Consultation comments**

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

- This statement could lead to significant improvements in classifying, quantifying, auditing and simplifying recording. All of which will lead to better standards of management in future.
- Support for this statement in terms of patient safety. This could be a reliable systemic barrier to prevent avoidable harm, for instance, when patients receive medication they are clearly documented as being allergic too. With improved access to Electronic Health Record (EHR) this will enable this to become the norm. However all prescribing and dispensing IT systems will need interaction ability with this information for it to be useful. This is not as easy as might be hoped.
- No knowledge of any centres currently implementing this but strongly supported for the NHS to achieve this aim.

- Documentation should include copying information regarding drug allergies to patients or families of children.
- Concern raised that secondary care settings may struggle to achieve this. Significant time will also be required to achieve compliance with process change and audit needed.
- The importance of documentation consistency and accuracy cannot be over emphasised so the aim of having a single code is supported.
- Nationally agreed codes for electronic medical records and electronic prescribing systems will enable this.
- Request for ‘one code’ to be defined.
- Statement applies to all populations.

- **Consultation comments on data collection**
- This is already present in IT systems but management of codes is variable, with subsequent variations in sensitivity and accuracy. There should be a common gold standard.
- All GP practices are now electronic but only a minority of hospital services have electronic medical records such as Addenbrookes in Cambridge therefore this is not a major developmental area.
- Agreement that this reflects an important emerging area of service delivery and technology with the increasing use of electronic medical records, electronic prescribing systems and electronic transmissions of prescriptions.
  As different systems use different ‘IT languages’ [ICD10, ISD etc] and underpinning databases, this will require redesign and enforcement of the need to ensure necessary interface o rmapping of the terms used to minimise duplication or loss of information when transferred and communicated between care providers.

6 Suggestions for additional statements

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

- Good communication and clear documentation across all healthcare settings along the patient pathway through an integrated approach.
- Joint working with patients' carers and families to establish good communication especially when dealing with any communication difficulties such as language barriers, physical, sensory or learning disabilities.
- Patient awareness on drug avoidance in similar drug groups.
- Pharmacist involvement (including community pharmacists) in asking about drug allergy.
- Improvements to the current GP prescription form through standardisation and redesign to record drug avoidance in order to reduce drug allergy risk.
- Drug reaction reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) yellow card system or allergy status errors to the National Reporting and Learning System (NRLS).
- Inclusion of drug allergy in undergraduate and postgraduate curricula training in terms of clear documentation of drug allergy history.
- Drug allergy documentation should be carried at all times.
- A drug allergy or intolerance box on every prescription, notes, and registration information sheet. Big enough to be seen with a need to be duplicated in as many places as possible.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	University College London Hospital NHS Foundation Trust	General	Yes this draft quality standard accurately reflects the key areas for quality improvement
2	British Association of Dermatologists	General	This document raises issues of great concern that the majority of serious drug reactions are in patients given a drug to which they have previously had an adverse reaction. We agree that inadequate recording of drug allergy information on patient notes, prescriptions, electronic records et al. is a major problem. For simplicity a drug allergy/intolerance 'box' on every prescription, notes, and registration information sheets (where personal details are recorded at beginning of notes) would be an important advance. These 'drug allergy/intolerance boxes' need to be big enough to be seen and need to be duplicated in as many places as possible. The possibility of adding this to the FP10 prescription is an excellent idea [N/B. intolerance in addition to allergy, as some can be serious such as acute intermittent porphyria]. The prominence of the drug allergy/intolerance warning box is also important as these currently are small and easy to miss.
3	Royal College of Paediatrics and Child Health	General	Invariably, these standards will need to an increased pressure on the already stretched allergy services. From personal experience, there are insufficient resources for drug allergy services for children in the NHS. There may need to be some co-ordination in difficult/rare drug allergies between the paediatric and adult services, especially in areas like oncology drugs and anaesthetic agents which are not seen too frequently in children
4	British Association of Dermatologists	General	The quality standard does reflect the key areas for quality improvement but it is unclear why this standard would directly lead to improvement in outcomes relating to exposure to unnecessary broad spectrum antibiotics or antimicrobial resistance rates.
5	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation

[1]PLEASE 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]
Statement 1			
6	NHS England	1	· It is unclear what level of allergy should be recorded on the patient held information i.e. is it only immediate, rapidly evolving reactions or all reactions listed in boxes 1-3 · It would be helpful if there was a suggested format for the personal drug information that is suggested is carried by patients i.e. a template for such or mention of generic "alert" bracelets · There is no mention of how you actually decide if a patient has had a true allergic reaction that is life threatening or important, other than the table (boxes 1-3)
7	Royal College of Paediatrics and Child Health	1	The wording "…based on timing of onset" is insufficient. Though time of onset is important in drug hypersensitivity reactions (DHR), it is not the sole or even the most important criterion. This part should preferably be removed from the statement, as it is complete even without adding this part, or could be changed to "including time of onset". The vital aspect of this standard is the use of a standardised structured assessment.
8	NHS England	1	Service providers (GPs, A&E departments and secondary care) ensure that people with suspected drug allergy have their drug reaction documented by a healthcare professional using a structured assessment guide based on timing of onset. Could / should this include community pharmacies or how do community pharmacists deal with this?
9	University College London Hospital NHS Foundation Trust	1	The focus of the quality statement appears to be new onset allergies, whereas the quality statement is applicable to any person reporting a suspected drug allergy.
10	Royal College of Pathologists	1	Doctors and other healthcare professionals. Success will be crucially dependent on these individuals having the necessary knowledge of the clinical features of allergic reactions.
11	British Association of Dermatologists	1	One important aspect of taking a history of drug allergy is to keep taking it every time that you see the patient and need to prescribe. This is because patients forget which drugs they are taking and which they are allergic to. It is important to extend in detail the drug history to OTC medicines as NSAIDs are a common cause of drug allergy.
12	British Association of Dermatologists	1	Further clarification regarding how use of the structured assessment guide is implemented should be provided.
13	British Infection Association	1	BIA welcomes this QS. We would like NICE to consider, under the documentation section, the possibility of systems to manage the discovery of incorrect allergy diagnoses. Consultant Microbiologists in particular spend a very significant time of their working day answering requests for advice on patients who are reportedly allergic to various

ID	Stakeholder	Statement number	Comments[1]
			antibiotics. The patient safety issue here is not just the avoidance of exposure to an allergen but the administration of less efficacious and/or more toxic antibiotics to patients because of an inappropriate allergy diagnosis. Sometimes it becomes clear that the diagnosis is erroneous. We then need a way of "de-labelling" the patient. This is often difficult because each admission or contact with healthcare gives another opportunity for a health professional to copy a previous erroneous note in the records, thus perpetuating the error. Similar consideration should be given to those situations were allergen testing has been carried out and has proved negative or desensitisation has been successful. It will be all too easy for patients to become labelled again without a robust process of documentation and change process.
14	British Society for Allergy and Clinical Immunology	1	Audience descriptor: What about if the reaction occurred in hospital?
15	NHS England	1	Data source: Local data collection. b) Number of repeat allergic drug reactions (including patient-reported episodes) This may prove very difficult to collect in practice
16	NHS England	1	Outcome a) Medication errors (inappropriate prescribing or administration of drugs) Suggest should also include "dispensing" of drugs
Statement 2			
17	Royal College of Paediatrics and Child Health	2	First we need to standardise the written information given to families of patients with a diagnosed drug allergy. It should include a statement that this document should be carried at all times. This should be a standard by itself. Only then can we measure whether this standard is being properly applied.
18	University College London Hospital NHS Foundation Trust	2	The detailed list of information makes sense prior to Drug Allergy evaluation. Once patient has been investigated in Drug Allergy Clinic this information can be simplified to enable decision making by other health professionals in the future. For example: "This patient is allergic to Drug/Class of drugs and should avoid it for life". Or in a patient whose index reaction was to Amoxicillin, and who tested positive to Amoxicillin, but also tested positive to Cefuroxime/Ceftazidime/Ceftriaxone. "This patient is allergic to Amoxicillin/Penicillin and should avoid all Penicillins and Cephalosporins for life." Alternatively, (when Penicillin allergic patient has tested negative to specific Cephalosporin, eg Cefuroxime and then tolerated it through dose escalated challenge): "This patient is allergic to Penicillin and should avoid it for life. If Beta

ID	Stakeholder	Statement number	Comments[1]
			Lactam antibiotic is required, she/he can receive Cefuroxime safely."
19	British Association of Dermatologists	2	In view of the problem of information regarding drug allergies not being effectively recorded and shared, informing the patient not just verbally but in copy letters is essential.
20	University College London Hospital NHS Foundation Trust	2	Numerator – the number of people who receive advice to carry the information about their drug allergy reaction at all times. Patients who are given this advice may or may not follow it. For example not all patients who are advised to obtain a medic alert bracelet do so.
21	NHS England	2	Data source: Local data collection. c) Proportion of people with drug allergy whose family members or carers receive advice to carry information for the person about the drug reaction at all times. This may prove very difficult to collect in practice
22	NHS England	2	Outcome a) Self-management of drug allergy. Data source: Local data collection. Suggest this would be preferable to the process measures but without any detail about what to collect will be difficult to complete What about the proportion of patients with documented allergy carrying information with denominator of patients known to have a documented allergy?
Statement 3			
23	Royal College of Nursing	3	We welcome this statement. It is essential that if someone has severe drug reaction they are referred to specialist drug allergy service.
24	Royal College of Paediatrics and Child Health	3	Definition of severe drug allergy needs to be clarified upfront. There is usually no specialist drug allergy service for children in the NHS. Maybe the term should be changed to specialist allergy service for children. The standard should be stronger, all patients with a severe drug allergy should be assessed by a specialist service, the primary physician should not be left with the decision whether patient will need this class of drug in future.
25	University College London Hospital NHS Foundation Trust	3	Severe drug reaction implies anaphylaxis. We feel this should be changed to likely IgE related drug reaction. The severity of the reaction is dependent on patient and drug factors hence urticarial rash and itchy eyes with oral Amoxicillin can present as anaphylaxis when Amoxicillin is next administered intravenously.

ID	Stakeholder	Statement number	Comments[1]
			Equally, "…if they may need this class of drug in the future", often patients use multiple medication at the same time, it may not be clear which drug provoked their reaction, hence we feel the above statement should include "or when it is not clear which drug has provoked their reaction."
26	Royal College of Pathologists	3	Penicillin and beta-lactam based antibiotics – it is vital to avoid the twin traps of over diagnosis and under diagnosis of penicillin allergy because of the well-documented adverse healthcare and economic consequences of incorrect diagnosis. Approximately 20% of hospitalised patients carry a label of penicillin allergy but yet only 1-10% of this group will have objective evidence of IgE-mediated allergy on testing (Mirakian et al BSACI guideline – management of allergy to penicillins and other beta-lactams. Clin Exp Allergy 2015; 45: 300-327) Examples of patient groups who are likely to frequently require penicillin-based antibiotics : patients with chronic chest disease, recurrent urinary infections, asplenia, immunodeficiency
27	British Association of Dermatologists	3	In the immediate management of a severe drug reaction with cutaneous manifestations, it should be advised that patients require urgent assessment by a dermatologist. In severe reactions the diagnosis is not always clear, especially in the early stages. There are differential diagnoses such as pustular psoriasis vs AGEP, TEN vs scalded skin syndrome, etc. Dermatologists should give advice on the immediate skin management. How widely available are specialist drug allergy services? Referring to an allergist for subsequent diagnostic tests is of very limited value as there are no reliable diagnostic tests, especially for TEN/SJS. The diagnosis is often made on clinical grounds and histology – lymphocyte transformation tests, etc. remain experimental. Patch testing (again, something within dermatologists' expertise, has a limited role with some drugs and some rashes).
28	British Society for Allergy and Clinical Immunology	3	Severe is one reason for referral and just drug allergy and needing drug in future is another reason. this statement has incorrectly combined two of the recommendations and thus become misleading.
29	British Society for Allergy and Clinical Immunology	3	This does not apply to General anaesthetic (GA) allergy as everyone who develops anaphylaxis during GA should be referred
30	University College London Hospital NHS Foundation Trust	3	The statement "whether a reaction is due to drug allergy or not… they should investigate further" is a little vague and should be more explicit in terms of any recommendations or examples to illustrate when further investigations may be required.
31	NHS England	3	Outcome d) Inappropriate avoidance of drugs. Data source: Local data collection. May prove difficult to collect in practice without EPR. Suggest make a developmental standard only.

ID	Stakeholder	Statement number	Comments[1]
Statement 4			
33	University College London Hospital NHS Foundation Trust	4	The term 'one code' needs to be defined. Does this mean a single coding framework, or a single code to define patients with any known allergies, or a single code for each medicine patients may be allergic to, or a single code for each reaction type…?
34	Royal College of Physicians	4	The RCP is grateful for the opportunity to respond to the NICE Quality Standard consultation. One key recommendation is that documentation (including where necessary documentation 'No known drug allergy') should be improved / mandatory, with all GP referrals, hospital records / documentation implementing this. This would include copying information regarding drug allergies to patients / families (eg child cases). Our experts wish to flag that secondary care settings are likely to fall short of this standard. Significant time will be required to achieve compliance - process change and audit will be needed.
35	Royal College of Pathologists	4	Importance of consistency and accuracy in documentation cannot be over-emphasized. Hence, the aim of having a single code to document drug allergy in a patient's electronic medical record makes eminent sense. I'm unaware of any centres that have implemented this but would strongly support any moves by the NHS to achieve this aim.
36	British Society for Allergy and Clinical Immunology	4	Not sure what the one code refers to?
37	Royal College of Nursing	4	We welcome this statement. We consider that it will improve patient safety if healthcare professionals were to document a person's allergy status in their electronic medical record using one code.
38	The Royal College of General Practitioners	Consultation Question 1	Yes – these are the most important areas identified by CG183. Reanalysis of past suspected drug allergy (which may be incorrectly diagnosed) is also very important but not covered by the guideline and the quality standard.
39	Royal College of Pathologists	Consultation Question 2	Agree draft standard does reflect key areas for quality improvement in the recognition, documentation and management of drug allergy. Assuming that the necessary systems and structures are in place, it should be possible to collect data for the proposed quality measures.
40	The Royal College of General Practitioners	Consultation Question 2	Yes – this is pragmatic. It would be ideal to assess the use of structured templates for all potential allergic drug reactions, some of which will be subsequently discounted. However, it is unlikely that an audit process could differentiate these from documented drug side-effects unless new diagnostic codes are introduced.
41	University College London Hospital NHS Foundation Trust	Consultation Question 2	Yes if the systems and structures were available, it would be possible to collect the data for the proposed quality measures

ID	Stakeholder	Statement number	Comments[1]
42	Royal College of Pathologists	Consultation Question 3	Achieving success in all quality statements is critically dependent on getting the NHS to have a clear and consistent method of accurately documenting drug allergy. Inclusion of drug allergy in undergraduate and postgraduate curricula is an important first step in ensuring that doctors are able to elicit and document a clear history of drug allergy. A direct consequence of a poor history is the burden of inappropriate or inadequate referrals to specialist drug allergy clinics which impedes the prompt investigation of patients with genuine allergy.
43	The Royal College of General Practitioners	Consultation Question 3	'Which drugs or drug classes to avoid' – this is a surprisingly grey area. Accurate and proportionate information must be provided for GPs and pharmacists. Currently, IT system warnings are overly sensitive and highlight cross-reactivity with distant relatives, and as a result there is a danger of both over-avoidance and under-recognition of potential significant reactions.
44	University College London Hospital NHS Foundation Trust	Consultation Question 3	**Statement 1.** Improve Drug allergy education and awareness through: -Drug Allergy (assessment and documentation) as part of mandatory organisation training in organisations. -Greater emphasis on assessing and documenting suspected drug allergies based on timing of onset, as well as those who report pre-existing allergies e.g. drug allergy taught in the final year of medical, nursing and pharmacy schools as part of therapeutics and preparation for practice teaching and examination. -Dissemination and promotion of NICE drug allergy algorithm (essential questions to ask) through local clinical guidelines. -Increase awareness of drug allergy referral processes and pathways via various routes i.e. intra-hospital, direct from GPs and other community referral pathways. **Statement 2.** Empower patients to own and volunteer their drug allergy information as part of each healthcare interaction through: - Clear information and education about the difference between allergy and sensitivities or other intolerance. - Patient/ family held information about allergies e.g. medic alert bracelets, upload the information onto their phone (photograph of discharge letter/clinic outcome), clinic outcome emailed to the patient, use of "Patient Passport". -Information provided to patients regarding any changes to their drug allergy status on discharge or following drug allergy consultation. **Statement 3.** List Drug Allergy Services within the NICE guidelines, including newly established services. Describe a

ID	Stakeholder	Statement number	Comments[1]
			clear referral pathway to all Drug Allergy Clinics. **Statement 4**. Nationally agreed codes for electronic medical records and electronic prescribing systems to enable this.
45	University College London Hospital NHS Foundation Trust	Consultation Question 4	Statement 1 – applies to all populations Statement 2 - In case of children, parents, family members or carers should be advised to carry the relevant Drug Allergy related information. In case of competent adults it will be patients who should carry the information. In case of adults lacking capacity, family members and carers will take this responsibility. Statement 3 - Neonates may have to be differentiated from adults and children. Drug allergy is more common in adults compared to children. However, the diagnosis and management pathway applies to children and adults equally. As the population of children with drug allergy is much smaller compared to adults it might make sense for all children suspected of drug reactions to be reviewed by specialist Drug Allergy Clinics. These children often grow up with the label of drug allergy unnecessarily. Statement 4 – applies to all populations.
46	Royal College of Paediatrics and Child Health	Consultation Question 5	This will need some basic training, but at least all doctors (and nurse practitioners) should be responsible for documentation using standardised structured questionnaire. If a web-based resource could be made available to all NHS staff, it would help non-allergists to quantify the drug hypersensitivity reactions (DHR). The resource could include short articles about the types of DHR/adverse drug reactions (ADR), with plenty of pictures. It should then be up to the specialist service to update the information following their consultation.
47	The Royal College of General Practitioners	Consultation Question 5	The person who diagnoses – commonly the GP but could be extended role nurses or pharmacists in some situations.
48	University College London Hospital NHS Foundation Trust	Consultation Question 5	Anaesthetists when the reaction is related to general anaesthesia. A&E clinicians (including nurse practitioners) when the reaction occurs as a result of treatment administered in A&E or when the patient presents to emergency services with drug reaction. Medical and Surgical Clinicians when drug reaction occurs as a result of medical or surgical treatment in hospital. Primary care doctors, nurse practitioners and practice pharmacists when patients present with a drug reaction resulting from prescribed or over the counter treatment. Any prescribers, including non-medical prescribers, involved in reviewing suspected drug reaction. Any healthcare professional involved in conducting medicines reconciliation for patients with known drug allergies

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			e.g. pharmacists or other trained healthcare professionals.
49	British Society for Allergy and Clinical Immunology	Consultation Question 5	Yes apply to all
50	The Royal College of General Practitioners	Consultation Question 6	Antibiotics – as overdiagnosis, greatest limitations on use, but occasional severe reactions.
51	British Society for Allergy and Clinical Immunology	Consultation Question 6	Doctor responsible for the acute care of the patient following DA or the first doctor seen by the patient following an acute drug allergic reaction.
52	University College London Hospital NHS Foundation Trust	Consultation Question 6	Beta-Lactam antibiotics Important for quality improvement because: - Most frequently prescribed antibiotics. - Most frequently reported drug allergy - Relatively few side effects and generally well tolerated - Inexpensive and effective -Narrow spectrum (active against mostly gram positive bacteria) hence lower risk of developing resistance Specific populations: -All patients with suspected Beta-Lactam allergy aged 60 or over -All immunocompromised patients -All patients undergoing chemotherapy or planned for chemotherapy -All patients with underlying chronic medical condition (diabetes, asthma, cardiac problems) -All patients planned for complex surgery, which is likely to require antibiotics in the post op period (including orthopaedic surgery such as joint replacement) -Suspected drug reaction under general anaesthesia (GA) Important for quality improvement because: -Patient likely to need to complete the surgery or require another surgery in the future -Multiple drugs given simultaneously hence impossible to establish the culprit without allergy testing -Anaphylaxis under GA is often related to drugs other than general anaesthetics and hence high likelihood patient will come across them even if no future surgery needed -Drugs used in GA can be cross reactive with other drugs used hence difficult to avoid unless allergy confirmed and

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			cross reactivity established by Drug Allergy review (Vancomycin and Teicoplanin) -Specific populations: All patients who suffered anaphylaxis/drug reaction under anaesthesia
53	Royal College of Paediatrics and Child Health	Consultation Question 6	In children, the 2 commonest drug classes are Antibiotics (eg. AminoPenicillins) and NSAIDs.
54	NHS England	Consultation Question 7	From a patient safety point of view this issue is critical as "documenting a person's drug allergy status in their electronic medical record using one code" is a reliable systemic barrier to prevent avoidable harm. (i.e. patients receiving medication they are clearly documented as being allergic too) As EHR becomes quickly more readily available this will allow this to become the norm. However all the IT systems for prescribing and dispensing will need to be able to interact with this information for it to be useful and this is not as easy as might be hoped.
55	The Royal College of General Practitioners	Consultation Question 7	This is already present in IT systems – but management of codes is variable, with subsequent variations in sensitivity and accuracy. There should be a common (gold) standard.
56	British Society for Allergy and Clinical Immunology	Consultation Question 7	Antibiotics needed by those with a history of recurrent infection or those susceptible to recurrent infection GA anaphylaxis – everyone
57	British Society for Allergy and Clinical Immunology	Consultation Question 7	All GP practices are now electronic but only a minority of hosp services have electronic med records - such as Addenbrookes in Cambridge therefore this is not a major developmental area.
58	University College London Hospital NHS Foundation Trust	Consultation Question 7	We agree that Statement 4 reflects an important emerging area of service delivery and technology, with the increasing use of electronic medical records, electronic prescribing systems and electronic transmissions of prescriptions. As different systems use different "IT languages" [ICD10, ISD etc] and underpinning databases, this will require redesign and enforcement of the need to ensure necessary interface/ mapping of the terms used to minimise duplication or loss of information when transferred and communicated between care providers.
59	Royal College of Paediatrics and Child Health	Consultation Question 7	It would lead to significant improvements in classifying/quantifying/auditing and simplifying recording, all of which will lead to better standards of management in future.
60	British Association of Dermatologists	Additional Quality	The importance of an integrated approach with good communication at all times amongst those involved in the patient pathway is essential. Clear documentation of a person's drug allergy status in their medical record, on

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		Statement	prescriptions and in correspondence is essential. Patients should be made aware of the need to avoid drugs in similar groups.
61	British Society for Allergy and Clinical Immunology	Additional Quality Statement	Prescriptions issued in all healthcare settings are standardised and redesigned to record which drugs to avoid in order to reduce drug allergy risk.
62	British Society for Allergy and Clinical Immunology	Additional Quality Statements	There is no information on 1. communicating drug allergy information between different healthcare professionals 2. involvement of pharmacists in asking about drug allergy 3. improving the current GP prescription form 4. including drug allergy information in all healthcare communications
63	Royal College of Nursing	Additional Quality Statement	The draft quality standard appear to be comprehensive. We agree that there needs to be good communication between the healthcare professionals and all the patients regardless of their age. It is important to work with patients' carers and families establishing good communication channels particularly dealing with any communication difficulties such as language barriers, physical, sensory or learning disabilities.

Registered stakeholders who submitted comments at consultation

- British Association for Dermatologists
- British Infection Association
- British Society for Allergy & Clinical Immunology
- Department of Health
- NHS England
- Public Health England
- Royal College of GPs
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Physicians
- UCLH NHS Foundation Trust