NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

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Quality standards and indicators

Briefing paper

Quality standard topic: Drug allergy: diagnosis and management in adults, children and young people

Output: Prioritised quality improvement areas for development.

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1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for drug allergy: diagnosis and management in adults, children and young people. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development source referenced in this briefing paper is:

Drug allergy: diagnosis and management of drug allergy in adults, children and young people NICE clinical guideline 183 (2014).

2 Overview

2.1 Focus of quality standard

This quality standard will cover the diagnosis and management of drug allergy in adults, young people and children. It will not cover treatment of the acute phase including anaphylaxis, because this will be covered by a separate quality standard.

2.2 Definition

All drugs have the potential to cause side effects, also known as 'adverse drug reactions', but not all of these are allergic in nature. Other reactions are idiosyncratic, pseudo-allergic or caused by drug intolerance. The British Society for Allergy and Clinical Immunology (BSACI) defines drug allergy as an adverse drug reaction with an established immunological mechanism. The mechanism at presentation may not be apparent from the clinical history and it cannot always be established whether a drug reaction is allergic or non-allergic without investigation. Therefore, NICE clinical

guideline 183 (2014) has defined drug allergy as any reaction caused by a drug with clinical features compatible with an immunological mechanism.

2.3 Incidence and prevalence

Between 1996 to 2000, Hospital Episode Statistics (HES) reported that drug allergies and adverse drug reactions accounted for approximately 62,000 annual hospital admissions in England. Also, between 1998 and 2005, it was reported that these reactions are increasing with serious adverse drug reactions rising 2.6-fold. Importantly, up to 15% of inpatients have their hospital stay prolonged as a result of an adverse drug reaction.

2.4 Management

Diagnosing drug allergy can be challenging and there is considerable variation both in how drug allergy is managed and in access to specialist drug allergy services. This can lead to under diagnosis, misdiagnosis and self-diagnosis. This variation may be caused by insufficient awareness of available services or by a lack of local provision of drug allergy centres. Some people are never offered referral to specialist services and instead stay in primary care while others have their drug allergy managed in other disciplines. Therefore, only a small proportion of people are treated in specialist allergy centres.

See appendices 1 and 5 for the associated care pathway and algorithms from NICE clinical guideline 183.

2.5 National Outcome Frameworks

Tables 1–2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS Outcomes Framework 2015–16

Domain	Overarching indicators and improvement areas
2 Enhancing quality of life for people with long-term conditions	***Overarching indicator*** 2 Health-related quality of life for people with long-term conditions (ASCOF 1A**) ***Improvement areas*** **Ensuring people feel supported to manage their condition** 2.1 Proportion of people feeling supported to manage their condition**
4 Ensuring that people have a positive experience of care	***Overarching indicator*** 4a Patient experience of primary care i GP services 4b Patient experience of hospital care ***Improvement areas*** **Improving people's experience of outpatient care** 4.1 Patient experience of outpatient services **Improving access to primary care services** 4.4 Access to i GP services
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	***Overarching indicators*** 5a Patient safety incidents reported 5b Safety incidents involving severe harm or death 5c Hospital deaths attributable to problems in care ***Improvement areas*** **Reducing the incidence of avoidable harm** 5.4 Incidence of medication errors causing serious harm
Alignment across the health and social care system ** Indicator complementary with Adult Social Care Outcomes Framework (ASCOF)	

Table 2 Public health outcomes framework for England, 2013–2016

Domain	Objective and indicator
4 Healthcare public health and preventing premature mortality	***Objective*** Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities ***Indicator*** 4.3 Mortality rate from causes considered preventable** (NHSOF 1a)
Alignment across the health and social care system **Complementary to indicators in the NHS Outcomes Framework (NHSOF)	

3 Summary of suggestions

3.1 Responses

In total 11 stakeholders responded to the 2-week engagement exercise 03/11/2014-17/11/2014. Three stakeholders responded as ‘no comment’.

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

NHS England’s patient safety division submitted a full patient safety report for this topic, which is presented alongside this document which are summarised in this paper and can be found in full in appendix 4.

Full details of all the suggestions provided are given in appendix 6 for information.

Table 3 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
Assessment • Understanding of drug allergy signs and symptoms	SCM, NHS CCG, RCPath
Documenting and sharing information with other healthcare professionals • Recording drug allergy status • Documenting new suspected drug allergic reactions • Maintaining and sharing drug allergy information	SCM, NHS CCG
Providing information and support to patients • Providing information and support to patients	SCM
Non-specialist management and referral to specialist services • Non-steroidal anti-inflammatory drugs (including selective cyclooxygenase 2 inhibitors) • Beta-lactam antibiotics • General anaesthesia	SCM, BSACI
Additional areas • Lack of in vitro (serum specific IgE and cellular) testing • Drug allergy reaction difference between adults and children • Pharmacogenomics • Junior doctors' prescribing training • Allergy listing on prescriptions • Improved diagnostic tests for delayed type drug allergy reactions • Designing systems for documenting drug allergy • Oral antibiotic challenge for diagnosing antibiotic allergy in children	SCM, BSACI, NHS CCG

BSACI, The British Society for Allergy and Clinical Immunology
NHS CCG, NHS Durham Dales, Sedgefield and Easington CCG
RCPath, Royal College of Pathologists
RCPCH, Royal College of Paediatrics and Child Health
SCM, Specialist Committee Member

4 Suggested improvement areas

4.1 Assessment

4.1.1 Summary of suggestions

Understanding of drug allergy signs and symptoms

A stakeholder highlighted that as there is limited availability of specialist allergy services, most diagnoses will continue to be made in primary care by non-experts so improved record keeping of symptoms, signs and other relevant factors at the time of drug allergy diagnosis in primary care is essential.

Stakeholders reported a current lack of clinical understanding and poor prognosis at the time of presentation of a drug allergy reaction including signs and symptoms. This can lead to confusion when healthcare professionals document a new drug allergic reaction, recommend safe alternative drugs and warn people of which drugs to avoid in future.

A stakeholder identified the need for education on allergy types, presentations and timings. In line with this, a number of stakeholders supported the assessment boxes 1-3 in recommendation 1.1.1 (please see appendix 1) and the algorithm (please see appendix 5) in Drug allergy (2014) NICE guideline CG183 as a beneficial guide on when to suspect drug allergy with clear advice on how this should be done with timings for optimal effect. The algorithm was also supported to increase diagnosis accuracy thereby addressing over-diagnosis, inappropriate withholding of treatment and reducing hospital length of stay. A stakeholder suggested that this algorithm should be made widely available and published in the British National Formulary (BNF) to allow clinicians to differentiate between drug intolerance and drug allergy.

Another stakeholder highlighted that prompt assessment at hospital admission or for patients with a history of possible penicillin allergy is important in order to confirm or refute a penicillin allergy diagnosis and thus ensure optimal antibiotic choice.

4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Understanding of drug allergy signs and symptoms	**Assessment** NICE CG183 Recommendations 1.1.1 (KPI) and 1.1.2

Assessment

NICE CG183 – Recommendation 1.1.1 (key priority for implementation)

When assessing a person presenting with possible drug allergy, take a history and undertake a clinical examination. Use the following boxes (please see appendix 1) as a guide when deciding whether to suspect drug allergy.

NICE CG183 – Recommendation 1.1.2

Be aware that the reaction is more likely to be caused by drug allergy if it occurred during or after use of the drug and:

- the drug is known to cause that type of reaction **or**
- the person has previously had a similar reaction to that drug or drug class.

4.1.3 Current UK practice

The NICE costing analysis for clinical guideline 183 reported that in 2012-13, approximately 500,000 people in England were admitted to NHS hospitals with a recorded drug allergy in their hospital episode.[1],[2]

Also, the 2005- 2013 NHS England's analysis of patient safety incidents (please see appendix 4) reported by the National Reporting and Learning System (NRLS) identified 18,079 incidents involving drug allergy. These included 6 deaths, 19 'severe harms', 4980 'other harms' and 13,071 'near-misses' reported. It was reported that the majority of these incidents involved a drug that was prescribed, dispensed or administered to a patient with a previously known allergy to that drug or drug class.

[1] NICE costing report for clinical guideline 183 (2014)
[2] Hospital Episode Statistics, Admitted Patient Care, England- 2012-13 (2013) The Health and Social Care Information Centre.

4.2 Documenting and sharing information with other healthcare professionals

4.2.1 Summary of suggestions

Recording drug allergy status

Stakeholders highlighted the issue of diagnostic ‘labelling’ of drug allergy with the most common being penicillin allergy labelling. Another stakeholder reported that the current approach to drug allergy recording lacks consistency. Recording drug allergy status was highlighted by a stakeholder as important, in particular, documenting any known drug allergy when a drug is being dispensed and stating ‘none known’ allergy status to ensure that full information is recorded.

Documenting new suspected drug allergic reactions

A stakeholder highlighted that in order to improve the quality of initial clinical documentation following an allergic drug reaction, a structured approach should be followed to aid communication in relation to the reaction’s nature and severity and also to reduce the likelihood of accidental re-administration.

Maintaining and sharing drug allergy information

A stakeholder highlighted the need for standardising clinical documentation including GP referral letters, hospital discharge letters, prescriptions, administration records and electronic patient records to enable accurate record keeping and improve information sharing. Prescription standardisation was also supported to enable drug allergy information to be recorded as standard in a specific area of the prescription form.

In general, clear documentation and record keeping was highlighted by a stakeholder to promote better use of drug allergy status information separate from adverse drug reactions. Classification was also highlighted as key to inform prescribing healthcare professionals when there are only a few drug treatment options.

In addition, a stakeholder also noted that when a drug is deemed important to the patient and the referral is indicated in line with Drug allergy (2014) NICE guideline CG183 it is vital that the specialist service has access to the relevant decision making findings from the original problem. Sharing this information is key.

Another stakeholder also supported increasing the resources available to prescribers to positively reduce the likelihood of drug allergy errors and enable an immediate redesign of the prescription form FP10 to include a drug allergy box. This would also aid communication of drug allergy details between prescribers and pharmacists.

4.2.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

Table 5 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Recording drug allergy status	**Recording drug allergy status** NICE CG183 Recommendations 1.2.1 and 1.2.2
Documenting new suspected drug allergic reactions	**Documenting new suspected drug allergic reactions** NICE CG183 Recommendation 1.2.3 (KPI)
Maintaining and sharing drug allergy information	**Maintaining and sharing drug allergy information** NICE CG183 Recommendations 1.2.4 (KPI), 1.2.5, 1.2.6 (KPI) and 1.2.7

Recording drug allergy status

NICE CG183 Recommendation 1.2.1

Document people's drug allergy status in their medical records using 1 of the following:

- 'drug allergy'
- 'none known'
- 'unable to ascertain' (document it as soon as the information is available).

NICE CG183 Recommendation 1.2.2

If drug allergy status has been documented, record all of the following at a minimum:

- the drug name
- the signs, symptoms and severity of the reaction (see recommendation 1.1.1)
- the date when the reaction occurred.

Documenting new suspected drug allergic reactions

NICE CG183 Recommendation 1.2.3 (key priority for implementation)

When a person presents with suspected drug allergy, document their reaction in a structured approach that includes:

- the generic and proprietary name of the drug or drugs suspected to have caused the reaction, including the strength and formulation
- a description of the reaction (see recommendation 1.1.1)
- the indication for the drug being taken (if there is no clinical diagnosis, describe the illness)
- the date and time of the reaction
- the number of doses taken or number of days on the drug before onset of the reaction
- the route of administration
- which drugs or drug classes to avoid in future.

Maintaining and sharing drug allergy information

NICE CG183 Recommendation 1.2.4 (key priority for implementation)

Prescriptions (paper or electronic) issued in any healthcare setting should be standardised and redesigned to record information on which drugs or drug classes to avoid to reduce the risk of drug allergy.

NICE CG183 Recommendation 1.2.5

Ensure that drug allergy status is documented separately from adverse drug reactions and that it is clearly visible to all healthcare professionals who are prescribing drugs.

NICE CG183 Recommendation 1.2.6 (key priority for implementation)

Check a person's drug allergy status and confirm it with them (or their family members or carers as appropriate) before prescribing, dispensing or administering any drug (see also recommendation 1.3.4). Update the person's medical records or inform their GP if there is a change in drug allergy status.

NICE CG183 Recommendation 1.2.7

Ensure that information about drug allergy status is updated and included in all:

- GP referral letters
- hospital discharge letters.

4.2.3 Current UK practice

The GDG for clinical guideline 183 reported that approximately 500,000 people annually admitted to NHS hospitals have a diagnostic 'label' of drug allergy, with the most common being penicillin allergy. About 10% of the general population claim to have a penicillin allergy; this has often been a result of a skin rash that occurred during a course of penicillin in childhood. It was however reported that fewer than 10% of people who think they are allergic to penicillin are truly allergic. Therefore, penicillin allergy could potentially be excluded in 9% of the population.

Stakeholders identified a number of studies highlighting people with a label of penicillin allergy are more likely to be treated with broad-spectrum antibiotics.[3],[4] These studies reported that use of such antibiotics in people with an unsubstantiated label of penicillin allergy may harmfully lead to antibiotic resistance and, in some cases, ineffective treatment with a 30% increased rate of clinical complications, such as Clostridium difficile leading to increased hospital stay.[5]

[3] The incidence of antimicrobial allergies in hospitalized patients: implications regarding prescribing patterns and emerging bacterial resistance. (Lee at al, 2000) Archives of Internal Medicine.
[4] Role of environmental contamination as a risk factor for acquisition of vancomycin-resistant enterococci in patients treated in a medical intensive care unit (Martinez et al, 2003) Archives of Internal Medicine.
[5] Healthcare use and serious infection prevalence associated with penicillin 'allergy' in hospitalised patients: A cohort study (Macy et al, 2014) Journal of Allergy Clinical Immunology.

Also a 2013 pilot study[6] on a sample of five London acute hospital NHS trusts implemented standardised charts for two months to try to eliminate prescribing errors and monitor adverse drug reactions more effectively. Overall, there was positive feedback regarding the charts. Staff were however unsure whether it improved the safety of prescribing, dispensing and administering medicines.

Also, the 2005-2013 NHS England analysis of patient safety incidents (please see appendix 4) reported to the National Reporting and Learning System (NRLS) identified 18,079 incidents involving drug allergy. These included 6 deaths, 19 'severe harms', 4980 'other harms' and 13,071 'near-misses' reported. It was reported that the majority of these incidents involved a drug that was prescribed, dispensed or administered to a patient with a previously known allergy to that drug or drug class.

A 2007 clinical audit study[7] also concluded that a combination of clinical audit and continual pharmacist review of prescription charts can improve the quality of prescriptions at a Mental Health Unit.

A 2002 study[8] also reviewed the quality of 834 electronic medical records of patients receiving 167 physicians (117 internists and 50 paediatricians). It was reported overall low completion rates of drug allergy records with approximately 62% for internists and approximately 50% for paediatricians.

[6] Standard prescription chart improves allergy records (Jani, 2013) Pharmaceutical Journal online.
[7] Improving prescription quality in an inpatient mental health unit: three cycles of clinical audit (2007) Ved et al, The psychiatric bulletin
[8] Quality and correlates of medical record documentation in the ambulatory care setting. (2002) Soto et al, BMC Health Service Research

4.3 Providing information and support to patients

4.3.1 Summary of suggestions

Stakeholders highlighted that advice provision to patients is currently poor with one stakeholder reporting that there is often confusion for patients following a suspected drug allergic reaction with several questions unanswered such as:

1) If a drug was responsible for the symptoms at all?
2) Which drug caused the reaction especially if the person was taking multiple drugs at the time?
3) If it would be safe to take the same or related drug again?
4) Can the drug and related drugs be safely avoided without harming the patient?
5) Will this be a lifelong allergy?
6) If the drug is required in future – is there a way of confirming or excluding drug allergy?

Another stakeholder raised that patients are often not provided with complete information on the drug which they are allergic to, the possibility of this drug being present in other medications and the need to carry this information with them at all times. It was also highlighted that when the patient is diagnosed with an allergy they are also not often provided with relevant patient support information in line with recommendations in patient experience in adult NHS services (NICE clinical guideline 138). This was highlighted as crucial to minimise patients' fear, enhance communication and enable the patient to self-manage.

4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

Table 6 Specific area for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Providing information and support to patients	**Providing information and support to patients** NICE CG183 Recommendations 1.3.1 (KPI), 1.3.2 and 1.3.4 NICE CG138 Patient experience in adult NHS services
Providing information and support to people who have had specialist drug allergy investigations	**Providing information and support to people who have had specialist drug allergy investigations** NICE CG183 Recommendations 1.3.5 (KPI) and 1.3.6

Providing information and support to patients

NICE CG183 Recommendation 1.3.1 (key priority for implementation)

Discuss the person's suspected drug allergy with them (and their family members or carers as appropriate) and provide structured written information (see recommendation 1.2.3). Record who provided the information and when.

NICE CG183 Recommendation 1.3.2

Provide information in line with the recommendations in Patient experience in adult NHS services (NICE clinical guideline 138).

NICE CG183 Recommendation 1.3.4

Advise people (and their family members or carers as appropriate) to carry information they are given about their drug allergy at all times and to share this whenever they visit a healthcare professional or are prescribed, dispensed or are about to be administered a drug.

Providing information and support to people who have had specialist drug allergy investigations

NICE CG183 Recommendation 1.3.5 (key priority for implementation)

Allergy specialists should give the following written information to people who

have undergone specialist drug allergy investigation:

- the diagnosis – whether they had an allergic or non-allergic reaction
- the drug name and a description of their reaction (see recommendation 1.1.1)
- the investigations used to confirm or exclude the diagnosis
- drugs or drug classes to avoid in future
- any safe alternative drugs that may be used.

NICE CG183 Recommendation 1.3.6

Explain to people in whom allergy to a drug or drug class has been excluded

by specialist investigation that they can now take this drug or drug class safely

and ensure that their medical records are updated.

4.3.3 Current UK practice

No published studies on current practice data were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

The 2009 Care Quality Commission National Report[9] on patients managing medicines after hospital discharge reported a need for improved patient communication to ensure that they understand their medicines and how to take them. It was also highlighted that Acute trusts and GPs need to ensure that they provide better patient information in regards to their prescriptions, and spend more time discussing with patients about their experience of medication regimens. Significant variation in the resources available across GP practices and the community to support patients to take their medicine was also reported.

[9] Managing patients' medicines after discharge. (2009) Care Quality Commission

4.4 Non-specialist management and referral to specialist services

4.4.1 Summary of suggestions

A stakeholder highlighted the importance of improving allergy knowledge in primary care as currently some GPs lack an understanding of drug allergy and when to refer. It was also highlighted that there is a significant lack of specialists offering the type of service patients with drug allergy require. It was suggested that specific patients with a severe drug allergy or those for which the culprit drug avoidance has a high impact on quality of life for instance, should be referred for specialist investigation in line with NICE clinical guideline 183.

In addition, a stakeholder highlighted that specialist referral and/or advice is particularly key for all patients who would specifically benefit from taking a drug to which they have suffered a previous suspected allergic reaction and when this reaction occurred during treatment such as a non-selective non-steroidal anti-inflammatory drug (NSAID), a beta-lactam antibiotic, general anaesthesia or local anaesthetics.

Non-steroidal anti-inflammatory drugs (including selective cyclooxygenase 2 inhibitors)

A stakeholder raised that there is considerable uncertainty in regards to the provision of an anti-inflammatory drug for people with a suspected allergy to a non-selective non-steroidal anti-inflammatory drug (NSAID). It was reported that NSAID drug reactions are common so there is need for improved predictors as to whether a person will react to NSAIDs including selective cyclooxygenase 2 (COX-2) inhibitors as a safe alternative drug. A stakeholder supported the need for better predictors of drug allergy to COX-2 inhibitors as this may avoid referring people for unnecessary specialist testing, drug reactions and consequential cost.

A stakeholder also suggested that NICE should raise awareness to non-specialists about the importance of co-factors in causing an allergic reaction to a drug, in particular for delayed reactions and for specific drugs such as NSAIDs.

Beta-lactam antibiotics

A stakeholder highlighted that all people requiring penicillin or other beta-lactam antibiotics should undergo specialist investigation in line with Drug allergy (2014) NICE clinical guideline 183.

General anaesthesia

It was reported by a stakeholder that specific patients who experience anaphylaxis-type reactions during general anaesthesia may be denied this treatment in the future

unless a safe combination of drugs can be identified. However, it was also emphasised that everyone should have the right to have general anaesthesia if they are medically fit to do so.

The stakeholder suggested that all people who have experienced allergic reactions during general anaesthesia must be referred to specialist investigation in order to identify the culprit drug. This may allow any drug cleared of blame to be re-prescribed in future and the culprit drug and all related drugs to be avoided enabling safe future anaesthesia for the patient.

4.4.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source(s) that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

Table 7 Specific area for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Non-steroidal anti-inflammatory drugs (including selective cyclooxygenase 2 inhibitors)	**Non-steroidal anti-inflammatory drugs (including selective cyclooxygenase 2 inhibitors)** NICE CG183 Recommendation 1.4.4 (KPI)
Beta-lactam antibiotics	**Beta-lactam antibiotics** NICE CG183 Recommendation 1.4.8 (KPI)
General anaesthesia	**General anaesthesia** NICE CG183 Recommendation 1.4.11 (KPI)

Non-steroidal anti-inflammatory drugs (including selective cyclooxygenase 2 inhibitors)

NICE CG183 Recommendation 1.4.4 (key priority for implementation)

For people who have had a mild allergic reaction to a non-selective NSAID but need an anti-inflammatory:

- discuss the benefits and risks of selective cyclooxygenase 2 (COX-2) inhibitors (including the low risk of drug allergy)
- consider introducing a selective COX-2 inhibitor at the lowest starting dose with only a single dose on the first day.

Beta-lactam antibiotics

NICE CG183 Recommendation 1.4.8 (key priority for implementation)

Refer people with a suspected allergy to beta-lactam antibiotics to a specialist drug allergy service if they:

- need treatment for a disease or condition that can only be treated by a beta-lactam antibiotic **or**
- are likely to need beta-lactam antibiotics frequently in the future (for example, people with recurrent bacterial infections or immune deficiency).

General anaesthesia

NICE CG183 Recommendation 1.4.11 (key priority for implementation)

Refer people to a specialist drug allergy service if they have had anaphylaxis

or another suspected allergic reaction during or immediately after general

anaesthesia.

4.4.3 Current UK practice

The NICE costing analysis for clinical guideline 183 reported there are currently:

- 31 specialist allergy centres in England and Wales (17 staffed by immunologists)
- 19 paediatric centres (7 of which are staffed by paediatric immunology specialists and 12 by paediatric allergy specialists and some of which are co-located with the adult service).[10],[11]

In addition to this, the report also predicted variation in local referral levels depending on factors such as the availability of allergy services and the awareness of patient, GP, anaesthetists and emergency department.

The 2005-2013 NHS England analysis of patient safety incidents (please see appendix 4) reported to the National Reporting and Learning System (NRLS) concluded that antibiotics accounted for 75% involved in incidents with known NSAID drug allergies accounting for only 4%.

The GDG for clinical guideline 183 reported that allergic reactions to non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, diclofenac, naproxen and aspirin, are common. In particular, 5–10% of people with asthma are affected. It was

[10] NICE costing report for clinical guideline 183 (2014)
[11] Allergy services: still not meeting the unmet need. (2010) Joint Royal College of Physicians and Royal College of Pathologists Working Party

highlighted that approximately a third of people with chronic urticaria have severe reactions to NSAIDs, involving angioedema and anaphylaxis.

The GDG for clinical guideline 183 also reported that anaphylaxis-type reactions occur in approximately 1 in 1000 of the general population and during general anaesthesia anaphylaxis occurs between 1 in 10,000–20,000. These patients may be denied general anaesthesia in the future unless a safe combination of drugs can be identified.

4.5 Additional areas

4.5.1 Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise however they were felt to be outside the remit of quality standards or are addressed by other NICE quality standard topics.

There will be an opportunity for the QSAC to discuss these areas at the end of the session.

Lack of in vitro (serum specific IgE and cellular) testing

A stakeholder highlighted that due to lack in vitro (serum specific IgE and cellular) testing, skin testing and/or drug challenge testing becomes necessary which are both labour-intensive. Another stakeholder suggested that NICE should promote a UK audit to assess the value of serum specific IgE testing as a first step towards drug allergy diagnosis in general practice. Positive patients should then be challenge tested in hospital. It was reported that GPs request serum specific IgE testing even if CG183 does not recommend them as routine practice (recommendation 1.1.7).

Drug allergy reaction difference between adults and children

A stakeholder reported drug allergy reaction difference between adults and children with children in general far less likely to be allergic than adults. Based on this reported difference, the stakeholder queried whether we need different criteria to bring more children for challenge testing to prove more are not truly drug allergic.

Pharmacogenomics

A stakeholder highlighted the importance of genetic testing to predict drug allergy or drug reactions which is not widely utilised in clinical practice. This could reduce unnecessary morbidity and cost.

Junior doctors' prescribing training

A stakeholder raised the importance of junior doctors' prescribing training with reminders at induction in order to improve the allergy box completion rate. A 2007 clinical audit also concluded that a combination of clinical audit and continual pharmacist review of prescription charts can improve the quality of prescriptions at a Mental Health Unit.[12]

[12] Improving prescription quality in an inpatient mental health unit: three cycles of clinical audit , Ved et al (2007)

Allergy listing on prescriptions

A stakeholder highlighted the need for allergy listing on prescriptions to encourage double-checking by prescriber and dispenser. However it was also argued that unless past allergy coding is corrected then this may detrimentally cause many false alarms and may prove difficult to add to FP10s as a significant number of patients are coded for multiple allergies and some of which are not correct.

Improved diagnostic tests for delayed type drug allergy reactions

A stakeholder highlighted that delayed type drug reactions can be just as dangerous as established reactions (some reported with 35% mortality if untreated) as these are poorly recognised, often confused, and often inappropriately treated. For delayed drug allergy reactions the only available current diagnostic tests (patch and intradermal tests) are of low diagnostic value which means patients are either incorrectly diagnosed or advised that nothing can be done. Based on this, many patients even refuse to take any future medication. The stakeholder also reported that delayed hypersensitivity is more complicated as there are no high yield diagnostic tests available to the NHS and morbidity and mortality are high on accidental re-exposure. Therefore there is need for improved diagnostic testing.

Designing systems for documenting drug allergy

A stakeholder highlighted that drug allergy is not well recorded in most hospital electronic or paper system, this means that despite careful primary or secondary care diagnosis, patients may still be exposed to harm through accidental re-exposure. In addition, it was reported that secondary care systems should communicate effectively between internal departments to ensure that drug allergy status is efficiently transmitted across an organisation and with primary care, for instance.

Another stakeholder also highlighted that some IT systems do not adequately distinguish between side effects and allergy. Accidental over-diagnosis must also be addressed.

Oral antibiotic challenge for diagnosing antibiotic allergy in children

A stakeholder highlighted the need to challenge antibiotic allergy in children directly (without prior skin or intradermal tests) with oral antibiotic testing. This would mean more challenges are performed and consequentially would allow more drug allergies to be ruled out in children rather than being simply advised to avoid specific drug groups. Skin prick testing was also reported as being painful and disliked by both children and parents.

Appendix 1: Additional information

Assessment[13]

Boxes 1–3 Signs and allergic patterns of suspected drug allergy with timing of onset[1]

Box 1 Immediate, rapidly evolving reactions

Anaphylaxis – a severe multi-system reaction characterised by: • erythema, urticaria or angioedema **and** • hypotension and/or bronchospasm	Onset usually less than 1 hour after drug exposure (previous exposure not always confirmed)
Urticaria or angioedema without systemic features	
Exacerbation of asthma (for example, with non-steroidal anti-inflammatory drugs [NSAIDs])	

Box 2 Non-immediate reactions without systemic involvement

Widespread red macules or papules (exanthema-like)	Onset usually 6–10 days after first drug exposure or within 3 days of second exposure
Fixed drug eruption (localised inflamed skin)	

[13] Note that these boxes describe common and important presenting features of drug allergy but other presentations are also recognised

Box 3 Non-immediate reactions with systemic involvement

Drug reaction with eosinophilia and systemic symptoms (DRESS) or drug hypersensitivity syndrome (DHS) characterised by: • widespread red macules, papules or erythroderma • fever • lymphadenopathy • liver dysfunction • eosinophilia	Onset usually 2–6 weeks after first drug exposure or within 3 days of second exposure
Toxic epidermal necrolysis or Stevens–Johnson syndrome characterised by: • painful rash and fever (often early signs) • mucosal or cutaneous erosions • vesicles, blistering or epidermal detachment • red purpuric macules or erythema multiforme	Onset usually 7–14 days after first drug exposure or within 3 days of second exposure
Acute generalised exanthematous pustulosis (AGEP) characterised by: • widespread pustules • fever • neutrophilia	Onset usually 3–5 days after first drug exposure

Common disorders caused, rarely, by drug allergy: • eczema • hepatitis • nephritis • photosensitivity • vasculitis	Time of onset variable

Appendix 2: Key priorities for implementation (CG183)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

Assessment

- When assessing a person presenting with possible drug allergy, take a history and undertake a clinical examination. Use the following boxes as a guide when deciding whether to suspect drug allergy.[recommendation 1.1.1]

Documenting new suspected drug allergic reactions

- When a person presents with suspected drug allergy, document their reaction in a structured approach that includes:
    - the generic and proprietary name of the drug or drugs suspected to have caused the reaction, including the strength and formulation
    - a description of the reaction (see recommendation 1.1.1)
    - the indication for the drug being taken (if there is no clinical diagnosis, describe the illness)
    - the date and time of the reaction
    - the number of doses taken or number of days on the drug before onset of the reaction
    - the route of administration
    - which drugs or drug classes to avoid in future [recommendation 1.2.3].

Maintaining and sharing drug allergy information

- Prescriptions (paper or electronic) issued in any healthcare setting should be standardised and redesigned to record information on which drugs or drug classes to avoid to reduce the risk of drug allergy. [recommendation 1.2.4]

- Check a person's drug allergy status and confirm it with them (or their family members or carers as appropriate) before prescribing, dispensing or administering any drug (see also recommendation 1.3.4). Update the person's medical records or inform their GP if there is a change in drug allergy status. [recommendation 1.2.6]

Providing information and support to patients

- Discuss the person's suspected drug allergy with them (and their family members or carers as appropriate) and provide structured written information (see recommendation 1.2.3). Record who provided the information and when. [recommendation 1.3.1]

- Ensure that the person (and their family members or carers as appropriate) is aware of the drugs or drug classes that they need to avoid, and advise them to check with a pharmacist before taking any over-the-counter preparations.[recommendation 1.3.3]

Providing information and support to people who have had specialist drug allergy investigations

- Allergy specialists should give the following written information to people who have undergone specialist drug allergy investigation:

- the diagnosis – whether they had an allergic or non-allergic reaction

- the drug name and a description of their reaction (see recommendation 1.1.1)

- the investigations used to confirm or exclude the diagnosis

- drugs or drug classes to avoid in future

- any safe alternative drugs that may be used. [recommendation 1.3.5]

Non-specialist management and referral to specialist services

General

Refer people to a specialist drug allergy service if they have had:

- a suspected anaphylactic reaction (also see Anaphylaxis, NICE clinical guideline 134) **or**
- a severe non-immediate cutaneous reaction (for example, drug reaction with eosinophilia and systemic symptoms [DRESS], Stevens–Johnson Syndrome, toxic epidermal necrolysis). [recommendation 1.4.2]

Non-steroidal anti-inflammatory drugs (including selective cyclooxygenase 2 inhibitors)

- For people who have had a mild allergic reaction to a non-selective NSAID but need an anti-inflammatory:
  - discuss the benefits and risks of selective cyclooxygenase 2 (COX-2) inhibitors (including the low risk of drug allergy)
  - consider introducing a selective COX-2 inhibitor at the lowest starting dose with only a single dose on the first day. [recommendation 1.4.4]

Beta-lactam antibiotics

Refer people with a suspected allergy to beta-lactam antibiotics to a specialist drug allergy service if they:

- need treatment for a disease or condition that can only be treated by a beta-lactam antibiotic **or**
- are likely to need beta-lactam antibiotics frequently in the future (for example, people with recurrent bacterial infections or immune deficiency). [recommendation 1.4.8]

General anaesthesia

Refer people to a specialist drug allergy service if they have had anaphylaxis or another suspected allergic reaction during or immediately after general anaesthesia. [recommendation 1.4.11]

Appendix 3: Glossary

Anaphylaxis A serious allergic reaction that is rapid in onset and may cause death. It typically causes a number of symptoms including an itchy rash, throat swelling, and low blood pressure. Common causes include insect bites and stings, foods, and medications.

IgE Immunoglobulin E (IgE) is 1 of the 5 subclasses of antibody related to allergic reactions present in the blood, usually in very low concentrations or found on the surface of cells such as mast cells.

IgE testing A test that measures the blood level of IgE. The IgE test is often performed as part of an initial screen for allergies.

Appendix 4: Patient Safety Report to Inform the NICE Quality Standard on Incidents Relating to Known Drug Allergies

1. Introduction

This paper has been prepared at the request of the National Institute for Health and Clinical Excellence (NICE), in order to inform the development of the Quality Standard on Drug Allergies.

Quality has three key dimensions – patient safety, clinical effectiveness, and patient experience. The NHS England Patient Safety Domain supplies patient safety reports to NICE to help ensure Quality Standards reflect equally all three dimensions of quality.

2. The National Reporting and Learning System

This paper includes a review of incidents reported to the National Reporting and Learning System. The National Reporting and Learning System (NRLS) was established in 2003 to provide a national database of incidents relating to patient risks and harm. Reports of patient safety incidents (PSIs) while under NHS care must be reported to the NHS organisations' local risk management systems. These reports must, in turn, be uploaded to the NRLS. The NRLS reports contain a number of fields, most of which are categorical. These have varying degrees of completion, partly because it is not mandatory to complete all fields. The largest fields are free text descriptions of the incident and subsequent actions. It is largely from these fields that the content of this document is drawn. As with any voluntary reporting system, interpretation of the data must be undertaken with caution as the data are subject to bias. Many incidents are not reported and those that are reported may be incomplete, having been reported before the patient outcome and any contributory factors or underlying causes are known.

3. Patient Safety

Every day more than a million people are treated safely and successfully in the NHS, but the evidence tells us that in complex healthcare systems things will and do go wrong, no matter how dedicated and professional the staff. When things go wrong, patients are at risk of harm, and the effects are widespread and often devastating for patients, their families and the staff involved. Safety incidents also incur costs through litigation and extra treatment. These incidents are often caused by poor system design rather than the error of individuals. The untoward incidents were in essence, 'accidents waiting to happen'.

Thus, patient safety could be summarised as ‘The identification and reduction of risk and harm associated with the care provided to patients ‘or ‘Preventing patients from being harmed by their treatment’.

4. **NICE accredited guidance relevant to drug allergies**

No NICE accredited Alerts exists but the NPSA Alert *Standardising wristbands improves patient safety*

http://www.nrls.npsa.nhs.uk/resources/?entryid45=59824&p=13 .

notes the important of an unambiguous systems for signalling risks specific to the patient, including allergies

5. **NRLS analysis**

Incidents reported as medication error category of ‘patient allergic to treatment’; within the date range **01 April 2005 to 31 March 2013** were extracted.

A random sample of 400 incidents were individually reviewed and extrapolated to assess the number of reports related to incidents where a patient was prescribed, dispensed or administered a medication they had a previous known allergy to.

All incidents reported to have an outcome of serious harm were individually reviewed to identify themes and were necessary recoded for actual severity of harm.

Results

Within the incident date range, a total of **18,079 incidents** were reported with a medication error category as ‘patient allergic to treatment’.

Table 1. Medication Process	**Number of reports**	**Percentage (%)**
*Administration / supply of a medicine from a clinical area	8,954	50%
Prescribing	7,540	42%
Other	806	4%
Monitoring / follow-up of medicine use	397	2%

Preparation of medicines in all locations / dispensing in a pharmacy	263	1%
Advice	85	<1%
Supply or use of over-the-counter (OTC) medicine	34	<1%
Grand Total	**18,079**	**100%**

* It should be noted that if administered in error then it is highly likely that the patient was erroneously prescribed a medicine that they were known to be allergic in the first place

Table 2. Degree of Harm	**Number of reports**
Death	6
Severe	19
Moderate	1,153
Low	3,827
No Harm	13,071
Unrelated / not recorded	3
Grand Total	**18,079**

Previous known drug allergy

Incidents reports where an error occurred that is ‘preventable’ include when a patient has **a** previous known drug allergy.

14,544[14] incident reports were reported as having involved a patient being prescribed, administered or dispensed a medicine with a known drug allergy.

Of the reports that have led to **serious harm**, 5 of the reported Deaths and 8 incidents of Severe harm involved patients with a previous known drug allergy.

Example incidents

Patient prescribed IV Augmentin. First dose given at [time]. Patient later arrested and died. As patient appeared to be fitting I checked drug chart for diazemuls to realise she was ?penicillin allergic. An arrest call was put out and doctors informed of allergy and Antibiotic allergy. Patient immediately given IV adrenalin and Hydrocortisone 200 mg IV. CPR was not successful and patient died. ***(Death)***

*Augmentin prescribed for penicillin allergic patient . Drug administered . Patient developed erythematous rash . This incident is being investigated as a SUI . Patient was prescribed Augment and Tazocin IV , developed and erythematous rash . Transfered to PICU where she died….****(Death)***

The majority of reports involving a previous known drug allergy had this information documented somewhere in their clinical notes, medication card or allergy bracelet / red wrist band.

In many cases,

- Patients had a red “warning” wrist band insitu, but this does not appear to have been checked/ acted upon.
- Patients or carers were not asked if they had any known drug allergies or had not disclosed this information prior to prescribing, dispensing or administering of the drug.
- Documentation was not available at time of prescribing or the drug allergy box not completed.
- Patient allergy was documented, but staff were not aware that what they were prescribing or administering was actually what the patient was allergic to. I.e.Flucloxacillin (with penicillin allergy) or allergy to ingredient/excipient in the formulation.

Example incidents

Patient complained of feeling breathless and itchy. Said she feels like this when she has taken Diclofenac. Patient was wearing a red name band stating allergy to Diclofenac. I looked on the prescription sheet and Diclofenac was given by the

[14] Figure calculated following extrapolation of a random sample of 400 incidents.

Senior Nurse earlier. It had been prescribed by doctor. Patient experienced anaphylactic shock. ***(Severe Harm)***

Patient was prescribed Flucloxicillin 250mg (capsules), one to be taken four times a day by general practice. General Practice had received a discharge flimsy for a previous admission which stated penicillin allergy and this was not coded on the records. Patient had an allergic reaction and required hospitalisation. ***(Moderate Harm)***

*Patient complaining of feeling light headed following the administration of IV antibiotics , he asked staff to check what he had been given as stated he normally only has bag of infusion but had also been given an injection & questioned whether it was penicillin as the reaction felt familiar . When checked, patient had been given fluoxacillin 500mg given at [time] by Senior nurse. Patient stated clearly all allergies & patient had a red band on. Patient's reactions became very severe - resps increased to 52 bp 142 / 92 , HR 104 , fast bleeped house officer, applied 100% on non - rebreather & awaited doctor arrival . Doctor gave adrenalin , & patient able to communicate , BP 103 / 65 , HR 83 , resp 14 , at this point patient complaining of chest pain , bp 84 / 58 , HR 59 , Resp 12 , ECG obtained which was indicative of myocardial infarction .****(Severe Harm)***

Contacted by patient this afternoon who informed me that her dispensed medicines had naseptin cream in it which contains peanuts. Patient allergic to nuts which was documented on the drug kardex & TTO form . ***(No harm)***

Therapeutic group

The vast majority of medicines involved in incidents with known patient drug allergies include Antibiotics, followed by Opioid medicines. The following tables (table 3, 4 and 5) provides figures populated following extrapolation from a random sample.

Table 3. Therapeutic Group	**Number of reports**	**Percentage**
Antibiotic	10885	75%
Opioid	1174	8%
NSAID	542	4%
Paracetamol	497	3%

Iodine	136	1%
Benzodiazepine	90	1%
Anaesthetic	45	<1%
Other	1039	7%
(Not stated)	136	<1%
Total of reports with previous known allergy	**14544**	**100%**

Penicillin allergy

The majority of incidents involve patients with a known allergy to Penicillin, yet the patient is still prescribed, dispensed or administered an antibiotic that is a penicillin or component i.e. Co-amoxiclav/ Augmentin, Tazocin®, Timentin®, etc. It may be that staff are not aware that the medicines prescribed, dispensed or administered is in fact a type of penicillin.

Table 4. Antibiotic that led to previous allergy	**Number of reports**	**Percentage**
Penicillin	9797	90%
Trimethoprim	544	5%
Other antibiotic	311	3%
Metronidazole	133	1%
Cephalosporin	44	<1%
Total of Antibiotic	**10885**	**100%**

Table 5. Type of Penicillin given	Number of reports	Percentage
Co-amoxiclav (Augmentin®)	3550	36%
Flucloxacillin	1798	18%
Amoxycillin	1708	17%
Piperacillin with tazobactam (Tazocin®)	899	9%
Ticarcillin with clavulanic acid (Timentin®)	449	5%
Benzylpenicillin	360	4%
*Cephalosporin (cross sensitivity)**	315	3%
Phenoxymethylpenicillin	45	<1%
(Not stated)	674	7%
Grand Total	**44**	**100%**

* A number of reports involve errors where a cephalosporin has been given to a penicillin allergic patient without consideration of potential cross-sensitivity.

Example Incident

Patient allergic to penicillin (written in allergy box). Patient prescribed tazocin (contains a penicillin). Florid rash developed over body - maculopapular rash ***(Moderate Harm)***

6. Implications of NRLS findings to the NICE Quality Standard

Analysis of NRLS incidents indicate that incidents involving allergies to Penicillin are the most prevalent, in particular those containing co-penicillin products e.g.

Augmentin®, Tazocin®, Timentin®. Incidents around drug allergy are believed to be predominantly due to failures in the checking process by Health Professionals. In addition there is evidence of a lack of education about which Antimicrobial products contain Penicillin.

If the safety of patients is to be given appropriate consideration within the Quality Standard, we believe it is essential for the Quality standard to include these areas:

- Need for all Health care professionals to understand the need to become more responsible and accountable for checking allergy status before prescribing or administering medication.eg Checking patient allergy status for every patient every time and not proceeding with the prescribing , administration or dispensing process unless this has been completed, documented and acted upon (unless a life threating situation and unable to determine allergy status)

- Need for IT solutions to minimise the risk of failed human checking processes e.g. Electronic Prescribing with decision support, Bar coding enabled electronic administration systems

- Need for physical identifiers to alert all Health Professionals when dealing with patients with known drug allergies. For instance clearly highlighting the drug allergy box to stand out. Patient wearing specific coloured wrist bands with clear indication that the patient is allergic to medications

- Education , perhaps under the umbrella of Antimicrobial Stewardship, for Health Professionals e.g. posters/ electronic guidance about which Antibiotics are safe to use in patients allergic to Penicillin

Report prepared by:

Steven Williams

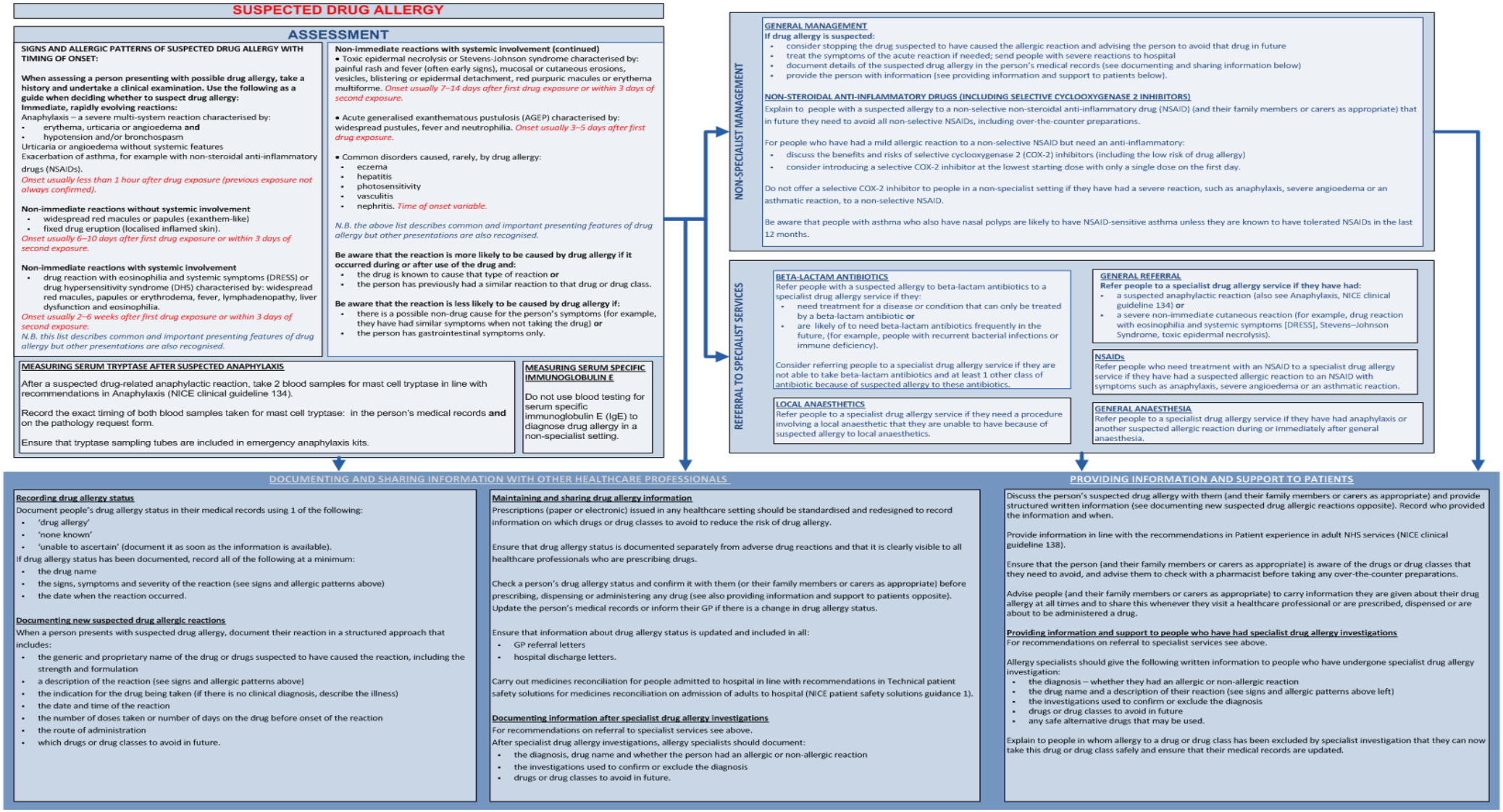
Senior Head of Medication Safety

Patient Safety Domain

NHS England

17 November 2014

Appendix 5: Assessment algorithm in NICE clinical guideline 183



Appendix 6: Suggestions from stakeholder engagement exercise

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
4.1 Assessment					
001	SCM1	Guideline algorithm	An understanding of the signs and symptoms of drug allergy remains poor amongst clinicians. This leads to confusion when documenting a new drug allergic reaction and recommending safe alternative drugs and warning of which drugs to avoid in future.	A copy of the algorithm developed by the NICE Drug allergy GDG should be made widely available and published in the BNF to allow clinicians to differentiate between drug allergy and intolerance	NICE Drug allergy clinical guideline 183
002	NHS Durham Dales, Easington and Sedgefield CCG	Diagnosis of drug allergy	Increase precision of diagnosis – accurate diagnosis	Education about types of allergy, presentations and timings (the latter are sometimes misunderstood)	
003	Royal College of Pathologists	Prompt assessment on admission for patients with a history of possible penicillin allergy	Prompt assessment on admission for patients with a history of possible penicillin allergy to confirm or refute a diagnosis of penicillin allergy and thus ensure optimal choice of antibiotics Several studies have shown that most patients with a label of penicillin 'allergy' are not allergic to penicillin and related beta-lactam antibiotics (Salkind AR et al.Is this patient allergic to penicillin? An evidence-based	However,the failure to clarify this history leads to skewed antibiotic choices (fluoroquinolones,clindamycin,vancomycin) and consequently, a higher prevalence of hospital acquired infections and longer hospital stays in comparison to control patients as shown in this recent study from California (Macy et al Healthcare use and serious infection prevalence associated with penicillin 'allergy' in hospitalised patients. J Allergy Clin Immunol 2014;133:790-6). I'm unaware of a similar study from the UK but clinical experience suggests that these	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			analysis of the likelihood of penicillin allergy.JAMA 2001;285;2498-505)	findings are likely to be replicated.	
4.2 Documenting and sharing information with other healthcare professionals					
004	SCM1	Diagnostic label of penicillin allergy	Studies have shown that those with a label of penicillin allergy are more likely to be treated with broad-spectrum antibiotics, such as quinolones, vancomycin, and third-generation cephalosporins (Lee, 2000). Use of broad-spectrum antibiotics is associated with up to a 30% increase in rates of clinical complications, such as antibiotic resistance and Clostridium difficile leading to increased hospital stay (Macy,2014). Patients in intensive care who developed vancomycin-resistant enterococcus (VRE) were 5 times more likely to have been treated with vancomycin and third generation cephalosporins during the previous month (Martinez, 2003). Therefore, an unsubstantiated label of penicillin allergy may lead to the inappropriate use of broad spectrum, non-penicillin antibiotics leading to antibiotic	1) Improving the quality of patient information following an allergic reaction 2) Improving the quality of clinical documentation following an allergic reaction due to a drug 3) Ensuring that all patients requiring penicillin or other beta lactams undergo specialist investigation as per the NICE guidelines 4) With 1 million admissions each yr for people with a label of drug allergy and the majority with a label of penicillin allergy there could be a saving of 265,000 hospital bed days each yr with accurate diagnosis (assuming 50% of labels due to penicillin and 90% of those with a label not allergic) 5) With 1 million admissions each yr for people with a label of drug allergy and the majority with a label of penicillin allergy there could be a saving of 265,000 hospital bed days each yr with accurate diagnosis (assuming 50% of labels due to penicillin and 90% of those with a label not allergic)	NRLS from NHS England HES data on hospital admissions Macy et al J of Allergy Clini Immunol 2014 CMO report on antibiotic resistance

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			resistance and in some cases sub-optimal therapy. Patients with a label of penicillin allergy also remained in hospital an average of 0.59 days longer than those without this label.		
005	SCM1	Documenting new suspected drug allergic reactions	Analysis of patient safety incidents reported to the NHSE National Reporting and Learning System between 2005 and 2013 identified 18,079 incidents involving drug allergy. These included 6 deaths, 19 'severe harms', 4980 'other harms' and 13,071 'near-misses'. The majority of these incidents involved a drug that was prescribed, dispensed or administered to a patient with a previously known allergy to that drug or drug class.	1) Improving the quality of initial clinical documentation following an allergic reaction due to a drug – using a structured approach will help to improve communication of the nature and severity of each event 2) Improving the quality of patient information following an allergic reaction using a structured approach will also improve communication of the nature and severity of a person's drug allergy and reduce the likelihood of inadvertent readministration 3) Increasing the resources available to prescribers to reduce the likelihood of drug allergy mistakes which include immediate redesign of the prescription form FP10 to include a drug allergy box will help to communicate drug allergy details between prescribers and pharmacists 4) Ensure that information about drug allergy status is updated and included in all GP referral letters and hospital discharge letters	NICE Drug allergy clinical guideline 183

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
006	SCM2	Recording of information relating to drug allergy	This is important because of the possible risk of a drug being given in the future that will cause a reaction in the patient due to lack of knowledge of the allergy	At present there is not enough consistency in the way recording takes place. The NICE guideline gives clear advice on how this should be done for the best effect	NICE Drug allergy clinical guideline 183 and patient experience
007	SCM2	Standardise prescriptions	So that drug allergy information can be recorded as standard in a specific area of the prescription form	This is key as it will show any known drug allergy when a drug is being dispensed. It is also important to show “no known allergy” to ensure note has been taken of the need for the information to be listed	NICE Drug allergy clinical guideline 183 and patient experience
008	NHS Durham Dales, Easington and Sedgefield CCG	Diagnosis of drug allergy	Increase precision of diagnosis – addressing over-diagnosis	Inappropriate witholding of treatment (for antibiotics may lead to use of less effective/ more costly/ broader-spectrum treatments)	Use of diagnosis table in NICE Drug allergy clinical guideline 183
009	SCM3	Standardise documentation	Standardise the documentation for allergy status history for GP referral letters, hospital discharge letters, prescriptions, administration records and electronic patient records For accurate record keeping and sharing information	Clear documentation and record keeping will promote better use of a patients allergy status information particularly if adverse drug reactions are classified as true allergies, severe adverse effects, or vague reactions (drug should be avoided); drug intolerance and mild or moderate adverse effects; excessive pharmacologic effects; or no reaction experienced.	Findings of a pilot study conducted across five London hospital NHS trusts. Researchers recorded the difference in the quality of allergy status documentation after introducing standardised charts, staff were asked to review after two months of use. Safety features on the charts included: a cut-out section to ensure that the

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
					patient's demographic and allergy status information was visible Pharmaceutical journal 8 Sep 2013
010	SCM3	Classification of adverse drug reactions	Recommend that adverse drug reactions are classified To inform prescribing where there are a few therapeutic drug options	The mechanism at presentation may not be apparent from the clinical history and it cannot always be established whether a drug reaction is allergic or non-allergic without investigation	NICE Drug allergy clinical guideline 183
011	SCM4	Recording of drug allergy symptoms and signs at diagnosis in primary care	There is limited availability of specialist allergy services, therefore, most diagnoses will continue to be made in primary care by non experts. However, in cases where the drug is deemed important to the patient, and referral is indicated as in the guidelines, it is very important that the specialist service has access to the relevant decision making findings from the original problem. As this does not happen routinely, most cases have to be investigated as though they are the most severe and potentially dangerous reactions. This adds cost and complicates specialist testing.	Improved record keeping in primary care of symptoms, signs and other relevant factors at the time of drug allergy diagnosis	NICE Drug allergy clinical guideline 183

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
012	SCM4	Avoidance of accidental re-exposure to known drugs causing allergy	Drug allergy diagnosis is pointless if the patient accidentally is re-exposed to the known culprit drug. This can happen for a variety of reasons but some reasons are common e.g. lack of knowledge regarding the constituent components of a medication (eg that Tazocin contains a penicillin – piperacillin); poor communication of diagnosis between healthcare professionals; lack of healthcare safeguarding systems to prevent re-exposure to known allergic causes; lack of pharmacist awareness of drug allergy status	Drugs should be labelled and prescribed in such a way that the constituent parts are clear. Drug allergy status should be transmitted on all communications between healthcare organisations and be transmitted efficiently within organisations Healthcare systems should be designed to alert clinicians if a drug is being given to which an allergy is recorded. Pharmacists should be alerted to drug allergy status through inclusion of this on all prescriptions.	NICE Drug allergy clinical guideline 183
4.3 Providing information and support to patients					
013	SCM2	Patient information	Patients need full information on their allergy and how it will impact on life	Patients are often not given full information on the drug they are allergic to and the possibility of this drug being present in other medications and the need to carry this information with them at all times. They are not often given information on relevant patient support which can be crucial when diagnosed with an allergy	NICE Drug allergy clinical guideline 183 and patient experience
4.4 Non-specialist management and referral to specialist services					
014	SCM1	General anaesthesia	Anaphylaxis-type reactions occur in approximately 1 in 1000 of the	Ensure that ALL patients who have experienced allergic reactions during GA	

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			general population. Anaphylaxis during general anaesthesia occurs in between 1 in 10,000–20,000 anaesthetics.46,47 These patients may be denied general anaesthesia in the future unless a safe combination of drugs can be identified. It should be a right for everyone to have general anaesthesia if they are medically fit to do so.	are referred to specialist investigation in order to identify the culprit drug. This should allow any drug absolved of blame to be re-prescribed in future and the culprit drug and all related drugs to be avoided enabling safe future anaesthesia.	
015	SCM1	Referral criteria	When someone has a suspected allergic reaction to a drug there is often confusion about: 1) If a drug was responsible for the symptoms at all 2) Which drug caused the reaction especially if the person was taking multiple drugs at the time 3) If it would be safe to take the same or related drug again 4) Can the drug and related drugs be safely avoided without harming the patient 5) Will this be a lifelong allergy 6) If the drug is required in future – is there a way of confirming or excluding drug allergy	Ensure specialist referral and/or advice for all patients who would benefit from taking a drug to which they have suffered a previous suspected allergic reaction - particularly if the reaction occurred during GA or LA therapy, a NSAID or a beta lactam antibiotic.	Referral criteria from NICE Drug allergy clinical guideline 183

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
016	SCM5	Allergy to NSAID	These reactions are common, and there is a need for improved predictors of whether a person will react to COX-2 inhibitors, which are the alternative drugs.	Better predictors of drug allergy to COX-2 inhibitors could avoid unnecessary drug challenges and reactions, with their attendant costs	
017	SCM2	Improving specialist services	Specific patients need to be referred to a specialist service as recommended in the NICE guidelines	There is a severe lack of specialists offering the type of service patients with drug allergy require	NICE guidelines and patient experience
018	SCM2	Improving allergy knowledge in primary care	GPs need to know when to refer patients for specialist investigation and how to manage those who stay within primary care	Currently, some GPs lack an understanding of drug allergy and when to refer	NICE guidelines and patient experience
019	British Society for Allergy & Clinical Immunology	Co-factors	NICE should make aware the non Specialists of the importance of co-factors in causing an allergic reaction to a drug. This is particularly important for non - immediate reactions and for certain drugs such as NSAIDs	Some drugs, such as Amoxicillin, can cause non immediate exanthems through the activation of endogenous 'dormient' viruses. NSAID can cause a reaction in association with alcohol/food or exercise.	Mardivirin L et al Eur J Dermatol 2010; 20; 68-73 Nakamura K et al Ann Allergy Asthma Immunol 2006;97:712-3
020	SCM4	Referral for specialist investigation	Cases of severe drug allergy or in those where the culprit drug avoidance has a high impact on quality of life, should be referred for specialist investigation (CG183), but it is important that the referral should be directed to specialists in drug allergy investigation. Not all allergy units	Inappropriate referral to non-specialist centres will make the outcome of these guidelines different to that which was intended. Drug allergy is a complicated sub-speciality of allergy and dermatology and appropriate expertise is required to be able to safely manage patients with drug allergy.	NICE Drug allergy clinical guideline 183

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			have expertise in the management of type 1 allergy. Generally, allergy departments don't have expertise in the management of type 4 allergy and these referrals should be sent to dermatologists with the relevant expertise.		
4.5 Additional areas					
021	SCM5	In vitro diagnosis of drug allergy – specific IgE antibodies	Specific IgE testing is only available for a few drugs	Absence of in vitro tests means that skin testing and/or drug challenge becomes necessary. Both of these are labour-intensive	
022	SCM5	In vitro diagnosis of drug allergy – cellular testing	In vitro testing for non-IgE mediated reactions not widely available	Absence of in vitro tests means that skin testing and/or drug challenge becomes necessary. Both of these are labour-intensive	
023	SCM5	Pharmacogenomics	Genetic testing to predict drug allergy/drug reactions not widely utilised in clinical practice	Prediction of drug allergy/reactions could avoid unnecessary morbidity and cost	
024	British Society for Allergy & Clinical Immunology	Specific IgE testing	Among ''further informations' the following should be added: NICE should promote an UK Audit to precisely assess the value of specific IgE tests (not only for beta lactams but also for latex, chlorhexidine, NMB etc) as a first step towards the diagnosis of DA in general practice. Positive	Even if a only a small number of IgE positive patients could eventually be identified in this way, this type of study should be in the long term helpful to reduce the number of patients admitted to hospital for testing/challenge	Blanca M et al Allergy 2001;56;862-70 Fontaine C et al Allergy 2007: 62;47-52

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			patients should then be challenged in the hospital. GPs request specific IgE testing even if NICE does not recommend them as routine practice. IgE tests are very specific although not as sensitive		
025	NHS Durham Dales, Easington and Sedgefield CCG	IT systems and drug allergy recording	Some IT systems do not adequately distinguish between side-effects and allergy	Address accidental over-diagnosis	NICE Drug allergy clinical guideline 183
026	NHS Durham Dales, Easington and Sedgefield CCG	Allergy listing on prescriptions	Allergy listing on prescriptions encourages double-checking by prescriber and dispenser. However, unless past allergy coding is corrected (this isn't in the guidance) then the move will produce many false alarms and may prove difficult to add to FP10s (though may suit e-prescribing?) as a significant number of patients are coded for multiple allergies some of which are not correct.	Reduced errors but potential for disruption	
027	SCM3	Junior doctors' training on prescribing	Junior doctors' training on prescribing and prompts at induction	Training at induction for junior doctors led to improvement of the allergy box completion rate at a Mental Health Trust	Onalaja O, Saffrey R, Jones E, et al. Audit of in-patient prescription and administration records on

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
			To improve allergy box completion rate		acute psychogeriatric wards in a teaching hospital. Psychiatr Bull 2001; 25: 381−3. Improving prescription quality in an in-patient mental health unit: three cycles of clinical audit Psychiatric Bulletin (2007) 31: 293-294
028	SCM4	Systems communication of drug allergy status	Drug allergy is not well catered for in most hospital electronic or paper systems. This means that despite careful primary care diagnosis or secondary care diagnosis, patients may still be exposed to harm through accidental re-exposure	Secondary care systems should communicate effectively internally between departments to ensure that drug allergy status is effectively transmitted across an organisation. Systems should be developed to ensire that this communication also bridges primary to secondary care etc.	NICE Drug allergy clinical guideline 183
029	SCM4	Lack of understanding/basic knowledge of the clinical presentation of a drug allergy reaction and poor understanding of the prognosis.	Widespread lack of understanding/basic knowledge of the clinical presentation of a drug allergy reaction and poor understanding of the prognosis. Although anaphylaxis is relatively well recognised, the delayed type drug reactions that can be just as dangerous (some with 35% mortality if untreated) are poorly	Toxic epidermal necrolysis has an average mortality of 35%, DRESS is 10%. Despite this most clinicians (primary and secondary care) will not be familiar with constellation of signs that reflect the diagnoses and inappropriate management is frequent. It has been well shown that effective management of TEN lowers mortality and that early identification of DRESS is important to outcome.	NICE Drug allergy clinical guideline 183, British Ascn. Dermat SJS/TEN guidelines 2014

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			recognised, often confused, and often inappropriately treated.		
030	SCM4	Diagnostic tests for delayed type drug allergy reactions	Although diagnostic protocols for anaphylaxis type/immediate drug reactions are well established, this is not the case for delayed type reactions where the only currently available diagnostic tests (patch and intradermal tests) are of low diagnostic value. This means that patients are told incorrect diagnoses or told that nothing can be done and many patients refuse to take any medications ever again.	There is no point following all the good practice points in CG183 unless the underlying diagnosis is correct. Delayed hypersensitivity is more complicated as there are no high yield diagnostic tests available to the NHS and morbidity and mortality are high on accidental re-exposure. Thus improved diagnostic tests need to be established.	NICE Drug allergy clinical guideline 183, others
031	SCM6	Children- Different drug allergy reaction criteria	Children are different to adults in that generally even if had a reaction to a drug they are far less likely than adults to be allergic.	Therefore do we need different criteria to bring more children for challenge i.e. prove more not drug allergic?	Immunol Allergy Clin North Am. 2004 Aug;24(3):345-56, Classification and epidemiology of hypersensitivity drug reactions. Demoly P, Hillaire-Buys D.
032	SCM6	Children- without intradermal testing	Could we challenge children safely without intradermal testing? This is painful and is a barrier to challenging more children to rule out drug allergies. Disliked by both children and parents.	If challenges could go straight from skin prick testing to an oral challenge without intra-dermals this would mean more challenges are performed and therefore allow more drug allergies to be ruled out in children rather than simply being told to avoid specific groups of drugs	

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033	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.			
034	Royal College of Nursing	This is to inform you that the Royal College of Nursing have no comments to submit to inform on the engagement exercise for the Drug Allergy –Diagnosis & Management topic. We look forward to participating in the next stage.			
035	Royal College of Paediatrics and Child Health	Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the Drug allergy topic engagement exercise. We have not received any responses for this consultation.			