

Drug allergy: diagnosis and management

NICE quality standard

Draft for consultation

March 2015

Introduction

This quality standard covers the diagnosis and management of drug allergy in adults, young people and children. It does not cover treatment of the acute phase, including anaphylaxis, because this will be covered by a separate quality standard. For more information see the drug allergy [topic overview](#).

Why this quality standard is needed

All drugs can cause side effects, also known as 'adverse drug reactions', but not all of these are allergic in nature. Some reactions are idiosyncratic (rare and unpredictable), some are pseudo-allergic (with similar presentation to allergic reactions but different causes) and some are 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. It is not always clear from a person's clinical history whether a drug reaction is allergic or non-allergic without investigation. The NICE guideline on [drug allergy](#) (CG183) defines drug allergy as any drug reaction with clinical features compatible with an immunological mechanism.

Hospital Episode Statistics (HES) for 1996 to 2000 show that drug allergies and adverse drug reactions accounted for approximately 62,000 hospital admissions each year in England. Between 1998 and 2005, there was an increase in these reactions, with serious adverse drug reactions rising 2.6-fold. Importantly, up to 15% of inpatients have their hospital stay prolonged by an adverse drug reaction.

Diagnosing drug allergy can be challenging and there is considerable variation in management and in access to specialist drug allergy services. This can lead to under diagnosis, misdiagnosis and self-diagnosis. This variation may be caused by a

lack of local drug allergy centres or awareness of available services. Some people are never offered a referral to specialist services and stay in primary care. Others have their drug allergy managed in other disciplines. Only a small proportion of people are treated in specialist allergy centres.

The quality standard is expected to contribute to improvements in the following outcomes:

- patient experience of care
- patient safety incidents reported
- mortality from causes considered preventable
- patient exposure to unnecessary broad-spectrum antibiotics
- antibiotic prescribing and antimicrobial resistance rates.

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measurable improvements in the 3 dimensions of quality – patient safety, patient experience and clinical effectiveness – for a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 2 outcomes frameworks published by the Department of Health:

- [NHS Outcomes Framework 2015–16](#)
- [Public Health Outcomes Framework 2013–2016](#).

Tables 1 and 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	<p>Overarching indicator</p> <p>2 Health-related quality of life for people with long-term conditions **</p> <p>Improvement areas</p> <p>Ensuring people feel supported to manage their condition</p> <p>2.1 Proportion of people feeling supported to manage their condition**</p>
4 Ensuring that people have a positive experience of care	<p>Overarching indicator</p> <p>4a Patient experience of primary care i GP services</p> <p>4b Patient experience of hospital care</p> <p>Improvement areas</p> <p>Improving people's experience of outpatient care</p> <p>4.1 Patient experience of outpatient services</p> <p>Improving access to primary care services</p> <p>4.4 Access to i GP services</p>
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	<p>Overarching indicators</p> <p><i>5a Deaths attributable to problems in healthcare</i></p> <p><i>5b Severe harm attributable to problems in healthcare</i></p> <p>Improvement areas</p> <p>Improving the culture of safety reporting</p> <p>5.6 Patient safety incidents reported</p>
<p>Alignment with Adult Social Care Outcomes Framework</p> <p>** Indicator is complementary</p> <p><i>Indicators in italics are in development</i></p>	

Table 2 [Public health outcomes framework for England, 2013–2016](#)

Domain	Objective and indicator
4 Healthcare public health and preventing premature mortality	<p>Objective</p> <p>Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities</p> <p>Indicator</p> <p>4.3 Mortality rate from causes considered preventable**</p>
<p>Alignment with NHS Outcomes Framework</p> <p>**Indicator is complementary</p>	

Patient experience and safety issues

Ensuring that care is safe and that people have a positive experience of care is vital in a high-quality service. It is important to consider these factors when planning and delivering services relevant to drug allergy.

NICE has developed guidance and an associated quality standard on patient experience in adult NHS services (see the NICE pathway on [patient experience in adult NHS services](#)), which should be considered alongside this quality standard. They specify that people receiving care should be treated with dignity, have opportunities to discuss their preferences, and are supported to understand their options and make fully informed decisions. They also cover the provision of information to patients and service users. Quality statements on these aspects of patient experience are not usually included in topic-specific quality standards. However, recommendations in the development source for quality standards that impact on patient experience and are specific to the topic are considered during quality statement development.

Coordinated services

The quality standard for drug allergy specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole drug allergy care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to people including children and young people with a drug allergy.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality. Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality drug allergy service are listed in Related quality standards.

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in assessing, caring for and treating people with drug allergy should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard. Quality statements on staff training and competency are not usually included in quality standards. However, recommendations in the development source on specific types of training for the topic that exceed standard professional training are considered during quality statement development.

Role of families and carers

Quality standards recognise the important role families and carers have in supporting people with a drug allergy. If appropriate, healthcare professionals should ensure that family members and carers are involved in the decision-making process about investigations, treatment and care.

List of quality statements

[Statement 1](#). People with suspected drug allergy have their reaction documented using a structured assessment guide based on timing of onset.

[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.

[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.

[Statement 4](#). (Developmental) Healthcare professionals document a person's drug allergy status in their electronic medical record using one code.

Questions for consultation

Questions about the quality standard

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

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

Question 3 For each quality statement what do you think could be done to support improvement and help overcome barriers?

Questions about the individual quality statements

Question 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?

Question 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?

Question 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?

Question 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?

Quality statement 1: Documentation using structured assessment

Quality statement

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

Rationale

After a suspected allergic reaction to a drug, it is important that full and accurate information is recorded so that prescribing errors and adverse drug reactions can be avoided in the future. Healthcare professionals can achieve this by following a structured assessment guide to record the drug reaction and its severity based on timing of onset.

Quality measures

Structure

Evidence of local arrangements to ensure that people with suspected drug allergy have their reaction documented using a structured assessment guide based on timing of onset.

Data source: Local data collection.

Process

Proportion of people with suspected drug allergy who have their reaction documented by a healthcare professional using a structured assessment guide based on timing of onset.

Numerator – the number in the denominator who have their reaction documented by a healthcare professional using a structured assessment guide based on timing of onset.

Denominator – the number of people with suspected drug allergy.

Data source: Local data collection.

Outcome

a) Medication errors (inappropriate prescribing or administration of drugs).

Data source: Local data collection.

b) Number of repeat allergic drug reactions (including patient-reported episodes).

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

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.

Healthcare professionals document drug reactions of people with suspected drug allergy using a structured assessment guide based on timing of onset.

Commissioners (NHS England area teams and clinical commissioning groups) ensure that people with suspected drug allergy have their reaction documented by a healthcare professional using a structured assessment guide based on timing of onset.

What the quality statement means for patients, service users and carers

People with suspected drug allergy should be examined by their GP or, for severe reactions, by A&E staff, who should also ask questions about the symptoms. They should record details of the reaction using a standard approach. They should ask how soon the symptoms started after taking the drug or how many doses were taken, and whether the person has had a similar reaction to that drug or type of drug before. If the doctor thinks that a person might have a drug allergy they should discuss what this means with them (and their family members or carers as appropriate). They should also give them some written information.

Source guidance

- [Drug allergy](#) (2014) NICE guideline CG183, recommendations 1.1.1 (key priority for implementation) and 1.2.3 (key priority for implementation).

Definitions of terms used in this quality statement

Structured assessment guide based on timing of onset

A structured assessment guide based on timing of onset of signs of suspected drug allergy is shown below:¹

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: <ul style="list-style-type: none"> • 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)	

¹ 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

<p>Drug reaction with eosinophilia and systemic symptoms (DRESS) or drug hypersensitivity syndrome (DHS) characterised by:</p> <ul style="list-style-type: none"> • widespread red macules, papules or erythroderma • fever • lymphadenopathy • liver dysfunction • eosinophilia 	<p>Onset usually 2–6 weeks after first drug exposure or within 3 days of second exposure</p>
<p>Toxic epidermal necrolysis or Stevens–Johnson syndrome characterised by:</p> <ul style="list-style-type: none"> • painful rash and fever (often early signs) • mucosal or cutaneous erosions • vesicles, blistering or epidermal detachment • red purpuric macules or erythema multiforme 	<p>Onset usually 7–14 days after first drug exposure or within 3 days of second exposure</p>
<p>Acute generalised exanthematous pustulosis (AGEP) characterised by:</p> <ul style="list-style-type: none"> • widespread pustules • fever • neutrophilia 	<p>Onset usually 3–5 days after first drug exposure</p>

<p>Common disorders caused, rarely, by drug allergy:</p> <ul style="list-style-type: none"> • eczema • hepatitis • nephritis • photosensitivity • vasculitis 	<p>Time of onset variable</p>
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Quality statement 2: Advice about carrying personal drug information

Quality statement

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.

Rationale

If people with drug allergy carry information about their drug reaction at all times, this can minimise the persons' fear, enhance communication with healthcare professionals and enable the person to better manage their drug allergy.

Quality measures

Structure

Evidence of local arrangements to ensure that people with drug allergy and their family members or carers receive advice to carry the information provided about their drug reaction at all times.

Data source: Local data collection.

Process

a) Proportion of people with drug allergy who receive advice to carry the information provided about their drug reaction at all times.

Numerator – the number in the denominator who receive advice to carry the information provided about their drug reaction at all times.

Denominator – the number of people with drug allergy.

Data source: Local data collection.

b) 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.

Numerator – the number in the denominator whose family members or carers receive advice to carry information for the person about the drug reaction at all times.

Denominator – the number of people with drug allergy.

Data source: Local data collection.

Outcome

a) Self-management of drug allergy.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

Service providers (primary and secondary care) ensure that people with drug allergy and their family members or carers receive advice to carry the information provided about the drug reaction at all times.

Healthcare professionals advise people with drug allergy and their family members or carers to carry the information provided about the drug reaction at all times.

Commissioners (NHS area teams and clinical commissioning groups) ensure that people with a diagnosis of drug allergy and their family members or carers receive advice to carry the information provided about the drug reaction at all times.

What the quality statement means for patients, service users and carers

People with drug allergy and their family members or carers are advised to carry the information they have been given about their drug allergy with them at all times.

Source guidance

- [Drug allergy](#) (2014) NICE guideline CG183, recommendations 1.2.3 (key priority for implementation) and 1.3.4

Definitions of terms used in this quality statement

Information provided about a drug reaction

People with drug allergy and their family members or carers carry personal drug information 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.

[Adapted from [Drug allergy](#) (2014) NICE guideline CG183, recommendation 1.2.3 key priority for implementation]

Quality statement 3: Referral to specialist drug allergy services

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.

Rationale

It is important to ensure appropriate referral to specialist drug allergy services so that people with drug allergy receive the care they need. Expert clinical opinion suggests that some people who are currently referred do not need specialist services whereas others need specialist referral but this is not offered.

Quality measures

Structure

Evidence of local arrangements to ensure that 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.

Data source: Local data collection.

Process

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

Numerator – the number in the denominator who are referred to a specialist drug allergy service for advice.

Denominator – the number of people who have had a severe drug reaction and may need this class of drug in the future.

Data source: Local data collection.

Outcome

a) Mortality.

Data source: Local data collection.

b) Repeat allergic drug reactions.

Data source: Local data collection.

c) Length of hospital stay.

Data source: Local data collection.

d) Inappropriate avoidance of drugs.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

Service providers (GP, A&E departments, dentists and secondary care) ensure that people are referred to a specialist drug allergy service for advice if they have had a severe drug reaction and they may need this class of drug in the future.

Healthcare professionals refer people to a specialist drug allergy service for advice if they have had a severe drug reaction and they may need this class of drug in the future.

Commissioners (NHS area teams and clinical commissioning groups) ensure that specialist drug allergy services are commissioned locally for people who have had a severe drug reaction and may need this class of drug in the future.

What the quality statement means for patients, service users and carers

People are referred to a specialist drug allergy service for advice if they have had a severe allergic reaction after taking a drug and they might need this type of drug in the future.

Source guidance

- [Drug allergy](#) (2014) NICE guideline CG183, recommendations 1.4.2, 1.4.8 (key priority for implementation), 1.4.10 and 1.4.11 (key priority for implementation)

Quality statement 4 (developmental): Recording drug allergy status in medical records

Developmental quality statements set out an emerging area of service delivery or technology currently found in a minority of providers and indicating outstanding performance. They will need specific, significant changes to be put in place, such as redesign of services or new equipment.

Developmental quality statement

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

Rationale

At present, the coding used in electronic documentation systems do not enable such systems to differentiate between a side effect and an allergic reaction. Consistent and comprehensive recording of drug allergy status is important to ensure that all patients with confirmed or suspected drug allergy have a full and accurate record within their electronic medical records. A change in practice will also prevent erroneous prescription or medication administration which would be highly beneficial in improving patient safety.

Quality measures

Structure

Evidence of local arrangements to ensure that healthcare professionals document a person's drug allergy status in their electronic medical record using one code.

Data source: Local data collection.

Process

Proportion of electronic medical records with drug allergy status recorded using one code.

Numerator – the number in the denominator with drug allergy status recorded using one code.

Denominator – the number of electronic medical records.

Outcome

a) Mortality.

Data source: Local data collection.

b) Repeat allergic drug reactions.

Data source: Local data collection.

c) Length of hospital stay.

Data source: Local data collection.

d) Inappropriate avoidance of drugs.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals, and commissioners

Service providers (NHS England) ensure that healthcare professionals document a person's drug allergy status in their electronic medical record using one code.

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

Commissioners (NHS England and clinical commissioning groups) ensure that healthcare professionals document drug allergy status using one code in the person's electronic medical record.

What the quality statement means for patients, service users and carers

People have a note in their electronic medical record of whether or not they have a drug allergy. This should be noted as 'drug allergy', 'none known' or 'unable to ascertain' (doctors aren't sure whether a reaction is due to drug allergy or not). If doctors aren't sure they should investigate further.

Source guidance

- [Drug allergy](#) (2014) NICE guideline CG183, recommendations 1.2.1 and 1.2.7

Definitions of terms used in this quality statement**Drug allergy status**

Drug allergy status should be kept up to date in a person's medical records and included in all GP referral letters and hospital discharge letters.

[[Drug allergy](#) (NICE guideline CG183) recommendation 1.2.7]

Documenting drug allergy status using one code

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).

[[Drug allergy](#) (NICE guideline CG183) recommendation 1.2.1]

Status of this quality standard

This is the draft quality standard released for consultation from 12 March to 13 April 2015. It is not NICE's final quality standard on drug allergy. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 13 April 2015. All eligible comments received during consultation will be reviewed by the Quality Standards Advisory Committee and the quality statements and measures will be refined in line with the Quality Standards Advisory Committee's considerations. The final quality standard will be available on the [NICE website](#) from July 2015.

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its [Indicators for Quality Improvement Programme](#). If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's [What makes up a NICE quality standard?](#) for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something

should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in Development sources.

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and [equality assessments](#) are available.

Good communication between healthcare professionals and adults, young people and children with drug allergy, and their families or carers (if appropriate), is essential. Treatment, care and support, and the information given about it, should be both age-appropriate and culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. People with drug allergy and their families or carers (if appropriate) should have access to an interpreter or advocate if needed.

Development sources

Further explanation of the methodology used can be found in the quality standards [Process guide](#).

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

- [Drug allergy](#) (2014) NICE guideline CG183

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- Joint Royal College of Physicians and Royal College of Pathologists Working Party (2010) [Allergy services: still not meeting the unmet need](#)
- Care Quality Commission (2009) [Managing patients' medicines after discharge](#)
- National Patient Safety Agency (2009) [Safety in doses: improving the use of medicines in the NHS](#)
- Department of Health (2007) [Government response to the House of Lords Science and Technology Committee report on allergy](#)
- House of Lords Science and Technology Committee (2007) [House of Lords Science and Technology Sixth Report](#)
- National Patient Safety Agency (2007) [Patient Safety Observatory Report 4: Safety in doses](#)

Related NICE quality standards

Published

- [Asthma](#) (2013) NICE quality standard 25
- [Patient experience in adult NHS services](#) (2012) NICE quality standard 15
- [Diabetes in adults \(including foot care\)](#) (2011) NICE quality standard 6

In development

- [Managing medicines in care homes](#). Publication expected March 2015

Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- Anaphylaxis
- Diabetes in children and young people
- Diabetes in pregnancy

- Medicines management: managing the use of medicines in community settings for people receiving social care
- Medicines optimisation (covering medicines adherence and safe prescribing)
- Perioperative care

The full list of quality standard topics referred to NICE is available from the [quality standards topic library](#) on the NICE website.

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 1. Membership of this committee is as follows:

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About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the [quality standards process guide](#).

This quality standard has been incorporated into the NICE pathway on [drug allergy: diagnosis and management](#).

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