One + all | we care

Royal Cornwall Hospitals NHS Trust

Allergies or Sensitivities to Medicines Procedure

V4.0

December 2022

Table of Contents

1. Introduction 3

2. Purpose of this Policy/Procedure 3

3. Scope 3

4. Definitions / Glossary 3

5. Ownership and Responsibilities 4

6. Standards and Practice 4

6.1. Establishing Allergy Status 4

6.2. Recording Allergy Status 5

6.3. Who can ascertain and document allergy and medicine sensitivity status 6

6.4. Good Practice to reduce the risk of allergic reaction 6

6.5. Patient experiencing a new allergic reaction 7

6.6. When a patient is administered a medicine to which they have a documented allergy 9

6.7. How to document if allergy status changes e.g. following successful desensitisation or a previous documented allergy is subsequently found to be incorrect or a sensitivity only 10

7. Dissemination and Implementation 10

8. Monitoring compliance and effectiveness 10

9. Updating and Review 11

10. Equality and Diversity 11

Appendix 1. Governance Information 12

Appendix 2. Equality Impact Assessment 15

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. If a patient receives medicines to which they have an allergy or other sensitivity it poses a significant risk to their wellbeing. 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.

1.2. 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.

1.3. Reactions that do not have a proven or suspected immunological mechanism should be treated as ‘Sensitivities’.

1.4. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

2.1. To ensure patient allergy and medication sensitivity status is known and appropriately recorded before any medicine is administered to a patient.

2.2. To outline how to ascertain allergy and medication sensitivity information.

2.3. To describe how the status should be documented.

2.4. To define who can ascertain and document allergy and medication sensitivity information.

2.5. To describe good practice that should be followed to reduce the risk of a patient being administered a drug to which they are allergic or have a sensitivity to.

2.6. Describe good practice that should be followed to the reduce the risk to patients of not giving drugs because of incorrect allergy records.

2.7. To describe what should happen when a patient is administered a drug to which they have a documented allergy or sensitivity.

3. Scope

All clinical staff who provide clinical care to patients at Royal Cornwall Hospital NHS Trust should ascertain and record allergies and medication sensitivity in accordance with this policy. This includes those who record allergy/sensitivity status, prescribe, or administer drugs using paper or electronic prescribing and administration systems.

4. Definitions / Glossary

4.1. Drug allergy - an adverse drug reaction with a suspected or established immunological mechanism.

4.2. Drug sensitivity - an abnormal reaction to a drug or to experience a significant side effect from taking a drug.

4.3. Non-drug allergy/sensitivity – a reaction to a food or other substance (e.g. excipient in a medicine or material).

5. Ownership and Responsibilities

5.1. This procedure is developed on behalf of the Medication Practice Committee (MPC).

5.2. All clinical staff are responsible for establishing and recording allergy and medicine sensitivity status as part of the medication reconciliation process.

5.3. All persons working in the pharmacy are responsible for ensuring supplies of any medicines on a prescription are not made if the allergy and medicine sensitivity status is not recorded on the prescription or accompanying information, whether written or electronic.

5.4. All persons administering medicines are responsible for not administering any medicines to a patient if the prescription or accompanying information, whether written or electronic, does not have the patient's allergy and medicine sensitivity status recorded.

5.5. The monitoring of the implementation and compliance with this procedure will be the responsibility of the MPC via the pharmacy team and the Medication Safety Group.

6. Standards and Practice

6.1. Establishing Allergy Status

ACTION	RATIONALE
Before any treatment can be administered, allergy and medicine sensitivity status must be established.	No treatment can be administered safely if the allergy and medicine sensitivity status of a patient has not been established.
The three categories of patient allergy status are:	
□ **None Known**	
□ **Drug allergy status undetermined**	
□ **Allergy or sensitivity known**	

ACTION	RATIONALE
None known- when confirmation has been received from a combination of the patient, the medical records and (where appropriate) the patient's carer or guardian, that the patient has not previously had a reaction to a medicine, food or latex.	
Drug allergy status undetermined - when the allergy and medicine sensitivity status of the patient cannot be confirmed as the patient may be unconscious and no medical records are available. Further attempts to establish allergy and medicine sensitivity status should be made as soon as possible and the status updated accordingly. This should be recorded as 'Drug Allergy Status Undetermined'.	There will be occasions when it is impossible to confirm the allergy status of a patient. The electronic prescribing system will prompt at each login to update the allergy status
Allergy or sensitivity Known- when confirmation has been received from a combination of the patient, the medical records and (where appropriate) the patient carer or guardian, that the patient has previously had a reaction to a medicine, food or latex. Allergy and medicine sensitivity status should be reconfirmed with the patient and recorded at each episode of care.	Allergy and medicine sensitivity status can change over time and therefore it is necessary to reconfirm allergy status on each episode of care. The electronic prescribing system will mandate update of allergies and medicine sensitivities at the start of each episode of care. If no allergy status is completed, the system will not allow any prescribing to occur

6.2. Recording Allergy Status

ACTION	RATIONALE
The allergy and medicine sensitivity status must be clearly documented in the medical notes and on the prescription (whether electronic or paper).	To make it as clear as possible to all those involved in the patient care pathway, the allergy and medicine sensitivity status of the patient.
When the patient or their carer reports a reaction to a medication or other substance the recorder should attempt to ascertain whether the reaction(s) are immunologically modulated or not.	

ACTION	RATIONALE
Immunological-based reactions should be recorded as ‘Allergies’ and other reactions should be recorded as ‘Sensitivities’. (N.B. the electronic prescribing system has limited certain reactions to only being available for recording as ‘Allergy’ or ‘Sensitivity’)	Patients frequently report being allergic to a drug, but this can often not be a ‘true allergy’. It is important to differentiate as it can limit treatment options.
When recording an allergen or sensitising agent, the healthcare professional must, wherever possible, document the nature of the reaction e.g. rash, swollen lips etc.	So that prescribers and administers are aware of the nature of the reaction that the patient experienced

6.3. **Who can ascertain and document allergy and medicine sensitivity status**

ACTION	RATIONALE
• Doctors • Nurses • Pharmacists • Pharmacy technicians competent in Medicines Management	All members of the multidisciplinary team involved in the prescribing, administering and supply of medication should be allowed and encouraged to ascertain and document allergy and medication sensitivity status

6.4. **Good Practice to reduce the risk of allergic reaction**

ACTION	RATIONALE
The healthcare professional will not be able to prescribe any treatment until allergy and medication sensitivity status is known and recorded in the electronic prescribing system	It is impossible to prescribe safely without establishing allergy and medication sensitivity status
Pharmacy will not supply any medication directly to a named patient unless patient allergy and medication sensitivity status is known and recorded	

ACTION	RATIONALE
No medicine will be administered to a patient until the allergy and medication sensitivity status is known and recorded Healthcare professionals should be clear which category of drug they are prescribing and the potential for cross- sensitivity with other drugs of the same group (for example penicillins, contrast agents). Such incidences will be highlighted by the electronic prescribing system	To reduce the risk of a patient receiving a medicine to which they are allergic or have a sensitivity.
Allergy and medication sensitivity status should be reconfirmed and documented for every admission/ episode (dynamic process with allergy documentation amended in light of both new allergies or disproven allergies).	
Review as soon as possible when a patient's allergy status is 'Drug Allergy Status Undetermined'	

6.5. **Patient experiencing a new allergic reaction**

ACTION	RATIONALE
When a patient experiences a new reaction to a drug during admission or because of a medicine prescribed at an outpatient appointment, the reaction should be clearly recorded in the notes and on the electronic prescribing system (if applicable).	To reduce the chance of the patient receiving the medication again
The patient's GP practice should be informed of the newly documented reaction by means of the e-discharge	To ensure that the GP Practice can keep their records up to date
Consider stopping any drug suspected of causing the reaction.	
A yellow card should be completed for all serious adverse drug reactions and any ADR for a black triangle drug (see BNF for details).	To ensure reactions are appropriately reported to the relevant national organisations who share this information
Treat the symptoms of an anaphylactic reaction)	

ACTION	RATIONALE
The patient should be referred to a specialist allergy service if they have had • A suspected anaphylactic reaction or • A severe non-immediate cutaneous reaction (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis) • Referral is made via the patient's GP to the allergy clinic in Plymouth, see link below for more information: https://rms.cornwall.nhs.uk/rms/primary_care_clinical_referral_criteria/rms/primary_care_clinical_referral_criteria/allergy/drug_allergy	This complies with NICE guidance CG 183
After a suspected anaphylactic reaction in adults or young people aged 16 years or older, take timed blood samples for mast cell tryptase testing as follows - a sample as soon as possible after emergency treatment has started	This complies with NICE guidance CG 183
- a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms. - A third sample at least 24 hours after complete resolution	
The patient must be thoroughly counselled on the details of the reaction and the implications for further treatment. This counselling must include: • The name of the drug implicated • The name of the class of drugs implicated (if applicable) • Details on whether this reaction means they are more prone to allergic reactions with other classes of drug e.g. penicillins and cephalosporins • The nature of the reaction • An explanation that although an initial reaction might be mild, a second exposure to the same drug/food may trigger a much more severe reaction	The principal side-effect of the cephalosporins is hypersensitivity and about 0.5–6.5% of penicillin-sensitive patients will also be allergic to the cephalosporins. If a cephalosporin is essential in patients with a historyof immediate hypersensitivity to penicillin, because a suitable alternative antibacterial is not available, then cefixime, cefotaxime, ceftazidime, ceftriaxone, or cefuroxime can be used with caution; cefaclor, cefadroxil, cefalexin, cefradine, and ceftaroline fosamil should be avoided. *(Online BNF guidance).*

ACTION	RATIONALE
• The importance of the patient informing other healthcare professionals of their allergy before they are prescribed, administered or dispensed a drug • Where an allergy is severe, the options of carrying an adrenaline syringe etc. • Advised to check with a pharmacist before taking any over the counter medicines	
Good practice: information to the patient regarding a newly discovered allergy should also be provided in writing. This should include details of the person providing the information and when.	

6.6. When a patient is administered a medicine to which they have a documented allergy

ACTION	RATIONALE
The patient should be monitored very closely Ensure immediate availability of injectable adrenaline, chlorphenamine and hydrocortisone in case they are required If required, the trust resuscitation guidelines should be followed If the patient doesn't have an allergic reaction to a drug they are documented as being allergic to, revisit the history of the allergy with the patient as it may be the patient was never allergic to the drug in the first place. Amend the records as necessary. **A trust Datix report must be completed for any incident when a patient is administered a medicine to which they have a documented allergy, even when no reaction occurs.** The patient's Primary Care provider should be informed of the allergy	It is very important that the trust learns from any incidents relating to allergy to inform policy and procedure development To ensure the appropriate transfer of information to primary care

6.7. How to document if allergy status changes e.g. following successful desensitisation or a previous documented allergy is subsequently found to be incorrect or a sensitivity only

Action	Rationale/comments
The allergy status on EPMA system and in the patient case notes needs to be amended. If the amendment is that a new allergy or sensitivity has been identified then this should be added as detailed above, taking care to include the date of the amendment.	It is important to have a clear audit trail showing what the allergy status of the patient was at what time. It is equally important that allergy status be accurate.
If the amendment is to remove an allergen or sensitising agent from the allergy status (e.g. patient has had successful desensitisation treatment and can now safely be prescribed that medication) then the EPMA system should be altered and an' Allergy' note on the electronic prescribing system should be used to record a more detailed explanation for the change. A contemporaneous record should also be made in the patient's clinical notes.	

7. Dissemination and Implementation

7.1. The document is available on the document library. Significant updates will be communicated via Trust-wide email.

7.2. Implementation of the policy will be via Trust-wide communication and supported by appropriate training for the relevant members of staff.

7.3. Training for this policy will be as set out in the medicines management section of core training matrix of the Trust Core Training Policy.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Incidents of patients administered medications they are allergic or have a documented sensitivity to.

Information Category	Detail of process and methodology for monitoring compliance
Lead	The lead pharmacist for clinical services will co-ordinate an audit that encompasses allergy on an annual basis. The clinical pharmacists will also check allergy status as part of the clinical screen of a drug. Incidents will be reviewed by the senior nurse for the area and the patient safety pharmacist.
Tool	An audit tool will be used to collect data on allergy. This tool will vary depending on which audit it is being used to collect the data e.g. the documentation audit, the antibiotic point prevalence audit or a specific allergy audit.
Frequency	An audit reporting on completion of allergy status will occur annually. Incidents will be reviewed as they are reported.
Reporting arrangements	The allergy audit will be reported to the Medication practice Committee (MPC) Incidents are reported to the Medication Safety Group (MSG), a sub-group of MPC, via the Lead Pharmacist for Patient Safety. Recommendations from this group will then be passed on to the MPC.
Acting on recommendations and Lead(s)	The MPC will sanction recommendations from MSG for them to act upon.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within the time frame outlined in the action plan. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with the relevant stakeholders.

9. Updating and Review

This procedure will be updated as necessary in response to any future publications, clinical incidents or by the review date.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Allergies or Sensitivities to Medicines Procedure V4.0
This document replaces (exact title of previous version):	Allergies or Sensitivities to Medicines Procedure V3.0
Date Issued/Approved:	Friday 18 October
Date Valid From:	December 2022
Date Valid To:	December 2025
Directorate / Department responsible (author/owner):	Neil Powell - Consultant Antimicrobial pharmacist
Contact details:	01872 250000 Ext 3548
Brief summary of contents:	The allergy and medication sensitivity status of all patients receiving treatment and care at/by Royal Cornwall Hospital NHS Trust must be known before any treatment is administered. This status must be clearly documented in the notes, on any prescription or electronic prescribing system. The procedure refers to drug allergies and sensitivities in the main, however the same rules and procedures should be followed for food or latex allergy.
Suggested Keywords:	Allergy, allergies, sensitivity, sensitivities, medicines, medication.
Target Audience:	RCHT: Yes CFT: No CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Medication Practice Committee Clinical Support Governance Group
General Manager confirming approval processes:	Richard Andrezuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None required

Information Category	Detailed Information
Related Documents:	Medicines Policy NICE Clinical Guideline 183
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Intranet Only
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
November 2010	V1.0	Final amendments approved; EIA Completed; document published	Ian Nicholls, Medication Safety Lead Pharmacist
June 2011	V1.1	Change into trust format and amend the dissemination and implementation and the monitoring guidance	Iain Davidson Chief Pharmacist
May 2012	V1.2	Removal of advice to use red wristbands; other minor amendments and updating in line with Electronic Prescribing and Medicines Administration	John Glinn, Head of Clinical Pharmacy Services
September 2012	V1.2a	Updated to reflect implementation of EPMA	Ian Nicholls Lead Pharmacist for Governance and EPMA
August 2015	V2.0	Updated to reflect NICE guidance	Ian Nicholls Lead Pharmacist for Governance and EPMA
May 2016	V2.1	Updated to reflect changes in the electronic prescribing system	Ian Nicholls Lead Pharmacist for Governance and EPMA
July 2019	V3.0	Version update as expiring. Included more detailed information on cross sensitivity with penicillin and cephalosporin reactions	Neil Powell Consultant Antimicrobial Pharmacist

Date	Version Number	Summary of Changes	Changes Made by
November 2022	V4.0	Version update as expiring. Transferred to new document version	Neil Powell - Consultant Antimicrobial Pharmacist Dan Hearsey – Antimicrobial Pharmacist

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Allergies or Sensitivities to Medicines Procedure V4.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dan Hearsey, Antibiotic Pharmacist
Contact details:	01872 252590

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To ensure patient allergy and medication sensitivity status is identified and appropriately recorded before any medicine is administered to a patient at the Trust.
2. Policy Objectives	• To ensure patient allergy and medication sensitivity status is known and appropriately recorded before any medicine is administered to a patient. • To outline how to ascertain allergy and medication sensitivity information. • To describe how the status should be documented. • To define who can ascertain and document allergy and medication sensitivity information. • To describe good practice that should be followed to reduce the risk of a patient being administered a drug to which they are allergic or have a sensitivity to.

Information Category	Detailed Information
	• Describe good practice that should be followed to the reduce the risk to patients of not giving drugs because of incorrect allergy records. • To describe what should happen when a patient is administered a drug to which they have a documented allergy or sensitivity.
3. Policy Intended Outcomes	Prevent administration of any medicine to a patient before allergy and medication sensitivity status is identified and appropriately recorded at the Trust.
4. How will you measure each outcome?	Compliance with the procedure will be measured six monthly
5. Who is intended to benefit from the policy?	Patients under the care of the Royal Cornwall Hospital Trust
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Antimicrobial Stewardship Management Committee Medicines Practice Committee
6c. What was the outcome of the consultation?	Agreed
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	

Protected Characteristic	(Yes or No)	Rationale
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:

Daniel Hearsey, Antibiotic Pharmacist

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis