One + all | we care

Royal Cornwall Hospitals NHS Trust

Allergies or Sensitivities to Medicines Procedure

V3.0

July 2019

Table of Contents

1. Introduction 3

2. Purpose of this Policy/Procedure 3

3. Scope 4

4. Definitions / Glossary 4

5. Ownership and Responsibilities 4

6. Standards and Practice 5

8. Monitoring compliance and effectiveness 11

10. Equality and Diversity 12

Appendix 1. Governance Information 13

Appendix 2.Initial Equality Impact Assessment Screening Form .... **Error! Bookmark not defined.**

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

The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

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. 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

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. The three categories of patient allergy status are: □ **None Known** □ **Drug allergy status undetermined** □ **Allergy or sensitivity known** **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.	No treatment can be administered safely if the allergy and medicine sensitivity status of a patient has not been established.
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 JAC 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 JAC 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.	
Immunological-based reactions should be recorded as 'Allergies' and other reactions should be recorded as 'Sensitivities'. (N.B. the JAC 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 JAC e-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	
No medicine will be administered to a patient until the allergy and medication sensitivity status is known and recorded	To reduce the risk of a patient receiving a medicine to which they are allergic or have a sensitivity.
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 JAC e-prescribing system	
Allergy and medication sensitivity status should be reconfirmed and documented for every admission/ episode	
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 as a result of a medicine prescribed at an outpatient appointment, the reaction should be clearly recorded in the notes and on the JAC e-prescribing system (if applicable).	to reduce the chance of the patient receving 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). Treat the symptoms of an anaphylactic reaction)	To ensure reactions are appropriately reported to the relevant national organisations who share this information
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)	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 • a second sample ideally within 1–2 hours (but no later than 4 hours) from the onset of symptoms.	This complies with NICE guidance CG 183
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	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 history of immediate hypersensitivity to penicillin, because a suitable alternative

allergic reactions with other classes of drug e.g. penicillins and	antibacterial is not available, then cefixime,
cefalosporins • 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 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	cefotaxime, ceftazidime, ceftriaxone, or cefuroxime can be used with caution; cefaclor, cefadroxil, cefalexin, cefradine, and ceftaroline fosamil should be avoided. *(Online BNF guidance).*
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.	It is very important that the trust learns from any incidents relating to allergy to inform policy and procedure development
The patient's Primary Care provider should be informed of the allergy	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 an 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.	
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 JAC 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.	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.

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 p olicy 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

Element to be monitored	Incidents of patients administered medications they are allergic or have a documented sensitivity to.
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, Diversity & 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

Document Title	Procedure for Allergies or Sensitivities to Medicines V3.0		
Date Issued/Approved:	July 2019		
Date Valid From:	July 2019		
Date Valid To:	July 2022		
Directorate / Department responsible (author/owner):	Neil Powell- consultant antimicrobial pharmacist Helen McClay- Lead Pharmacist for Clinical Services		
Contact details:	01872 252217		
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, medicines, medicine, food allergy, food		
Target Audience	RCHT	KCCG	CFT
	✓		
Executive Director responsible for Policy:	Medical Director		
Date revised:	July 2019		
This document replaces (exact title of previous version):	Procedure for Allergies or Idiosyncrasies to Medicines and Food V2.1		
Approval route (names of committees)/consultation:	Medication Practice Committee Clinical Support Governance Group		
Care Group General Manager confirming approval processes	Robin Jones		
Name and Post Title of additional signatories	Not Required		

Name and Signature of Care Group/Directorate Governance Lead confirming approval by specialty and care group management meetings	{Original Copy Signed}			
	Name: Kevin Wright			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Clinical / Pharmacy			
Links to key external standards	None required			
Related Documents:	Medicines Policy NICE Clinical Guideline 183			
Training Need Identified?	No			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
November 2010	V1	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	Updated to reflect NICE guidance	Ian Nicholls Lead Pharmacist for Governance and EPMA
May 2016	V2.1	Updated to reflect changes in the JAC EPMA system	Ian Nicholls Lead Pharmacist for Governance and

July 2019	V3	Version update as expiring. Included more detailed information on cross sensitivity with penicillin and cephlasporin reactions	Neil Powell Consultant Antimicrobial Pharmacist

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed Allergies or Sensitivities to Medicines Procedure V3.0					
Directorate and service area: Pharmacy			**New or existing document:** Existing		
Name of individual completing assessment: Iain Davidson			**Telephone:** 01872 252593		
1. *Policy* Aim* *Who is the strategy / policy / proposal / service function aimed at?*	To outline actions required when ascertaining and recording patient allergies				
2. *Policy* Objectives*	To ensure safe practice within the Trust for patients with allergies				
3. *Policy* – intended Outcomes*	Reduction in the incidences of patients receiving drug or food to which they are allergic				
4. *How will you measure the outcome?	Ongoing clinical audit				
5. Who is intended to benefit from the *policy*?	All inpatients within the Trust				
6a Who did you consult with	Workforce	Patients	Local groups	External organisations	Other
	X		X		
b). Please identify the groups who have been consulted about this procedure.	**Please record specific names of groups** The Medication Practice Committee, Nursing and Pharmacy staff.				
What was the outcome of the consultation?	Agreed.				

7. The Impact
Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step**.

Are there concerns that the policy **could** have differential impact on:				
Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		**X**		This policy describes activities within the capability of relevant staff

Sex (male, female, trans-gender / gender reassignment)		**X**		This policy describes activities not affected by gender
Race / Ethnic communities /groups		**X**		This policy describes activities not affected by race / ethnic communities / groups
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.		**X**		Only staff are required to comply with this policy and if they had a disability that prohibited them from complying the Trust would make suitable alternative arrangements to assist them
Religion / other beliefs		**X**		This policy describes activities not affected by faith and belief
Marriage and Civil partnership		**X**		This policy describes activities not affected marital status
Pregnancy and maternity		**X**		Only staff are required to comply with this policy and if pregnancy or maternity prohibited them from complying the Trust would make suitable alternative arrangements to assist them
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**X**		This policy describes activities not affected by sexual orientation

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**		**No**	**X**

9. If you are **not** recommending a Full Impact assessment please explain why.

Not indicated

Date of completion and submission	July 2019	Members approving screening assessment	Policy Review Group (PRG) **APPROVED**

This EIA will not be uploaded to the Trust website without the approval of the Policy Review Group.

A summary of the results will be published on the Trust's web site.