Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Penicillin allergy de-labelling (PADL) guidance in adult patients

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Date Revised	09/07/2025
Approved By (Committee/Group)	Drugs and Therapeutics 09/07/2025 PSRG 05/09/2025
Date Approved	05/09/2025
Date Issued	05/09/2025
Next Review Date	05/09/2028
Target Audience	All adult in patient areas

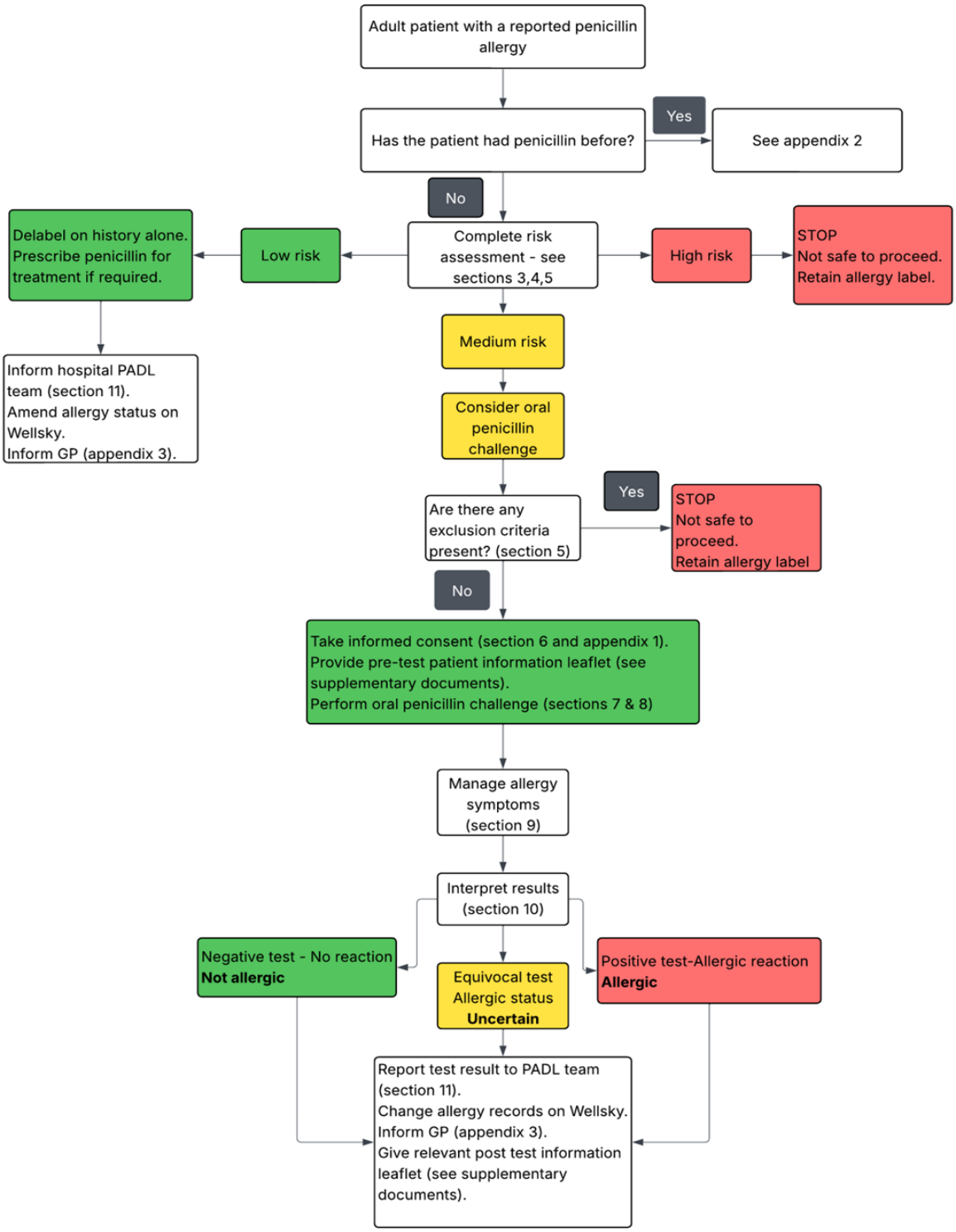
Amendment Form

Version	Date	Brief Summary of Changes	Author
Version 1	September 2025	New document, read in fill	PADL Team

Contents

Page No.

PADL algorithm



1. INTRODUCTION

In the UK, an estimated 2.7 million people are labelled as penicillin allergic (West 2019). However, formal testing reveals that only 5-10% of these cases are true allergies (Savic 2022). Spurious penicillin allergy has significant consequences for both individuals and the healthcare system. For most infections, outcomes are poorer when non-beta-lactam antibiotics are used (McDanel 2015, Huang 2018). Alternative antibiotics often have an unnecessarily broad spectrum of activity, contributing to the development of resistance, side effects (including C. difficile infection), and colonisation with resistant pathogens like MRSA or VRE (West 2019, Blumenthal 2018). Additionally, penicillin allergy is associated with increased healthcare costs due to longer hospital admissions and higher drug costs (Powell 2020).

Drug allergy assessment generally involves two steps: an initial risk stratification to identify severe allergies and then if appropriate, a direct challenge with the suspected allergen. Typically conducted by specialist immunology/allergy services, this process requires skilled personnel, and there is often limited access.

This protocol outlines the Penicillin Allergy De-Labelling (PADL) process, a simplified assessment for evaluating low-risk penicillin allergies that can be safely conducted by non-allergists (Cooper 2020). It aligns with the standards set by the Standards of Care Committee of the British Society for Allergy and Clinical Immunology (BSACI) (Savic 2022).

2. PURPOSE

- Identification of patients with a documented penicillin allergy who may be suitable for allergy challenge test and subsequent de-labelling
- To reduce inappropriate penicillin allergy labels and improve detail and accuracy of allergy history documentation in patients' clinical records, in order to optimise infection treatment and antimicrobial stewardship.

3. DEFINITION

Penicillin allergy de-labelling refers to a risk-based process to remove penicillin allergy labels from patients with unverified allergy.

4. EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality

schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Equality, Diversity, and Inclusion Policy (CORP/ EMP 59).

The purpose of the EIA is to minimise and if possible, remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 7).

5. DUTIES AND RESPONSIBILITIES

PADL protocol will initially be implemented for inpatients only. The patient's primary team is responsible for assessing whether their patient is suitable for PADL.
Penicillin challenge should only be performed in clinical areas where there is easy access to a resuscitation trolley. It should be performed on weekdays during normal working hours and not out of hours, weekends or bank holidays.
No formal training is required to deliver this protocol, but the following roles/skillsets are necessary to complete the whole protocol:
A) Assessor: Will assess whether patient is suitable for PADL. The decision to use the PADL protocol must be discussed and agreed with a registrar or consultant.
B) Prescriber: Prescribe the required medication.
C) Observer: Provide direct patient observation and periodic monitoring of vital signs for one hour after direct challenge, typically a healthcare assistant, nurse, doctor, PA or ACP.
D) Allergy Management: A healthcare provider trained in managing allergic reactions including anaphylaxis. They must be immediately available when needed.

6. PROCEDURE

6.1 ***What questions should you ask to get a relevant allergy history?***

Use the following questions with the decision support tool in section 4 and inclusion/exclusion criteria in section 5 to decide whether the patient is de-labelled on history alone OR is offered an oral challenge test OR cannot be offered any intervention.

1. Do you have any allergies that you know of?

2. Do you remember the details of the reaction? If a rash was present, can you describe it?

3. How many hours after having your first dose of the antibiotic did the reaction occur?

4. How many years ago did the reaction occur?

5. How was the reaction managed? What was the outcome?

6. Did the reaction resolve on stopping the antibiotic?

7. Which other antibiotics have you tolerated since this reaction?

6.2 *Use this tool to work out the nature and severity of allergic reaction*

Dermatological

Skin manifestation		Recommendation & Resultant allergy type	
Childhood exanthem (unspecified) *Mild rash with no severe features*		☐	**Unlikely to be significant (non-severe)**
Immediate diffuse rash ("itchy immediate rash") <2 hours post dose		☐	**Immediate hypersensitivity (likely non-severe)**
Diffuse rash or localized rash/swelling with no other symptoms	> 10 years ago or unknown	☐	**Delayed hypersensitivity (non-severe)**
	≤ 10 years ago	☐	**Delayed hypersensitivity (likely non-severe)**
Angioedema ("lip, facial or tongue swelling")		☐	**Immediate hypersensitivity (severe)**
Generalized swelling (outside of angioedema)		☐	**Immediate hypersensitivity (severe)**
Urticaria ("wheals and hives")		☐	**Immediate hypersensitivity (potentially severe)**
Mucosal ulceration ("mouth, eye or genital ulcers")		☐	**Delayed hypersensitivity (severe)**
Pustular, blistering or desquamating rash ("skin shedding")		☐	**Delayed hypersensitivity (severe)**

Respiratory or Systemic

Clinical manifestation	Recommendation & Resultant allergy type	
Laryngeal involvement ("throat tightness" or "hoarse voice")	☐	**Immediate hypersensitivity (severe)**
Respiratory compromise ("shortness of breath")	☐	**Immediate hypersensitivity (severe)**
Fever ("high temperature") Not explained by infection	☐	**Delayed hypersensitivity (severe)**
Anaphylaxis or unexplained collapse	☐	**Immediate hypersensitivity (severe)**

Haematological

Low platelets < 150 x10^9/L or unknown	☐	**Potential immune mediated (severe)**
Low neutrophils < 1x10^9/L or unknown	☐	**Potential immune mediated (severe)**
Low haemoglobin < 100 g/L or unknown	☐	**Potential immune mediated (severe)**
Eosinophilia (>0.7 x 10^9/L or unknown)	☐	**Delayed hypersensitivity (severe)**

Unknown

Clinical manifestation	Recommendation & Resultant allergy type	
Unknown reaction ≤ 10 years ago	☐	**Unknown (likely non-severe)**
Unknown reaction > 10 years ago or **family history** of penicillin allergy only	☐	**Unlikely to be significant (non-severe)**

Renal

Severe renal injury, failure or AIN (>50% reduction in eGFR from baseline or absolute serum creatinine increase of ≥26.5µmol/L, or transplantation, or dialysis)	☐	**Potential immune mediated (severe)**
Mild renal impairment (Does not meet criteria in box above)	☐	**Unlikely immune mediated (non-severe)**

Liver

Severe liver injury, failure or DILI (≥5x upper limit of normal (ULN) for ALT or AST, or ≥3x ULN for ALT with ≥2x ULN for bilirubin, or ≥2x ULN for ALP, or transplant)	☐	**Potential immune mediated (severe)**
Mild hepatic enzyme derangement (Does not meet criteria in box above)	☐	**Unlikely immune mediated (non-severe)**

Gastrointestinal, Neurological or Infusion-related

Gastrointestinal symptoms without other organ system symptoms ("nausea, vomiting, diarrhoea")	☐	**Unlikely immune mediated (non-severe)**
Mild neurological manifestation ("headache, depression, mood disorder")	☐	**Unlikely immune mediated (non-severe)**
Severe neurological manifestation ("seizures or psychosis")	☐	**Unknown or unclear mechanism**

Appropriate for direct de-labelling - removal of allergy label without testing [oral rechallenge if required]	**Low risk**
Appropriate for supervised direct oral rechallenge	**Moderate risk**
Consider referral to Immunology/Allergy clinic in Sheffield if deemed appropriate	**High risk**

6.3 *Inclusion and Exclusion Criteria*

6.3a Inclusion criteria (needs both):

A) Adult patient over 16 years old.

B) Reported penicillin allergy (this protocol is not appropriate for allergies to cephalosporins or carbapenems or any other non-penicillin antibiotic).

6.4b Exclusion criteria:

These include:

a) medical conditions/medications which prevent patients from having oral penicillin challenge

b) different allergic reactions which are also listed in decision support tool in section 5.

1) Current medical status/past medical history:

A) Any patients who are deemed to be acutely unwell or clinically unstable

B) Pregnant.

C) Severe or uncontrolled asthma/chronic obstructive airways disease.

D) Severe aortic stenosis.

E) Clinical concerns about poor gastrointestinal absorption.

F) Previous penicillin allergy testing which concluded that the patient was allergic to penicillin.

G) Oral antihistamine use within the last 72 hours

2) Allergy:

A) Documented or possible history of type 1 hypersensitivity reaction to penicillins, cephalosporins or carbapenems – symptoms may have included:

■ Immediate diffuse rash (less than 2 hours post dose).

■ Angioedema (e.g., lip, facial or tongue swelling).

■ Generalised swelling.

■ Urticaria (“wheals and hives”).

■ Respiratory compromise (“throat tightness”, “hoarse voice”, “shortness of breath”).

■ Wheeze.

■ Loss of consciousness and/or collapse.

B) Documented or reported type 4 hypersensitivity reaction to penicillins, cephalosporins and/or carbapenems – symptoms may have been delayed and may have included:

■ Pustular rash.

■ Blistering rash.

■ Desquamating rash (skin peeling/shedding).

■ Mucosal ulceration (e.g. eyes, mouth, genital ulcers).

■ Purpura.

■ Eosinophilia with one or more of the above skin abnormalities.

C) Patients who required hospital admission or urgent medical attention due to the previous reaction.

D) Patients who required medical intervention (including with adrenaline) for the previous reaction.

E) Any rash occurring within 2 hours of the first dose of penicillin.

F) Rash lasting more than 24 hours and/or affecting more than 10% of body surface.

G) History of rash/reaction less than 10 years ago

3) Hepatic:

Previous penicillin induced severe liver injury/failure or drug-induced liver injury (DILI) – defined:

■ Formally diagnosed by a gastroenterologist/hepatologist and/or

■ ALT/AST > 5 x upper limit of normal with no symptoms and/or

■ ALT/AST > 3 x upper limit of normal with symptoms and/or

■ ALT/AST > 3 x upper limit of normal with bilirubin > 2 x upper limit of normal and/or

■ ALP > 2 x upper limit of normal

■ Required liver transplant.

4) Renal:

Previous documented penicillin induced interstitial nephritis or severe renal injury – defined:

■ Formally diagnosed by a nephrologist and/or

■ >50% reduction in eGFR from baseline and/or

■ Increase in serum creatinine of > 26.5 umol/L and/or

■ Needed renal replacement therapy or renal transplantation.

5) Neurological:

■ Previous documented seizures or psychosis thought to be secondary to penicillin use

6) Haematological:

Previous documented penicillin induced cytopenia – defined:

■Formally diagnosed by haematologist and/or

■ Platelets < 150 x 10^6 and/or

■ Haemoglobin < 100 g/L and/or

■ Neutrophils < 1.0 x 10^6

6.4 *How to counsel and consent a patient for oral penicillin challenge*

6.4a Counselling:

Discussing allergies can be anxiety-provoking, potentially leading to physical symptoms that may complicate allergy testing. Many patients have carried penicillin allergy labels for decades, making these labels a deeply ingrained part of their medical history. Therefore, patient engagement and clear counselling are essential for a successful assessment. As part of the informed consent process, the protocol must be explained to the patient, including potential benefits and risks. **The patient should be given a copy of the "Patient Information Leaflet – Pre-test" document** and be given the opportunity to ask questions. (see Appendix 1 for a suggested script).

6.4b Informed consent:

Formal written consent using standard DBTH consent forms should be obtained before performing PADL. For patients who lack capacity, this protocol can still be offered, but clinicians should ensure that any decisions are made in the best interests of the patient and they outweigh any potential risk whilst also following appropriate legal and ethical guidelines. Monitor these patients closely in a controlled setting for allergy symptoms, as they may be unable to report them.

6.4c Suggestions for completing the consent form:

● Proposed Intervention: Penicillin allergy assessment with direct oral penicillin challenge.

● Intended Benefits: Evaluation of penicillin allergy status to ensure accurate medical records and optimised future antibiotic choices.

● Risks: Allergic reaction, possibly severe, requiring urgent medical attention or hospital admission. The risk of a severe reaction is likely to be low due to prior risk assessment. In a study involving over 1,200 patients using a similar method, there were no severe allergic reactions, and only 3.4% experienced mild reactions, such as rash or itch.

● Further Treatment That May Be Required: Symptomatic relief (e.g. antihistamines), urgent medical attention, adrenaline administration, hospital admission

6.5 Which antibiotic should you choose and how should you give it?

6.5a Choosing the challenge antibiotic:

- Selecting the appropriate antibiotic for the challenge is crucial for both safety and efficacy.
- Use the table below to guide challenge antibiotic choice:

Allergy scenario	**Antibiotic to use for the oral challenge**
Specific penicillin is listed in the allergy record and is available in oral form (e.g. "flucloxacillin" or "penicillin V")	The specific antibiotic listed in the allergy record For example, Flucloxacillin 500mg OR Penicillin V 500mg
Penicillin allergy (i.e. allergic to the penicillin class, but no specific antibiotic listed in the allergy record)	Amoxicillin 500mg
Co-amoxiclav (Augmentin)	May be allergic to amoxicillin or clavulanic acid. **Either:** **1**. Challenge with co-amoxiclav 625 mg, negative test = safe to use penicillins including co-amoxiclav, positive test = allergic to either amoxicillin or clavulanic acid. **OR** **2**. Amoxicillin 500mg only, negative test = safe to use penicillins but not co-amoxiclav specifically.
Specific penicillin is listed but not available in oral preparation (e.g. Tazocin, temocillin)	This protocol is not appropriate, do not continue
Allergy only to a non-penicillin class antibiotic (including cephalosporins, monobactams, carbapenems or other)	This protocol is not appropriate, do not continue

6.5b Dosing – single dose vs. prolonged challenge:

• In most cases, a single dose challenge will be sufficient to assess the allergy.

• If there is a clear history of a delayed penicillin reaction (i.e. symptoms occurring after 24 hours of exposure and otherwise meeting the above eligibility criteria), then a 72-hour course (prolonged drug provocation test) of challenge antibiotic can be used.

• If there is no reaction within one hour of the first dose, patients can be sent home with a 72-hour course. • The parent team performing the oral penicillin challenge will have to contact the patient after the 72 hours are completed, to confirm there was no delayed reaction.

• The decision to use a prolonged challenge needs to be balanced against the risk of promoting antimicrobial resistance.

• **The PADL team can provide further advice if required.**

6.5c Prescribing:

Prescribe the planned antibiotic as a stat dose on Wellsky, if single dose is to be used. Chlorphenamine tablets and nebulised Salbutamol can be prescribed as PRN medications at the same time.

6.6 Performing oral penicillin challenge

Procedure for oral penicillin challenge – use proforma in appendix 4:

• A baseline set of observations are recorded.

• The patient takes the oral challenge penicillin dose.

• Further observations are recorded at 10, 20, 40 & 60 minutes.

• Patients should be observed during this period and encourage to report any new symptoms.

• If symptoms develop then further assessment is required to determine if these are allergic in nature.

• **After 60 minutes, an interpretation of the challenge can be made**.

• Use proforma in appendix 3 to document.

Additional tips:

● Before starting the challenge, the team should assign their roles including how to escalate concerns/patient deterioration.

● The healthcare professional who will be contacted for a medical review should remain in the same clinical area for the duration of the challenge.

● They should always be contactable, either by mobile phone or bleep.

6.7 How to manage allergy symptoms following an oral penicillin challenge

Severe symptoms:
- Examples: Hoarse voice, stridor, wheeze, breathing difficulties, cyanosis, hypotension, drowsy, confusion, collapse, severe skin reaction, abnormal/worsening NEWS score.
- Urgent senior medial review & consider crash team (2222).
- Start anaphylaxis management (see latest Resuscitation Council Guidelines) including:
  - ABCDE assessment.
  - Intramuscular (IM) adrenaline.
  - High flow oxygen if hypoxic.
  - Fluid bolus

Mild symptoms:
- Examples: Itch, urticaria, sneezing, rhinitis (with no severe symptoms/abnormal NEWS score).
- Medical review.
- Consider if the symptoms could be related to anxiety as opposed to allergy, look for objective evidence of the reported abnormalities - for example:
  - Sensation of throat tightness is not the same as objective swelling of oropharynx.
  - Dizziness is not the same as objective evidence of hypotension.
  - Isolated itching is not the same as objective evidence of urticarial rash.
- If anxiety is suspected then reassurance may be all that is required.
- Consider the following if these is objective evidence of symptoms related to allergy:
  - Oral antihistamines (e.g. chlorphenamine 4mg)
  - Inhaled bronchodilators (e.g. 2 puffs of salbutamol)
  - Oral steroid (e.g. stat 30mg prednisolone)
- Continue to monitor the patient beyond the hour specified in the protocol to ensure resolution.

Interpretation of oral penicillin challenge

Negative test
- No symptoms & NEWS unchanged.
- Isolated nausea & no other features of a positive test.
- Isolated itch with no rash & no other features of a positive test.
- Isolated HR elevation (SpR/consultant to interpret if uncertain).

Action:
- Explain result to patient
- Provide neg test letter
- Document in notes
- Remove allergy label from Wellsky

Equivocal test:
- Symptoms do not fit in negative or positive categories.
- Doubt remains after review by SpR/consultant.

Action:
- Manage allergy symptoms.
- Take tryptase level.
- Explain result to patient.
- Provide equivocal test letter.
- Document symptoms & outcome in notes.
- Update allergy info on Wellsky
- Consider allergy referral.

Positive test:
- Itch with rash, urticaria, sneezing, rhinitis, breathing difficulties, facial swelling, hypotension, confusion, drowsy.
- Diagnosis of anaphylaxis.

Action:
- Urgent medical review
- Consider crash team (2222)
- Manage allergy symptoms.
- Take tryptase level.
- Explain result to patient.
- Provide positive test letter.
- Document symptoms & outcome in notes.
- Update allergy info on Wellsky

For details of documenting allergy status on Wellsky please see Appendix 6

Management of suspected allergic reactions – additional tips.

- Document symptoms clearly including timings in relation to antibiotic exposure and make a judgement of whether the symptoms are due to allergy.
- Treat symptoms as per figure in section 9.
- Add the allergy to the patient's medical record if the symptoms are due to allergy ('re-label').
- Consider referral to dermatology for a severe skin reaction (e.g. pustular, blistering, desquamating, mucosal ulceration, purpura and/or associated eosinophilia).
- Notify the PADL team with patient details, purported allergen, clinical assessment, and timing of symptom onset in relation to antibiotic exposure.
- Advise the patient they are allergic to penicillin antibiotics and give them a positive test patient information leaflet
- Reactions deemed to be equivocal can be referred to Immunology/Allergy, see section 13.
- Some patients may not react immediately but show a delayed reaction (> 1 hour after penicillin challenge). Patients who do not react immediately (< 1 hour) after receiving penicillin (apparently negative test) may potentially react in the next few hours or even days. Therefore, if inpatient, the parent team needs to be aware of this possibility. If patient is going home, they/carers should be made aware and, advised to dial 999 and seek help in case of any symptoms suggestive of an allergic reaction (see figure in section 9). The "Patient Information Leaflet – Post-test" document includes advice for the patient on how to respond to delayed symptoms.

6.8 How to interpret an oral penicillin challenge

- Follow the guidance in figure under section 9 to determine the test outcome as **positive, negative, or equivocal.**

- One hour after administering the oral dose, the assigned medic should review the patient, the procedure documentation including observations chart, and any reported symptoms.
- If symptoms were reported, discuss them further with the patient and the observing team member to gain an accurate account.
- Make a judgement as to whether the symptoms represent true allergy or not, see section 10.1
- Give the patient the appropriate "Patient Information Leaflet – Post-test" based on the test outcome.
- If using a prolonged challenge then prescribe additional doses up to 72 hours, counsel patients on symptoms to be aware of, and make arrangements to contact the patient after the challenge is completed to ensure there are no delayed symptoms.

Differentiating anxiety related symptoms from true allergy

• Allergy can provoke feelings of anxiety, and this may cause symptoms and signs that can be incorrectly interpreted as signifying allergy (i.e. a false positive challenge).

• If any symptoms develop then the patient should be reviewed, and a judgement made as to whether the symptoms are due to true allergy or not.

• The following symptoms usually don't indicate allergy: Throat tightness without visible oropharyngeal swelling or abnormal observations, Dizziness without hypotension or arrhythmia, isolated mild itching without objective evidence of rash, isolated mild tachycardia without any other features of severity.

Antibiotics that can be used after a negative test

• Patients with a negative penicillin oral challenge can have penicillins. They generally have the same risk of reacting to penicillin-based antibiotics as those who have never had a penicillin allergy label. Therefore, reactions to different penicillins might still occur, potentially due to an allergy to a specific side chain (e.g. flucloxacillin is relatively unique) or to a non-penicillin component including beta-lactamase inhibitors (e.g. clavulanic acid), or excipients.

• Some patients may only experience allergic symptoms after a longer course (i.e. more than 24 hours), see prolonged challenge above.

• The "Patient Information Leaflet – Post-test" document includes advice for the patient on how to respond to delayed symptoms.

• A negative penicillin allergy de-labelling test as described in this protocol does not mean the patient can safely use cephalosporins, monobactams or carbapenems, in case of suspected allergy to these antibiotics.

- **See Appendix 5**

6.9 Reporting

- Inform GP through discharge letter when patient is about to be discharged. Follow the script in appendix 3. If the primary care record is not updated, there is a risk of re-labelling where an incorrect allergy status is transcribed back from primary to secondary care notes.
- Email the results of penicillin challenge to PADL team at dbth.penicillinallergydelabelling@nhs.net. Include patient's details, date of penicillin challenge and the outcome.

6.10 *Referral to Immunology services*

Consider referral to STH outpatient immunology services in those who have an equivocal test with early onset symptoms (within one hour of the challenge) and one or more of the following apply:

- History of adverse reaction to more than one family of antibiotics.
- Patients with a chronic condition associated with an increased risk of recurrent infection (e.g. bronchiectasis).
- Due to undergo major medical intervention (e.g. pre-transplantation).

7. PATIENTS LACKING CAPACITY

Sometimes it will be necessary to provide care and treatment to patients who lack the capacity to make decisions related to the content of this policy. In these instances staff must treat the patient in accordance with the Mental Capacity Act 2005 (MCA 2005).

- A person lacking capacity should not be treated in a manner which can be seen as discriminatory.
- Any act done for, or any decision made on behalf of a patient who lacks capacity must be done, or made, in the persons Best Interest.
- Further information can be found in the MCA policy, and the Code of Practice, both available on the intranet.

There is no single definition of Best Interest. Best Interest is *determined on an individual basis. All factors relevant to the decision must be taken into account, family and friends should be consulted, and the decision should be in the Best interest of the individual. Please see S5 of the MCA code of practice for further information.*

8. TRAINING AND SUPPORT

No formal training is required to deliver this protocol, but the following roles/skillsets are necessary as documented in 5. Duties and responsibilities.
The PADL team will provide training and awareness raising across the Trust in line with the implementation of new guidance or updates.
Support is available from the PADL team as required.

9. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/Where Reported to
The policy will be reviewed in the following circumstances	Antimicrobial Stewardship Team and Infection Tea.	Every three years routinely, unless: • When new national or international guidance are received. • When newly published evidence demonstrates	Policy will be approved by drugs and Therapeutics and Patient Safety Review Group.

		need for change to current practice. • Action required for Patient Safety Incident	

10. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Antimicrobial Use in Penicillin Allergy – Section 5, Doncaster and Bassetlaw Medicines Formulary.

Equality Diversity and Inclusion Policy CORP/EMP 59

Equality Analysis Policy CORP/EMP 27

Mental Capacity Act 2005 - Policy and Guidance including Deprivation of Liberty Safeguards (DoLS) - PAT/PA 19

Privacy and Dignity Policy PAT/PA 28

11. DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

12. REFERENCES

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APPENDIX 1 SUGGESTED SCRIPT FOR PATIENT COUNSELLING

You have been identified as having a penicillin allergy and I would like to discuss that further with you, in particular whether you would be interested in an assessment of your penicillin allergy status. I will tell you a little bit of background information then explain the testing itself. Penicillins are an important class of antibiotics that are used very commonly to treat a variety of infections, including potentially severe and life-threatening infections like meningitis or blood stream infections. In many infections we know that penicillin antibiotics are better at fighting bacteria than many other antibiotics and therefore result in better outcomes. When a patient has a reported penicillin allergy it means that we have to use alternative groups of antibiotics that may be less effective and have a higher rate of side effects including acquiring resistant “superbug” bacteria like MRSA and C. difficile. Removing false penicillin allergies is also important in contributing to the fight against antibiotic resistance which is a major global public health problem. Approximately 1 in 10 people have a penicillin allergy label on their medical records but for every 10 people who have allergy testing only 1 will have a genuine allergy. For many people the symptoms they experienced after taking a penicillin were either due to the infection they had at the time and/or were actually side-effects such as diarrhoea or nausea. Whilst these symptoms are not pleasant, they are not a true allergy and shouldn't prevent someone having a penicillin antibiotic if they need it. Furthermore, allergy is not fixed and for many it can wane with time. From the information available to us it seems like you are at low risk of having a genuine penicillin allergy and we would therefore like to offer you a penicillin allergy assessment. This can be performed on the ward and will involve some discussion about your previous reported allergies. We will then proceed to the next stage where we will give you a single oral dose of a penicillin antibiotic. A member of staff will stay with you for one hour afterwards and they will monitor your observations (blood pressure, heart rate etc). If after one hour we have not observed any evidence of an allergic reaction we can safely remove the allergy label from your records, and we will write to your GP to ask them to do the same.

This type of assessment has been studied in thousands of patients and has proven to be effective and safe. The main risk of taking this test is developing an allergic reaction and although rare this could be severe including anaphylaxis. However, the testing is designed to exclude people who are at higher risk of developing a severe reaction. When studied in 1200 patients, a protocol like this was associated with zero episodes of anaphylaxis and only 3% developed any symptoms, mostly a mild itchy rash that resolved quickly. Importantly nearly all of those patients (96.5%) were able to safely have their penicillin allergy label removed. The main benefit of this test is that we will know exactly the nature of your penicillin allergy and your medical records will be more accurate. Being able to have penicillin antibiotics in the future should you develop a bacterial infection could potentially be lifesaving”.

APPENDIX 2 MANAGING PATIENTS WHO HAVE TOLERATED A PENICILLIN SINCE THE INDEX REACTION

Scenario	Recommendation	Explanation
A history consistent with an IgE mediated reaction to a known penicillin and has tolerated the same penicillin or amoxicillin since the index reaction.	De-label on history alone	Tolerating the index penicillin rules out IgE mediated reactions. Tolerating amoxicillin rules out IgE reaction to the beta-lactam ring and the most common R1 side chain allergen. Amoxicillin is the penicillin used to definitively rule out IgE allergic reactions during formal allergy testing.
A history consistent with an IgE mediated reaction to a known penicillin or unknown penicillin and has tolerated a penicillin antibiotic since but it wasn't the index penicillin or amoxicillin.	Cannot de-label based on the fact they have since tolerated penicillin.	IgE mediated reactions can be due to the beta-lactam ring or the R1 side chain. Selective reactivity can occur to amoxicillin, piperacillin-tazobactam and flucloxacillin R1 side chains. American studies suggest selective IgE mediated allergy to amoxicillin is very rare whereas European studies suggest it may be between 25-50% of patients with positive skin tests have selective allergy to amoxicillin.
A history consistent with a low-risk allergy history that meets criteria for a Direct oral challenge test but has tolerated any penicillin / unknown penicillin since the index reaction.	De-label on history alone	Low risk allergy histories that meet criteria for Direct oral challenge are not likely to re-react to penicillin when challenged. Ruling out beta-lactam ring sensitivity is sufficient in these patients.
An allergy history consistent with a severe delayed reaction (Gell and Coombs types 2-4) and includes DILI, cytopenia, AIN, AGEP, DRESS, SJS/TEN and tolerated any penicillin or unknown penicillin since index reaction	Avoid all beta-lactams	High risk allergy group and little is understood about the best method to de-label these patients. Prior tolerance does not rule out severe delayed reactions on subsequent exposure

APPENDIX 3 SUGGESTED SCRIPTS FOR GPS (ADD TO DISCHARGE LETTER)

Positive test – Penicillin allergy confirmed

Dear Dr XXXXXX

Your patient XXXXXX underwent assessment of their penicillin allergy label during a recent hospital attendance. After carefully reviewing their history, and discussion of risks and benefits, a supervised oral penicillin challenge was performed. A dose of XXX of XXXXXX antibiotic was administered on **[date]**.

There was evidence of an allergic reaction, as detailed below:

Give details of reaction

The patient has been informed that they **should not take penicillin-based antibiotics** in the future. Examples of these antibiotics include phenoxymethylpenicillin (penicillin V), amoxicillin, flucloxacillin, and co-amoxiclav (Augmentin).

Action for GP: Please record this description and date of observation in their medical record as confirmation of their allergy status. Please also ensure their allergy status is clearly documented in all future correspondence/records.

If you have any queries regarding the test process or outcome, please do not hesitate to contact me.

Thanks, and best wishes

Name and Grade

Enquiries contact:

Negative test – No allergic reaction to penicillin

Dear Dr XXXXXX

Your patient XXXXXX underwent assessment of their penicillin allergy label during a recent hospital attendance. After carefully reviewing their history, and discussion of risks and benefits, we removed this allergy record from our hospital's medical notes.

Patient gave a history as follows: [state patient's previous reaction/symptoms e.g. benign skin reaction in childhood / nausea]

Subsequent exposure to a penicillin antibiotic during inpatient stay: [state whether this was a supervised oral penicillin challenge using dose XXX of XXXXXX antibiotic OR a course of penicillin antibiotic for patients who are de-labelled on history alone]

Patient reported side effects: [state whether course or challenge was well tolerated. If not, include details of symptoms]

Action for GP: Based on this we can advise you that **there is no evidence to now support a "penicillin allergy" label.** We request that you remove this allergy label from your patient's medical record and record details of the allergy test (antibiotic and date). This information should be shared with other healthcare providers within your Practice and their regular community pharmacy and general dental practitioner if possible.

The risk of allergic reaction to penicillin in a de-labelled patient is the same as that of the general population and **they can therefore receive penicillin antibiotics**. This is important for management of any future infections as penicillins are often recommended as first line therapy due to their effectiveness and lower risk of driving antimicrobial resistance. **Your patient has also been informed that they can safely take penicillin-based antibiotics in future.**

If you have any queries regarding the test process or outcome, please do not hesitate to contact me.

Thanks and best wishes

Name and Grade

Enquiries contact:

Equivocal result to oral penicillin challenge

Dear Dr XXXXXX

Your patient XXXXXX underwent assessment of their penicillin allergy label during a recent hospital attendance. After carefully reviewing their history, and discussion of risks and benefits, a supervised oral penicillin challenge was performed. A dose of XXX of XXXXXX antibiotic was administered on **[date]**.

Patient developed the following symptoms after the challenge:

Give details of reaction

Although these symptoms do not fully confirm penicillin allergy, **true allergy cannot be ruled out.** We will make a referral to Immunology services for further evaluation (include this if parent team decides to send a referral to immunology). The patient has been informed that they **should not take penicillin-based antibiotics until their allergy is excluded**. Examples of these antibiotics include phenoxymethylpenicillin (penicillin V), amoxicillin, flucloxacillin, and co-amoxiclav (Augmentin).

Action for GP: Please record this description and date of observation in their medical record, and **retain their penicillin allergy label for now.**

If you have any queries regarding the test process or outcome, please do not hesitate to contact me.

Thanks, and best wishes

Name and Grade

Enquiries contact:

APPENDIX 4 PROTOCOL FOR THE ADMINISTRATION OF AN ORAL PENICILLIN CHALLENGE

Protocol for the administration of an oral penicillin challenge

Only for use after completion of the assessment algorithm + those classified as safe to proceed.

Patients must be closely observed throughout the procedure and must not leave the ward.

Urgent medical review (name/bleep/mob):

General advice:
- Obs = HR, BP, RR, SpO2 ± PEFR if asthmatic.
- Document all obs on Nerve center & monitor the calculated NEWS – escalate abnormalities as normal.
- Ask the patient to notify you if they experience any symptoms but avoid repeated questioning.
- Repeat obs at the specified time points after oral challenge & additionally if any symptoms reported.

Preparation:
- Prescribe the appropriate penicillin on Wellsky.
- Confirm the team roles: observer, medical support.
- Resuscitation trolley is easily available & stocked.

Step 1
Time = 0 minutes: **Time:**
- HR, BP, RR, SpO2 ± PEFR.
- Administer oral penicillin as prescribed.

Step 2
Time = 10 minutes: **Time:**
- Repeat HR, BP, RR, SpO2 ± PEFR.

Step 3
Time = 20 minutes: **Time:**
- Repeat HR, BP, RR, SpO2 ± PEFR.

Step 4
Time = 40 minutes: **Time:**
- Repeat HR, BP, RR, SpO2 ± PEFR.

Step 5
Time = 60 minutes: **Time:**
- Repeat HR, BP, RR, SpO2 ± PEFR.
- Notify the assigned medic the test is complete.
- Medic to interpret the outcome of the test
- Explain the results to the patient & provide the relevant 'post test' Patient Information Leaflet.

Patient details

Severe symptoms:
- Hypotension
- Breathing difficulties
- Confusion/drowsy
- NEWS elevated

Initial action:
- Urgent medical review
- Consider crash team on 2222
- Start anaphylaxis management
- See overleaf for more advice.

Mild symptoms:
- Isolated rash
- Isolated itch
- Isolated increased heart rate
- All without elevated NEWS

Initial action:
- Medical review
- Reassure patient.
- Consider anxiety as a cause. •

See overleaf for more advice.

Document symptoms and time:

APPENDIX 5 SAFETY OF ANTIMICROBIALS IN CONFIRMED PENICILLIN ALLERGY

Penicillin-based drugs should not be prescribed and/or administered to patients with penicillin allergy. As general guidance, the list below gives information on which antibiotics are contraindicated, considered safe, or to be used with caution in patients with a penicillin allergy. This list is not exhaustive- please contact a member of the Infection/PADL team for further advice if needed

For suitable alternatives in patients with documented penicillin allergy, please refer to the appropriate Trust guideline for the infection being treated.

Contraindicated (discuss with PADL/Infection Consultant if no suitable alternative)

Amoxicillin/Ampicillin	Flucloxacillin	Piperacillin/tazobactam
Benzylpenicillin	Pivmecillinam	Temocillin
Co-amoxiclav	Phenoxymethylpenicillin (Penicillin V)	

Caution – Not for use in patients with serious penicillin allergy i.e. anaphylaxis, breathing difficulties, facial swelling, urticarial rash or other major skin reactions (rashes which are **not raised** and **not itchy**; and developed over several days are not usually associated with severe reactions). If in doubt, contact the Microbiology Department.

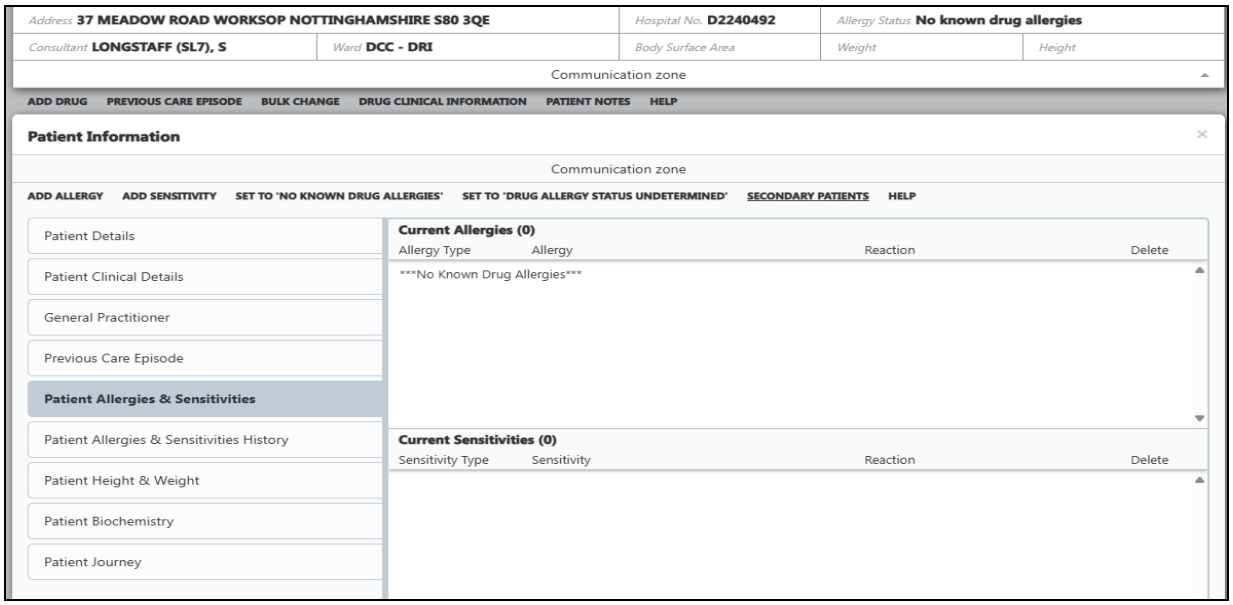
Aztreonam	Cefixime	Cefotaxime	Meropenem
Cefalexin	Cefradine	Ceftazidime	Ertapenem
Cefaclor	Cefuroxime	Ceftriaxone	Imipenem
Cefazolin	Cefiderocol		

Considered Safe

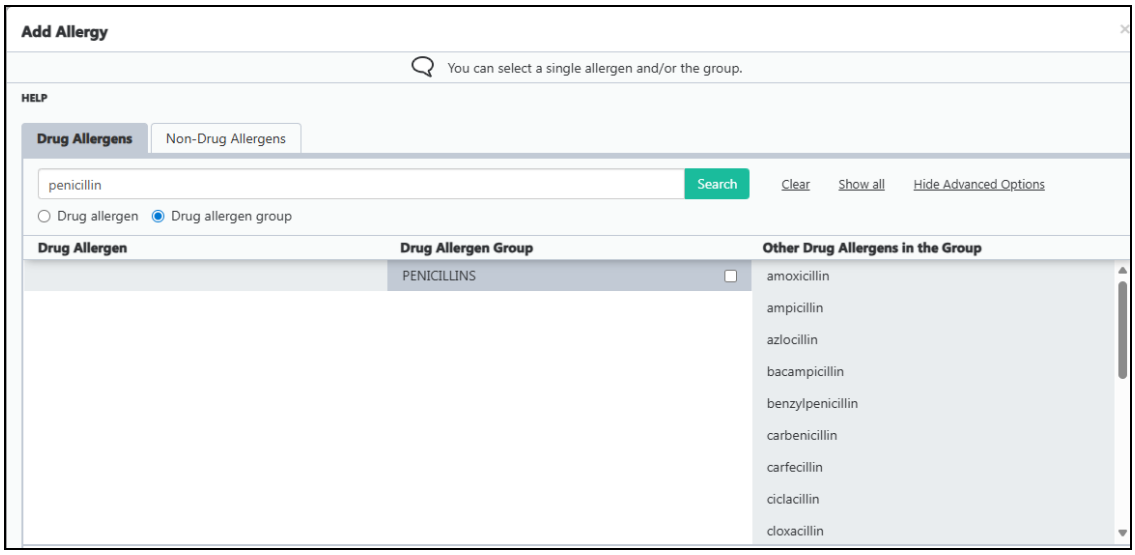
Amikacin	Clindamycin	Erythromycin	Metronidazole
Azithromycin	Colistimethate	Fosfomycin	Nitrofurantoin
Ciprofloxacin	Co-trimoxazole	Linezolid	Trimethoprim
Clarithromycin	Doxycycline	Levofloxacin	Tetracycline
Gentamicin	Dalbavancin	Teicoplanin	Vancomycin

APPENDIX 6 RECORDING ALLERGY STATUS ON WELLSKY

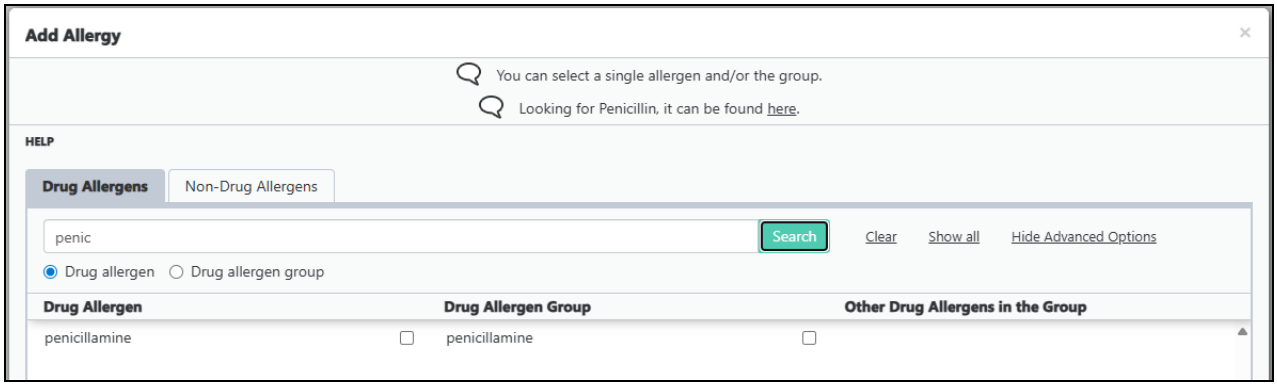
- Click on the allergy status box and select an option from the top.



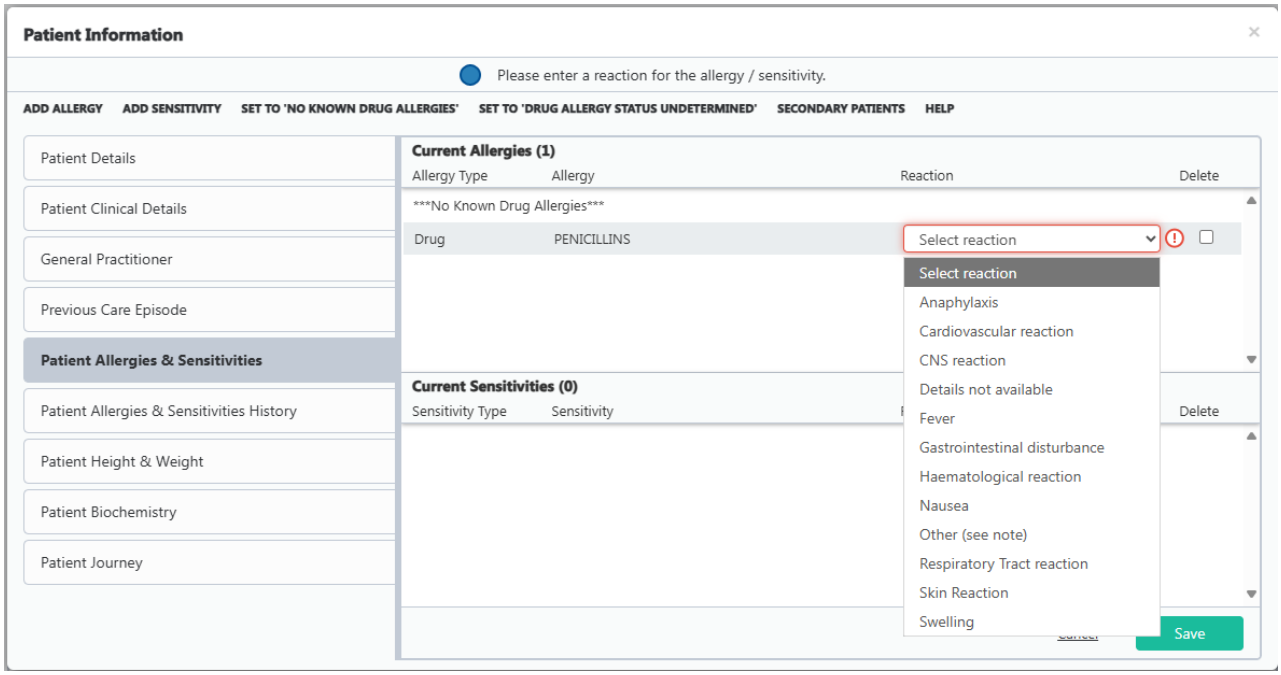
- To remove an allergy select the delete box and save, or click 'set to no known allergies' if there are none
- To add a penicillin allergy, select **drug allergen group** and type penicillin in the search box



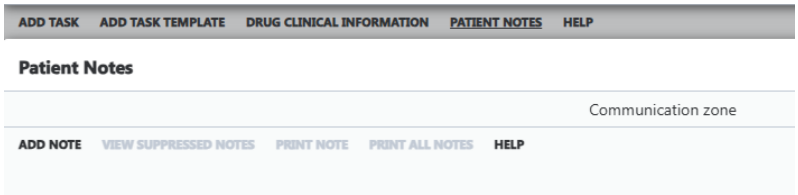
- Do not use the drug allergen option unless you are searching for a specific antibiotic as this will find penicillamine when penicil is searched.

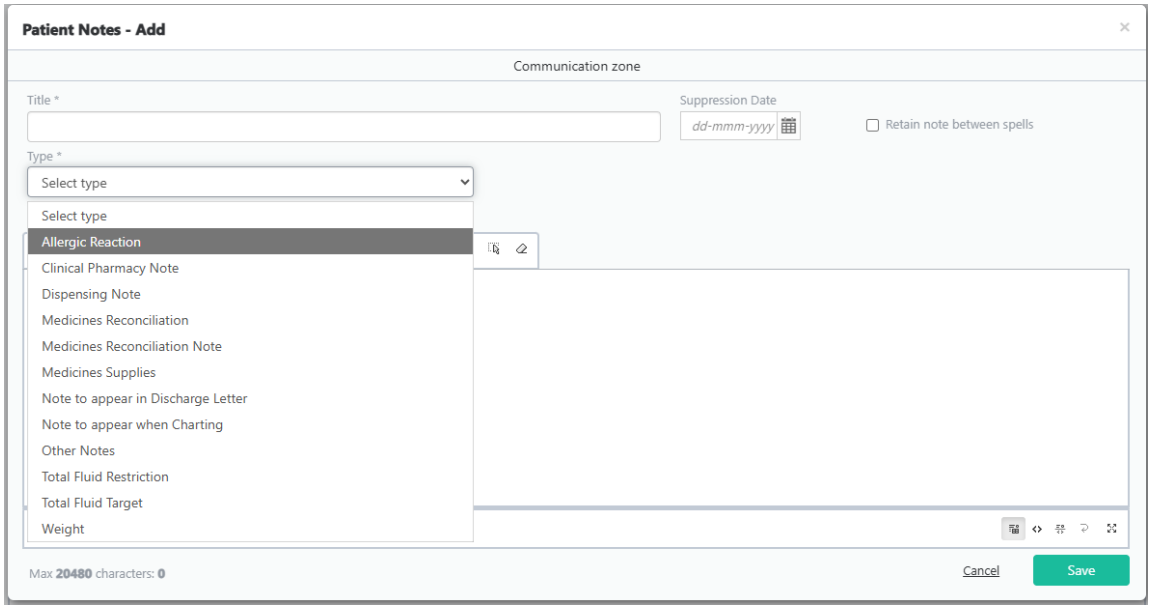


- Select an appropriate option from the dropdown list



- A note can be added to record additional details of reactions for further information.




Patient Notes - Add
Communication zone
Title *
Suppression Date
dd-mmm-yyyy
Retain note between spells
Type *
Select type
Select type
Allergic Reaction
Clinical Pharmacy Note
Dispensing Note
Medicines Reconciliation
Medicines Reconciliation Note
Medicines Supplies
Note to appear in Discharge Letter
Note to appear when Charting
Other Notes
Total Fluid Restriction
Total Fluid Target
Weight
Max 20480 characters: 0
Cancel
Save

APPENDIX 7. EQUALITY IMPACT ASSESSMENT - PART 1 INITIAL SCREENING

Service/Function/Policy/Project/Strategy	Division/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Penicillin allergy de-labelling guidance in adult patients PAT MM 14 v.1	Medicine	Heather Holt	New	05/09/2025

1) Who is responsible for this policy? Name of Division/Directorate**:** Medicine

2) Describe the purpose of the service / function / policy / project/ strategy? – Trust-wide Guidance

3) Are there any associated objectives? Legislation, targets national expectation, standards - National Guideline, Trust Strategy

4) What factors contribute or detract from achieving intended outcomes? - None

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, Maternity/pregnancy and religion/belief? - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation]

6) Is there any scope for new measures which would promote equality? No

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	Excluded from guideline in line with national guidance.
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4

Date for next review: September 2028

Checked by: Daniel Baynes **Date:** September 2025