

THIS PATIENT IS BEING CONSIDERED FOR A PENICILLIN ALLERGY CHALLENGE AND DE-LABELLING (PADL) EXERCISE

Name: _____
 CHI/DoB: _____
 Address: _____
 Postcode: _____

This guidance applies to the ADULT population of patients only

START HERE

Is there a history suggestive of a **Type IV Hypersensitivity Reaction** to a penicillin?
 1. Rash with blistering
 2. Oral or genital ulceration/blistering
 3. Rash associated with a severe systemic illness requiring admission to hospital

YES

If **YES** to any – Patient is **UNSUITABLE** for penicillin challenge

NO

Do **any** of the following criteria apply?
 1. Symptoms typical of intolerance rather than allergic reactions, such as **minor GI upset, nausea, headaches and fatigue**
 2. Family history of penicillin allergy but with no personal history of penicillin allergy
 3. History of tolerating a penicillin following the index reaction

If **YES**, history is inconsistent with allergy and can be **DIRECTLY DE-LABELLED** without need for an oral challenge

Patient disagrees with direct de-labelling

CONSIDER PENICILLIN CHALLENGE
 The overall risk of immediate allergy is low. Refer overleaf and complete documentation below

Determine the risk of an underlying **Type I Hypersensitivity Reaction** to a penicillin
 Were **any** of the following features reported following a penicillin dose?
 1. Collapse
 2. Facial +/- throat swelling
 3. Breathing difficulties
 4. Itchy rash

YES

If **YES** to any and within 1 hour of administration – There is a high probability of **Type I Hypersensitivity Reaction**
 Patient is **UNSUITABLE** for penicillin challenge

NO / UNCERTAIN

UNCERTAIN

Do **any** of the following criteria apply?
 1. Reaction occurred less than 10 years ago
 2. Patient was admitted to hospital or required urgent medical care because of the reaction
 3. Reaction occurred within an hour

YES

UNSUITABLE for penicillin challenge without specialist review
CONSIDER referral to a specialist for consideration of detailed allergy assessment (if available)

NO

CIRCLE WHICH IS APPLICABLE

CHALLENGE DOCUMENTATION

I confirm that the patient is categorically eligible for [*penicillin challenge / direct de-labelling*] YES NO

I have provided a PIL and [*obtained informed consent / Informed patient of direct de-label*] YES NO

Penicillin allergy [*de-labelled / adverse reaction updated*] on [*HEPMA / ECS*] YES NO

If inpatient, IDL updated with results of [*direct de-label / penicillin challenge*] YES NO N/A

Penicillin allergy de-labelling documented on Clinical Portal (see separate instructions) YES NO N/A

[*AMOXICILLIN*] < Patient challenged with > [*FLUCLOXACILLIN / OTHER (.....)*]
 [*DE-LABEL*] < Result of penicillin challenge > [*CANNOT DE-LABEL*]

Prescriber name: _____ Designation: _____ Signature: _____ Date: _____

PROTOCOL FOR THE ADMINISTRATION OF AN ORAL PENICILLIN CHALLENGE

This protocol is designed to be used in conjunction with the algorithm overleaf and should only be applied by staff trained and equipped in the management of an anaphylactic reaction. Antibiotic challenges can result in immediate allergic reactions, including **ANAPHYLAXIS**. Patients must be closely observed during the undertaking of this procedure and must not leave the ward.

Ensure that properly equipped resuscitation equipment is immediately available in the clinical area

PREPARATION

1. Review the exclusion criteria for oral challenge
 - **Oral antihistamines should be stopped for 72 hours prior to challenge as they may mask true allergy**
2. Select the antibiotic to be used.
3. Discuss the plan for an oral penicillin challenge with the patient and give them the patient information sheet
4. Record in the case notes that consent has been obtained

EXCLUSION CRITERIA

- Medically unstable (NEWS more than 2)
- Pregnant
- Uncontrolled asthma
- Unstable coronary artery disease
- Ongoing ACEi or Beta-blocker unless can be withheld 24 before challenge
- Antihistamine use within the past 72 hours

PROCEDURE

1. Measure the patient's observations (HR, BP, oxygen saturation, RR).
 - **If the patient has asthma, measure peak expiratory flow rate (PEFR)**
2. Medical staff should prescribe and administer the antibiotic and then remain within the clinical area for the first 20 minutes
3. The chosen antibiotic should be administered as a single oral dose
 - Amoxicillin 500mg OR Flucloxacillin 500mg
4. Inform the patient to notify you immediately if they experience any adverse symptoms
5. Measure the patient's observations (and PEFR if indicated) if they experience any symptoms and at regular intervals such as 10, 20, 40 and 60 minutes
6. Record any symptoms the patient experiences
7. **If the patient reports any of the symptoms of a positive test (see box) or they have a rising NEWS score, then the patient should be reviewed immediately by an appropriate senior member of staff**

MANAGING A REACTION

Severe symptoms such as **hypotension or breathing difficulties** institute immediate management of anaphylaxis, call for senior medical review and consider putting out a **2222**

Mild symptoms such as an isolated rash and an unchanged/unelevated NEWS score, administer an antihistamine and consider a single dose of prednisolone 30mg

POST-PROCEDURE CARE

1. Interpret the oral challenge as shown in the colored boxes below
2. If the challenge is negative (no reaction occurred)
 - Give the patient the patient information leaflet ([PIL](#))
 - Record in the discharge letter and ask the patient's GP to amend their allergy on the practice records
 - Update HEPMA if inpatient
 - Update ECS if outpatient
 - Update Clinical Portal (see separate instructions on how to do this)
3. **If the challenge outcome is positive, written and electronic records must clearly state this**
 - Give the patient the patient information leaflet ([PIL](#))
 - Record the outcome of the challenge in the discharge letter
 - Update HEPMA with reaction type if inpatient
 - Update ECS with reaction type if outpatient
4. The patient should be provided with the information leaflet and the GP informed of the outcome (if inpatient)

NEGATIVE TEST

No symptoms reported during the period of observation and patient's NEWS score does not rise

Patient experiences isolated nausea or isolated itch without any other features of a positive test

DE-LABEL

EQUIVOCAL TEST

If there is doubt about the interpretation of the test, this should be discussed with a senior clinical and referral to a local allergy service (if available) should be considered

CANNOT DE-LABEL

POSITIVE TEST

Patient experiences any of the following

1. Itchy rash
2. Breathing difficulties
3. Facial swelling
4. Hypotension

THIS DOCUMENT IS DEVELOPED IN CONJUNCTION WITH THE PENICILLIN DE-LABELLING QUALITY IMPROVEMENT PROJECT

FOR THE RESPONSIBLE CLINICIAN
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