Penicillin allergy de-labelling algorithm for adults

BOX 1

Severe Cutaneous Adverse Reactions (SCAR)
eg Drug reaction with eosinophilia and systemic symptoms (DRESS), Stephens – Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN) or Acute generalised exanthematous pustulosis (AGEP)

Is there a history of severe cutaneous adverse reactions (SCAR) (See box 1)?
OR
Were any of the following factors present:
- ❑ Rash with blistering?
- ❑ Oral or genital ulceration or blistering?
- ❑ Rash associated with a severe systemic illness requiring admission to hospital?

YES → **STOP and DO NOT administer a penicillin or other beta-lactam antibiotic to the patient**

NO

Is there a history suggestive of type 1 hypersensitivity reaction?
Were any of these features reported following of a dose of a penicillin antibiotic: Collapse, face or throat swelling, breathing difficulties or itchy rash?

NO

LOW RISK PATHWAY

Do any of the following criteria apply?

- ❑ symptoms typical of intolerance rather than allergic reactions, including minor gastro-intestinal upset, nausea, headache, fatigue
- ❑ family history of penicillin allergy but with no personal history of penicillin allergy
- ❑ history of tolerating penicillin following the initial reaction

YES

Is patient history unclear, or patient is unwilling to accept direct de-label

NO

Patient history is inconsistent with penicillin allergy
Patient does not require allergy testing or oral challenge
Directly de-label and record assessment process and outcome in medical records as “not penicillin allergic”
Communicate with GP to remove penicillin allergy label

UNCERTAIN

MEDIUM RISK PATHWAY

Do any of the following criteria apply?

- ❑ Did the reaction occur in the last 5 years?
- ❑ Was the patient admitted to hospital, or did they require urgent medical care as a result of the reaction?
- ❑ Did the reaction definitely occur within an hour?

NO

Consider oral challenge only in secondary care.
Overall risk of immediate allergy low.
- Review by experienced clinical practitioner required
- See oral challenge protocol for more information
- If oral challenge is negative, communicate with GP to remove penicillin allergy label
- Consider PEN-FAST in assessing risk (see box 2)

See protocol for the administration of oral challenge for use only in secondary care

YES

YES

HIGH RISK PATHWAY

If YES and the reaction was within one hour, then **HIGH PROBABILITY** of Type 1 hypersensitivity reaction

Avoid penicillin antibiotics and do not give other classes of beta-lactam antibiotic without specialist review.

- Give patient the post-assessment information for high risk patients and allergy warning card.
- Unsuitable for penicillin allergy de-labelling without specialist review.
- Consider referral to a specialist for consideration of detailed allergy assessment if available

BOX 2

Penicillin Allergy Decision Rule (PEN-FAST) (mdcalc.com) can be used to assess risks.
A score of less than 3 can identify low-risk patients suitable for oral challenge

Cautions:
- This algorithm is only appropriate for patients reporting allergy to penicillin. It is not intended for use in patients reporting allergy or intolerance to other antibiotic classes including cephalosporins and carbapenems.
- For patients taking beta-blockers and ACE inhibitors an oral challenge can be considered but see FAQs.
- Oral challenge should only be undertaken by staff who are trained and equipped in anaphylaxis management

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Protocol for the administration of oral penicillin challenge in secondary care

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This protocol is designed to be used in secondary care in conjunction with the penicillin allergy de-labelling (PADL) algorithm for patients who are considered suitable for oral penicillin challenge. It should only be applied by staff trained and equipped in anaphylaxis management.

Antibiotic challenges can result in immediate allergic reactions, including anaphylaxis. Patients must be closely observed during this procedure.

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

Preparation

1. Discuss the plan for an oral penicillin challenge and go over the oral penicillin challenge information leaflet with the patient.
2. Review the exclusion criteria for oral challenge. **Oral antihistamines should be stopped 72 hours prior to challenge since they may mask true allergy.**
3. Select the antibiotic to be used. In most cases this should be the penicillin antibiotic to which the patient had the adverse reaction. If the antibiotic is unknown, then amoxicillin is an appropriate choice.
4. Obtain informed consent and record this in patient notes.

Procedure for the oral challenge

1. Measure the patient's observations (HR, BP, oxygen saturations, RR). If the patient has asthma then measure peak expiratory flow rate (PEFR).
2. Competent prescribing practitioner should prescribe **and** administer the antibiotic and then remain within the clinical area for the first 20 minutes. The challenge will last about 60 minutes.
3. Antibiotics should be administered as a single oral dose:
   - Amoxicillin 500mg **OR**
   - Flucloxacillin 500mg
4. Tell the patient to notify you immediately if they experience any adverse symptoms.
5. Monitor the patient's observations (and PEFR if indicated) at regular intervals, eg at 10 minutes, 20 minutes, 40 minutes and 60 minutes, AND when any symptoms occur.
6. Record any symptoms that the patient experiences.
7. If the patient reports any symptoms of a positive test (see box) or they have a rising NEWS score, the patient should be reviewed immediately by an appropriately experienced member of staff.

Post-procedure care

1. Interpret the oral challenge as shown in the box.
2. If the challenge is negative, give patient the post-challenge information for no penicillin allergy.
3. Update hospital record eg HEPMA.
4. Send a letter to their GP to inform them of the outcome of penicillin de-labelling assessment and ask them to amend the allergy status on record. Also include this information in the discharge letter to GP.
5. If the challenge outcome is positive, written and electronic records must clearly state this. The patient should be provided with the post-challenge information for confirmed penicillin allergy and the GP informed of this outcome as above.

Exclusion Criteria

- Pregnancy
- Uncontrolled asthma (based on clinical judgement)
- Unstable coronary artery disease
- Medically unstable (NEWS ≥ 2)
  (If NEWS >2 and patient stable at clinician discretion)

Interpretation of Oral Challenge

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 of the other features of a positive test.

Equivocal test

If there is doubt about the interpretation of the test then it should be discussed with an experienced clinician. Consider referral to a local allergy service (if available).

Positive Test

Patient experiences any of the following: itchy rash, breathing difficulties, facial swelling, hypotension.

Management of Reactions

If severe symptoms - hypotension or breathing difficulties institute immediate management of anaphylaxis, call for experienced medical review and consider contacting cardiac arrest team via '2222'.

If mild symptoms – isolated rash and NEWS score not elevated then give antihistamine (ie 4mg chlorpheniramine).

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