**RIPAL Study Penicillin allergy assessment and de-label Protocol V1.0 23-05-22** (Adapted, with permission, from Health Improvement Scotland Scottish Antimicrobial Prescribing Group)

To be used in conjunction with a decision support algorithm and should only be carried out by staff trained in use the de-labelling algorithm, in an inpatient environment with access to anaphylaxis drugs and expertise in anaphylaxis management. Patients must be closely observed and must not leave the ward during testing.

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

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| **Preparation:**  1. Review the exclusion criteria for direct oral challenge. Oral antihistamines should be stopped 72 hours prior to challenge since they may mask true allergy.  2. 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.  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**  • Pregnant/breast feeding  • Respiratory or cardiac compromise (BP/ HR outside normal range or requiring oxygen)  • Brittle asthma, severe aortic stenosis  • Beta blocker unless can be withheld 24 hours before, antihistamines if can’t be withheld on day of testing, steroids in the last 10 days  • Anaphylaxis or history of SCAR (e.g. TEN)  • Severe/brittle asthma or unstable coronary artery disease, uncontrolled heart failure |
| **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. Prescribe and administer the antibiotic. Patient and observer to remain within the clinical area for 60 minutes.  3. Antibiotics should be administered as a single therapeutic oral dose: e.g. Amoxicillin 500mg  4. Inform the patient to notify you immediately if they experience any adverse symptoms  5. Ask the patient to report any symptoms & measure the patient’s observations (BP, pulse, Sp02, and PEFR if indicated) and at regular intervals e.g. at, 20 minutes, 40 minutes and 60 minutes and document.  6. Record any symptoms that 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. |  | **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 a senior clinician and referral to a local allergy service (if available) should be considered |
| **Positive Test**  Patient experiences any of the following: itchy rash, breathing difficulties, facial swelling, hypotension, collapse, tongue swelling….. |
| **Post-procedure care**  1. Interpret the oral challenge as shown in the box.  2.If the challenge is negative give the patient the patient information leaflet, record in the discharge letter and ask the patient’s GP to amend their allergy status on the practice records  3. In case of late phase response, the patient must be instructed to call 111 or visit their local Emergency Department should they develop symptoms of dyspnoea, wheezing, dizziness or severe pruritus.  4. If the challenge outcome is positive written and electronic record must clearly state this. The patient should be provided with the information leaflet and the GP informed of this outcome |  | **Management of Reactions**  If severe symptoms hypotension or breathing difficulties institute immediate management of anaphylaxis, call for senior medical review and consider contacting cardiac arrest team via ‘2222’  If mild symptoms - isolated rash and NEWS score not elevated then give antihistamine (i.e. 10mg cetirizine) |

Signs & Symptoms of allergic reactions in various target organs. (Used with permission from the ALABAMA study Team)

**Signs and symptoms of potential allergy**

Skin: Urticaria/Angioedema

Flushing

Erythematous pruritic rash

Atopic dermatitis

Gastro-intestinal tract: Pruritis and /or swelling of the lips, tongue or oral mucosa

Nausea

Abdominal cramping or colic

Vomiting or reflux

Diarrhoea

Respiratory tract: Nasal congestion

Rhinorrhoea

Pruritis/sneezing

Laryngeal oedema, staccato cough and/or dysphonia

Wheezing/ repetitive cough

Dyspnoea

Cardiovascular: Hypotension/shock

Dizziness

**Observational monitoring chart** (Used with permission from the ALABAMA study Team)

|  |  |  |
| --- | --- | --- |
| **Date:** | **Drug & dose Tested:** | **Patient Name:** |
|  |  | **NHS No / CR no.:** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Time** | **Dose Administered** | **Blood Pressure** | **Pulse** | **Sp02** | **Symptoms/Reactions** |
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**Testing performed by :………………………   Signature:………………..    Date:………………..…**

Document the result of the test clearly in the box below (After the D4-6 follow-up call):

|  |  |  |
| --- | --- | --- |
| **RESULT OF TEST:** | **NEGATIVE** | **POSITIVE** |
|  |  |  |
| ADVICE FOR PATIENT | SAFE TO TAKE DRUG AGAIN IN FUTURE | MUST AVOID DRUG IN FUTURE |

**Test result completed by: ……………………  Signature:………………..   Date:………………..…**

**Penicillin allergy assessment questions**

The answers to the questions below will be used with the decision support tool below to decide whether the patient is de-labelled on history alone, is offered an oral challenge test or whether no intervention is able to be offered. Those meeting criteria for allergist referral will be considered for allergist referral if they meet the local referral criteria (below).

1. **Which penicillin (s) are you allergic to?**
2. **Do you remember the details of the reaction?**
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?**

1. **Which other antibiotics have you tolerated post reaction?**

**Allergy risk category, and rationale for that category**

**Allergy history taken by**

**Date**

Cut and paste the questions above and the answers given in to a ‘Pharmaceutical Care Plan’ note in EPMA with a title that reflects the outcome of the allergy risk assessment. Choose one of the following titles;

• “RIPAL HIGH” –high risk allergy history as per decision tool

• “RIPAL LOW DDL” - low risk allergy history as per decision tool, eligible for direct de-label.

• “RIPAL LOW DOC” - low risk allergy history as per decision tool, eligible for oral challenge.

• “RIPAL unable to obtain history (revisit)” - if the reason for non-obtaining history is likely to resolve during patient stay

• “RIPAL unable to obtain history”- if the reason for non-obtaining history is likely permanent

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**Drug Allergy**

**When to consider referral**

<https://rms.kernowccg.nhs.uk/rms/primary_care_clinical_referral_criteria/rms/primary_care_clinical_referral_criteria/allergy/drug_allergy>

1.    Suspected anaphylaxis. Please include in the referral any preferred alternative classes of medication which could be considered in order to facilitate management to facilitate more directed investigations.

2. Non-immediate cutaneous reaction where that class of drug is considered essential to management.

3.    A severe non-immediate cutaneous reaction.  Please include in the referral any preferred alternative classes of medication which could be considered to facilitate more directed investigations.

4.    NSAID reactions involving urticaria, angioedema, or an asthmatic reaction to a  non-selective NSAID

5.    Beta lactam allergy when

a.    Beta lactams are considered essential for management

b.    There is likely to be frequent need for beta-lactam antibiotics in the future (eg recurrent bacterial infections or immune deficiency)

c.    There is suspected allergy to at least one other class of antibiotics in addition to beta lactams

6.    Suspected local anaesthetic allergy where a procedure involving local anaesthetic is needed

7.    Anaphylaxis or another suspected allergic reaction during or immediately after general anaesthesia. These referrals should be sent to the Anaesthetic Allergy Service inbox at:  [plh-tr.PlymouthAnaestheticAllergyService@nhs.net](mailto:plh-tr.PlymouthAnaestheticAllergyService@nhs.net)

8.    There is diagnostic uncertainty or multiple drugs were involved (especially where the reaction is systemic)