**Scope (area): Grampians Health – Ballarat & Horsham campuses in Adults only;** **not for delabelling in children.**

**Scope (staff): Nursing, Medical, Pharmacy staff.**

# Rationale

Patient reported antibiotic allergies or antibiotic allergy labels (AALs) have been an increasing public health issue with up to 10% of Australian hospital inpatients reporting a penicillin allergy. However in 85% of cases, these allergy ‘labels’ are inaccurate due to an incorrect diagnosis at the time of the “reaction” or because the patient has grown out of the allergy over time. This can lead to increased use of restricted antibiotics, worse clinical outcomes (including mortality and antibiotic resistance development), increased medical errors and delays to treatment, increase in length of stay and costs.

The Check Again Initiative, developed by Safer Care Victoria, is a state-wide collaborative to improve inpatient access to penicillin allergy assessment and delabelling of low-risk penicillin allergies. This procedure is designed to provide instructions on the process of investigation and removing the penicillin allergy label in patients who have previously been labelled as having a penicillin allergy.

# Expected Objectives / Outcomes

It is expected that a majority of the patients assessed as having a low-risk penicillin allergy will be able to have their penicillin allergy removed directly or by direct oral challenge. This will allow for patients previously thought to be penicillin allergic to be treated with these antibiotics when they are required.

# Definitions

## Inclusion criteria

* Age > 18 years (Note: **NOT for use in children**)
* *For direct delabelling*
	+ Patients previously labelled with an antibiotic allergy that is classified as an expected side effect of antibiotics (Type A reaction) e.g. nausea, vomiting, diarrhea, headache.
* *For oral penicillin challenge*
	+ Patients who have been assessed as low-risk utilising the Antibiotic Allergy Assessment Tool (AAAT; Appendix 1). Low-risk is defined as scoring “green” or “white” and includes:
		- Unknown reaction > 5 years ago or date that cannot be recalled.
		- Reaction is a known side effect (as above under *direct delabelling*), where the patients won’t accept direct delabelling.
		- History of unexpected childhood rash, localised injection site reaction only, or maculopapular exanthem greater than 10 years ago.

## Exclusion criteria

* Pregnancy.
* Allergy history unavailable due to patient cognitive impairment and it cannot be obtained from the GP or next of kin / guardian / carer.
* Moderate or severe allergy history. “Orange” or “Red” using the AAAT.
* History of any anaphylaxis or idiopathic urticarial / anaphylaxis.
* History of severe cutaneous adverse reactions (SCAR).
* History of acute kidney injury or severe liver impairment associated with antibiotic therapy.
* Haemodynamic instability (MET call criteria within the previous 24 hours).
* ICU admission during current episode of care – use clinical discretion .
* Concurrent use of antihistamines or prednisolone at a dose of 10 mg or greater (or equivalent corticosteroid dose).

# Detailed steps, procedures and actions

## Allergy identification and initial assessment

1. Patient identified as having an allergy or reaction to a penicillin antibiotic.
2. Nursing staff / Ward Challenge Champion / Ward pharmacist / treating doctor completes Antibiotic Allergy Assessment Tool (AAAT, Appendix 1).
3. ADR box on all current Medication charts and CAM (at Ballarat)/Alert Sheet (MR 100) (at Horsham) updated to include drug, reaction, timing and severity.
4. Patients identified as potentially suitable for de-labelling based on AAAT given patient information sheet “Penicillin Allergies and Side Effects” (CID0299).
5. Patients identified as having a low-risk penicillin allergy (i.e. “white” or “green” per AAAT) are brought to the attention of the AMS pharmacist using the AMS referral form in BOSSnet (at Ballarat)/ward pharmacist or consultant (at Horsham).

## Assessment of eligibility for direct delabelling or oral challenge

Patients with a penicillin allergy will be reviewed by the Ward Challenge Champions or the AMS pharmacist (at Ballarat)/ward pharmacist or consultant (at Horsham). The Ward Challenge Champion or AMS pharmacist (at Ballarat)/ward pharmacist or consultant (at Horsham) will review the results of the Antimicrobial Allergy Assessment Tool and undertake a review of the medication chart to determine suitability for direct delabelling or the need for an oral challenge. Recommendation to proceed with delabelling made to the AMS pharmacist or the ID team (at Ballarat)/consultant (at Horsham).

## Direct delabelling of antibiotic allergy

* AMS pharmacist or ID registrar / consultant to review the patient medication chart and CAM alert (at Ballarat)/Alert Sheet (MR 100) (at Horsham).
* Those with an antibiotic allergy that is classified as an expected side effect of antibiotics (Type A reaction) e.g. nausea, vomiting, diarrhea, headache can be directly delabelled.
* The results of allergy assessment will be discussed with patient/legal guardian and confirm patient consents to removing “allergy”.
* If consent is given by patient, it will be documented in patient’s history.

**Follow up documentation**

* AMS pharmacist or ID registrar / consultant to complete letter to GP describing outcome of delabelling and provide this to the treating team to be forwarded to the GP.
* AMS pharmacist or ID registrar / consultant to complete and provide a letter to patient describing outcome of delabelling.
* Ward pharmacist / AMS pharmacist to update CAM (at Ballarat)/Alert Sheet (MR 100) (at Horsham) and ADR box on all current medication charts.
	+ At Ballarat, if the penicillin label is the only ADR recorded in CAM, revoke the alert, and include the results of the antibiotic allergy assessment, date revoked and confirmation of patient consent.
	+ At Ballarat, if patient has multiple ADRs recorded in CAM, delete the de-labelled antibiotic from the top alert box. In the “other information” box document the drug de-labelled, results of the antibiotic allergy assessment, date revoked, confirmation of patient consent and name/designation of clinician removing the allergy.
	+ At Horsham, cancel the penicillin label on the Alert Sheet (MR 100) and document the results of the antibiotic allergy assessment, date revoked, confirmation of patient consent and name/designation of clinician removing the allergy.

## Oral antibiotic challenge

**Personnel able to perform or assist with the oral antibiotic challenge**

* AMS pharmacist, ID registrar / consultant.
* Medical officer responsible for the patient care .
* Ward Challenge Champion.
* Nursing staff (assist).

**Preparation**

* Confirmation by AMS pharmacist or ID registrar / consultant that the patient is suitable for oral challenge.
* Obtain and document consent (in patient’s medical record) from the patients’ treating team to conduct inpatient oral challenge.
* Ensure ANUM is aware and sufficient nursing staff are available to assist if needed.
* Inform ICU registrar (at Ballarat)/consultant (at Horsham) of planned oral challenge.
* Medical officer should be available to attend to patient if required (not required to remain on ward for duration of challenge).

**Procedure**:

* Only performed on the ward Monday – Friday between 9am – 3pm (excluding public holidays).
* Ensure following available on the ward:
	+ Adrenaline 1:1000 (1 mg/1 mL) ampoules.
	+ The required antibiotic for oral challenge (see below).
* Patient / legal guardian to be consented by AMS pharmacist, ID registrar / consultant or medical officer and the consent recorded in the notes.
* Notify the ward nursing staff looking after the patient and the nurse in charge.
* Antibiotic order and adrenaline order to be charted as a stat order by the ID registrar / consultant or medical registrar.

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| **Allergy described** | **Oral challenge antibiotic to be used** |
| Phenoxymethylpenicillin or benzylpenicillin  | Phenoxymethylpenicillin 250 mg |
| Amoxicillin or ampicillin | Amoxicillin 250 mg |
| Flucloxacillin | Flucloxacillin 250 mg |
| Penicillin unspecified and occurred prior to widespread use of amoxicillin in 1972 | Phenoxymethylpenicillin 250 mg |
| Penicillin unspecified and occurred after 1972 | Amoxicillin 250 mg |
| Augmentin (amoxicillin + clavulanate) | Amoxicillin 250 mgNB: if nothing happens then amoxicillin *only* will be delabelled; clavulanic acid allergy will remain |
| Piperacillin / tazobactam (Tazocin®) or dicloxacillin | Do not perform challenge |
| If Type A allergic reaction e.g. nausea, vomiting, diarrhea, headache, clear patient history, beta-lactam required | Remove the label following process above and administration of a full treatment dose can proceed without a test dose  |

## Nursing requirements

* Immediately prior to challenge, perform a baseline set of patient observations (heart rate, blood pressure, O2 sats, respiratory rate).
* Administer oral antibiotic as charted.
* Perform half-hour observations for 2 hours post challenge or if patient becomes clinically unwell.
* If respiratory distress occurs or tongue swelling then consider that the patient is having anaphylaxis:
	+ Administer 500 microgram (0.5 mL of 1:1000) adrenaline by intramuscular injection.
	+ Notify the medical team immediately for review. If medical team is not accessible then call a MET call.
	+ Also call a MET call if any MET criteria are met during the oral challenge process.
	+ If a MET call has been called then complete an incident report post treatment of the reaction.
* If there is a mild dermatological reaction (e.g maculopapular exanthem and localised itch) administer loratidine 10 mg oral.

## Follow up

* Visit by AMS pharmacist, ID registrar / consultant to inform the patient of the outcome of the challenge and complete documentation letters.
* If the challenge has been successful with no reaction:
	+ Discuss the outcome with the patient. This step is important for them to understand the outcome and that they can accept penicillin in the future. Document the discussion into patient’s medication history.
	+ Remove the penicillin allergy from the patient drug chart.
	+ Change the alert on CAM (at Ballarat)/Alert Sheet (MR 100) (at Horsham) to reflect the outcome of the delabelling following process described above.
* If there has been a reaction and thus deemed unsuccessful:
	+ Document in the patient notes, on the medication record and in the CAM alerts (at Ballarat)/Alert Sheet (MR 100) (at Horsham). The patient is **NOT** to be delabelled.
	+ Incident report to be completed.
* In all cases:
	+ Patients should be provided with the antibiotic delabelling card and letter outlining the result of the delabelling process.
	+ A letter should also be completed and provided to the GP, other treating physicians and local pharmacy outlining the results of the antibiotic delabelling challenge.
	+ Antibiotic Allergy Assessment Tool and letters developed are to be filed in the patients notes and scanned into medical record.s

**Appendix 1: See separate attachment**