INFECTIOUS DISEASES DEPARTMENT
GUIDELINE

ANTIBIOTIC ALLERGY ORAL CHALLENGE

Staff this document applies to:

- Infectious Diseases Department
- Austin Health nurses, doctors, and pharmacy staff

Related Austin Health policies, procedures or guidelines:

Austin Health Drug & Antibiotic Allergy Services (DAAS) Protocol

Antimicrobial Stewardship Antibiotic Allergy Ward Round

Trimethoprim/Sulfamethoxazole Adverse Drug Reaction Protocol

Antimicrobial Desensitisation Protocol

Anaphylaxis – Initial Management

Perioperative drug allergy guideline

Purpose:

To provide guidance on antibiotic allergy assessment and management of an oral antibiotic challenge in patients who have an antibiotic allergy.

Background:

Adverse drug reactions to antibiotics can be divided into two broad categories:

- **Type A reactions**: Non-immune mediated – for example, cytopenia, increased serum creatinine and gastrointestinal intolerance.
- **Type B reactions**: Immune-mediated – for example, rash, anaphylaxis, urticaria, angioedema, acute interstitial nephritis and severe cutaneous adverse reaction (SCAR). SCAR refers to a distinct group of diagnoses including Stevens-Johnson syndrome (SJS), Toxic epidermal necrolysis (TEN), Drug reaction with eosinophilia and systemic symptoms (DRESS) and Acute generalised erythematous pustulosis (AGEP).

The most common antibiotic allergies are to penicillins and sulfonamides.

Penicillin Allergy

A patient-reported "penicillin" allergy is documented in 9-15% of hospitalised patients[1]. These penicillin allergies are associated with inappropriate prescribing and inferior patient outcomes [1, 2]. Protocolised oral antibiotic challenge has been successful in patients with remote and mild allergy histories[3, 4]. Austin

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Health experience with oral penicillin rechallenge has also been published[5]. Penicillin oral challenge should be considered in patients that currently need or may need beta-lactam based therapy in the future.

Note:

- Penicillin allergy pre-1960 is likely due to phenoxymethylpenicillin or benzylpenicillin. Penicillin allergy post-1960 may be related to flucloxacillin/dicloxacillin or amoxicillin (post-1972).

Trimethoprim-sulfamethoxazole Allergy

Sulfonamide antibiotic allergy is the second most reported class of antibiotic allergy[6].

Patients with HIV are at a higher risk for developing allergic reactions to sulfonamide antimicrobials.

Due to molecular structure differences, there is a very low risk of cross-allergenicity between sulfonamide antibiotics and sulfonamide non-antibiotic agents (e.g.; furosemide, sulfonylureas).

Protocolised direct oral challenge in patients with a low to moderate risk trimethoprim-sulfamethoxazole allergy has been demonstrated to be a safe and effective alternative to trimethoprim-sulfamethoxazole desensitisation protocols[6,7]. Trimethoprim-sulfamethoxazole oral challenge should be considered in patients that currently need or may need sulfonamide antibiotic -based therapy in the future. Delabeling of low to moderate risk sulfonamide antibiotic allergy labels enables optimal antibiotic prescribing, particularly in immunocompromised patients who may require trimethoprim-sulfamethoxazole treatment or prophylaxis therapy.

Definitions and Abbreviations:

- **Penicillin –** Phenoxymethylpenicillin, benzylpenicillin, benzathine penicillin, penicillin "unspecified"
- **Aminopenicillin** – Amoxicillin, ampicillin, amoxicillin-clavulanate
- **TMP-SMX** – Trimethoprim-sulfamethoxazole
- **ADR** – Adverse drug reaction
- **MPE** – Maculopapular exanthema (rash without angioedema, urticaria, blistering, desquamation, internal organ involvement and/or mucosal involvement).
- **SCAR** – Severe cutaneous adverse reaction (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, acute generalised exanthematous pustulosis)
- **Type A** – Non-immune mediated pharmacologically predictable side effect (e.g., headache, gastrointestinal upset)
- **Type B** – Immune mediated ADR (e.g., anaphylaxis, urticaria, angioedema, rash, SCAR, acute interstitial nephritis, drug induced liver injury)

Oral Antibiotic Challenge - Inclusion & Exclusion criteria (Inpatient/ Outpatient):

Inclusion criteria:

1. Age > 16 years
2. Active Infectious Diseases inpatient/consult patient or patient identified by antimicrobial stewardship or Drug and Antibiotic Allergy Service (DAAS)
3. **For an INPATIENT oral challenge,** history of penicillins, aminopenicillin, TMP-SMX, or unspecified "sulfa" allergy that is **low risk.** (See Figure 1)
   - **Low risk** allergy criteria (either/or) - Use Appendix 1 and Appendix 2 to assess antibiotic allergy risk:
     a. Unknown reaction > 5 years previous or date that can't be recalled
     b. Type A ADR reaction where direct delabeling is not accepted by the patient
     c. History of benign childhood rash, non-urticarial rash, MPE or rash unspecified > 5-10 years previous*
     d. Local IM penicillin injection site reaction (only)

   **Patients reporting a benign childhood exanthem that is described as isolated urticaria may be challenged on a case-by-case basis*

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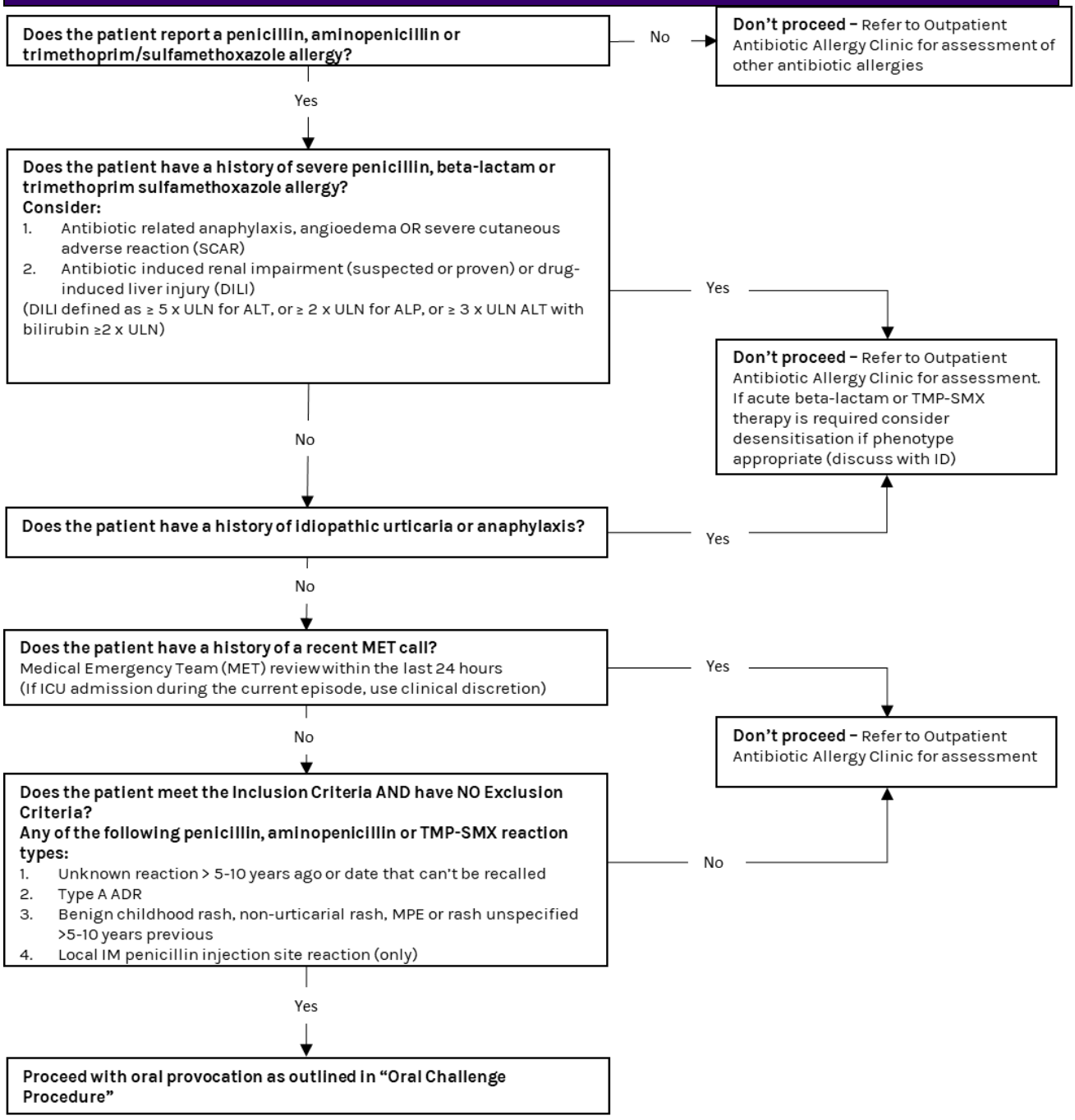
Exclusion criteria:

1. Haemodynamically unstable patients
2. Pregnancy
3. Allergy history unavailable due to patient cognitive impairment and no collateral history
4. History of antibiotic-associated anaphylaxis
5. History of antibiotic-associated Severe Cutaneous Adverse Reactions (SCAR)
6. History of acute kidney injury or severe liver impairment associated with antibiotic therapy
7. If ICU admission during current episode (relative contraindication) – use clinical discretion
8. Currently prescribed: prednisolone > 25 mg daily (or equivalent), systemic vasoconstrictors including terlipressin or H1-antagonist antihistamines

If the patient does not meet inclusion/exclusion criteria, they can be referred to the Outpatient Antibiotic Allergy Clinic if likely to require future antibiotic therapy.

Figure 1: Flow chart for determining suitability of patients for INPATIENT antibiotic oral challenge



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Oral challenge procedure

Inpatient antibiotic oral challenge

Inpatient oral challenge to be performed only after consultation with and consent by the Infectious Diseases Department, with infectious diseases medical or allergy nursing staff on site and available to be in attendance in the setting of an acute adverse event**.**

1. Ensure patient meets the criteria for antibiotic oral challenge (See Figure 1)

If the patient does not meet the criteria for inpatient antibiotic oral challenge, see Appendix 3 for antibiotic recommendations for patients who report a penicillin allergy.

For recommendations on alternative agents in patients with trimethoprim-sulfamethoxazole allergy, see the Trimethoprim/Sulfamethoxazole Adverse Drug Reaction Protocol or consult ID.

2. Obtain verbal consent from patient's treating Unit to perform inpatient antibiotic oral challenge.
3. Patient to be consented by Infectious Diseases / Immunology Consultant, Fellow or Registrar.
4. Coordinate timing of oral challenge with Infectious Diseases Department: 9am-3pm Monday to Friday
5. Drug order to be charted by Infectious Diseases / Immunology Consultant, Fellow or Registrar., using Cerner "ID Oral" Antibiotic Challenge Careset.

Oral Penicillin Challenge
Single dose: phenoxymethylpenicillin 250 mg or amoxicillin 250 mg or flucloxacillin 250 mg

- If reported allergy is phenoxymethylpenicillin or benzylpenicillin – give phenoxymethylpenicillin
- If reported allergy is amoxicillin or ampicillin – give amoxicillin
- If reported allergy is flucloxacillin – give flucloxacillin
- If reported allergy is "unknown penicillin" – give amoxicillin. Phenoxymethylpenicillin may be considered if patient reports "unknown penicillin" prior to 1970.
- If reported allergy is a Type A ADR (with clear history) and acute beta-lactam therapy required, administration of full treatment dose can proceed without test dose

Oral Trimethoprim-Sulfamethoxazole Challenge
Single dose: ½ x Trimethoprim-sulfamethoxazole 160/800 mg tablet. (This is half a "double strength" tablet).

6. Medical or specialised allergy nursing staff to be available during 1.5 hours of oral challenge observation period and available thereafter to attend patient immediately if required.
7. Resuscitation equipment must be available on the ward, however PRN prescription NOT required
8. NURSING requirements:
    a. Immediately prior to oral challenge, perform baseline patient observations (HR, BP, Sats, RR)
    b. Administer **orally** either a single dose of phenoxymethylpenicillin 250 mg or amoxicillin 250 mg or flucloxacillin 250 mg or ½ x trimethoprim-sulfamethoxazole 160/800 mg tablet as charted in Cerner (unscheduled order) by Infectious Diseases Department **(only)**
    c. Perform 30 minutely observations for 1.5 hours post oral challenge
9. If there is a history of delayed MPE and no current antibiotic requirements, consider additional testing with a 3-day oral challenge (phenoxymethylpenicillin 500 mg BD or amoxicillin 500 mg BD or flucloxacillin 500 mg BD or trimethoprim-sulfamethoxazole 160/800 mg DAILY) to exclude delayed hypersensitivity.
10. If no evidence of reaction, Infectious Diseases Department to remove penicillin, aminopenicillin or trimethoprim-sulfamethoxazole allergy from electronic medical record (Cerner) immediately post challenge. A letter will be sent to the patient, their other treating clinicians and general practitioner to notify them of the allergy removal.

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11. The patient is to be provided with Drug and Antibiotic Allergy Service (DAAS) dedicated 24-hour phone contact details to report any symptoms of a delayed reaction after the initial monitoring period.

Outpatient antibiotic oral challenge (at Antibiotic Allergy Clinic)
(Internal referrals can be made by paper referral - email: antibiotic.allergy@austin.org.au)

As per Inpatient antibiotic oral challenge procedure above, with the following modifications:

Oral Penicillin Challenge

Oral challenge may be preceded by skin testing.

Patients with a history of moderate to severe immediate allergy symptoms or PEN-FAST score >2 [8] (see Appendix 4) receive a two-dose oral challenge:
- 50 mg phenoxymethylpenicillin /amoxicillin/flucloxacillin, then if no reaction after 30 minutes
- 200 mg phenoxymethylpenicillin /amoxicillin/flucloxacillin.

Patients with a history of moderate to severe delayed allergy symptoms receive a single dose oral challenge:
- 250 mg phenoxymethylpenicillin /amoxicillin/flucloxacillin, with nursing observations for 1.5 hours, then;
- 3-day course oral challenge phenoxymethylpenicillin /amoxicillin/flucloxacillin, 500 mg BD.
- If a patient has received skin testing, routine follow-up photographs of the skin testing site are taken by the patient at 24 hours and 48 hours. Verbal and written instructions are provided to the patient to send skin testing site photographs to the DAAS phone which are then reviewed by DAAS Medical staff.
- Patients may also send photographs of a delayed rash or other reaction (regardless of prior skin testing) to the DAAS phone for Medical review.

Oral Trimethoprim-Sulfamethoxazole Challenge

Patients with a moderate risk history, i.e.: recent (<5 years) immediate symptoms OR remote (>5 years) anaphylaxis, receive a two-dose oral challenge:
- 1 mL trimethoprim-sulfamethoxazole 40 mg-200 mg/5 mL oral suspension, then if no reaction after 30 minutes
- 9 mL trimethoprim-sulfamethoxazole 40 mg-200 mg/5 mL oral suspension

If not requiring acute TMP-SMX therapy, consider 3-day course of oral trimethoprim-sulfamethoxazole 160/800 mg, 1 tablet DAILY.

- If a patient has received skin testing, routine follow-up photographs of the skin testing site are taken by the patient at 24 hours and 48 hours. Verbal and written instructions are provided to the patient to send skin testing site photographs to the DAAS phone which are then reviewed by DAAS Medical staff.
- Patients may also send photographs of a delayed rash or other reaction (regardless of prior skin testing) to the DAAS phone for Medical review.

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Author/Contributors:

Updated: February 2022

A/Prof Jason Trubiano (Infectious Diseases Physician, Drug and Antibiotic Allergy Services)

Dr Kyra Chua (Infectious Diseases Physician, Drug and Antibiotic Allergy Services)

Dr Jamie Waldron (Immunology Fellow, Austin Health)

Ms Elise Mitri (Antibiotic Allergy Pharmacist, Drug and Antibiotic Allergy Services)

Original Authors – 2019:

A/Prof Jason Trubiano (Infectious Diseases, Drug and Antibiotic Allergy Services)

Misha Devchand (Infectious Diseases Pharmacist)

Wendy Stevenson (Allergy Nurse Consultant)

Legislation/References/Supporting Documents:

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Authorised/endorsed by:

A/Prof Jason Trubiano (Director of Drug and Antibiotic Allergy Services)

Drug and Therapeutics Committee (DTC) Austin Health 2022

Primary Person/Department Responsible for Document:

A/Prof Jason Trubiano - Infectious Diseases/Drug and Antibiotic Allergy Services

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Appendix 1: Clinical assessment of a patient's antibiotic allergy history

Antibiotic allergy assessment questions

1. What is the name of the antibiotic you are allergic to? .....
2. Please describe the details of this reaction? (*"assessment of **type** " – overleaf for suggestions*)

   .....
3. How many years ago did the reaction occur? (*"assessment of **timing**"*) .....

   (circle the timing)

   Less than 5 years ago 5-10 years ago More than 10 years ago
4. How long after having the first antibiotic dose did the reaction occur? (*"assessment of **timing**"*)

   .....
5. How was this reaction managed? (*"assessment of **type** and **severity**"*)

   .....
6. Were you hospitalised as a result of this reaction? Yes ☐ No ☐
7. Which other antibiotics have you safely taken since the reaction? (*"assessment of **tolerance**"*)

Use the above answers to tick the correct allergy phenotype on the Antibiotic Allergy Assessment Tool (Appendix 2)

Following antibiotic allergy assessment (tick off completed tasks):

Cerner allergy updated (substance, reaction description, severity)? Yes ☐ No ☐

For **low risk allergies ("green"** OR **"white")** Antibiotic Allergy Services paged (pg 1547)?

Yes ☐ No ☐

Name..... **Signature**.....

Designation..... **Date**.....

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Appendix 2: Austin Health Antibiotic Allergy Assessment Tool

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 (non-severe)
Diffuse rash or localized rash/swelling with no other symptoms *(non-immediate or unknown timing)*	> 5 years ago; or unknown	☐	Delayed hypersensitivity (non-severe)
	≤ 5 years ago	☐	Delayed hypersensitivity (non-severe)
Angioedema ("lip, facial or tongue swelling")		☐	Immediate hypersensitivity (severe)
Generalized swelling (outside of angioedema)		☐	Immediate hypersensitivity (severe)
Urticaria ("wheals and hives") **isolated childhood urticaria may be challenged on a case-by-case basis*		☐	Immediate hypersensitivity (non-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 ≤ 5 years ago	☐	Unknown (non-severe)
Unknown reaction > 5 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 ("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
Anaphylactoid/infusion reaction (e.g. red man syndrome)	☐	Unknown or unclear mechanism

Appropriate for supervised direct oral rechallenge (or direct de-labelling) - Refer to ID, Pg 1547	☐ Low risk
Appropriate for supervised direct oral rechallenge – Refer to ID	☐ Low risk
May be appropriate for referral for specialized skin testing - Refer to OP antibiotic allergy service	☐ Moderate risk
May be appropriate for referral for specialized skin testing - Refer to antibiotic allergy service	☐ High risk

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Appendix 3: Recommendations for antibiotic therapy in patients with a reported penicillin allergy

Table 1. Recommendations for antibiotic use in patients with a primary reported penicillin allergy.

Allergy Phenotype	Recommendation
Immediate Penicillin Hypersensitivity (non-severe) *IgE-mediated* E.g: urticaria	Avoid penicillins and 1st generation cephalosporins (except cefazolin) Consider ≥ 2nd generation cephalosporin if history of remote immediate hypersensitivity or mild presentation (urticaria only) Safe for carbapenem Safe for monobactams (aztreonam)
Immediate Penicillin Hypersensitivity (severe) *IgE-mediated* E.g: anaphylaxis	Avoid penicillins, 1st and 2nd generation cephalosporins Consider ≥ 3rd generation cephalosporin Consider carbapenem Safe for monobactams (aztreonam)
Delayed Penicillin Hypersensitivity (non-severe) *T-cell-mediated* E.g: mild rash	Avoid penicillins Avoid aminocephalosporins (cephalexin/cefaclor) only if primary allergy to aminopenicillins (amoxicillin/ampicillin) Safe for cefazolin Safe for ≥ 2nd generation cephalosporins Safe for carbapenems and monobactams
Delayed Penicillin Hypersensitivity (severe) *T-cell-mediated* E.g: SCAR	Avoid all beta-lactams (penicillins, cephalosporins) Consider carbapenem Safe for monobactams (aztreonam)

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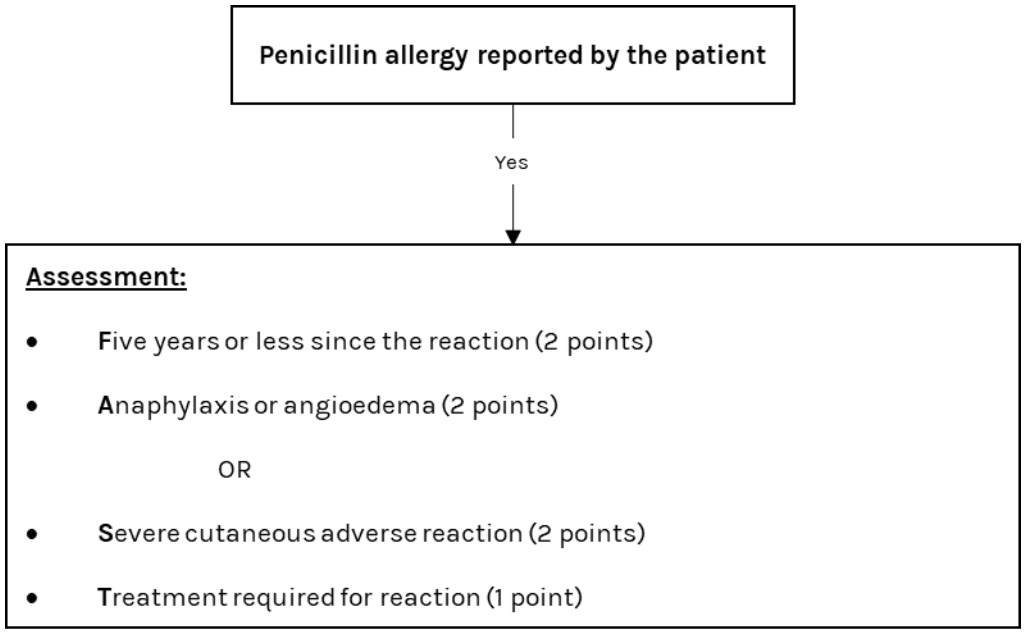
Appendix 4: PEN-FAST – Penicillin Allergy Clinical Decision Rule

Designed for point-of-care risk assessment of patient-reported penicillin allergies.



Interpretation:

0 points: **Very low risk** of positive penicillin allergy test , <1% (<1 in 100 patients reporting penicillin allergy)

1-2 points: **Low risk** of positive penicillin allergy test, 5% (1 in 20 patients)

3 points: **Moderate risk** of positive penicillin allergy test, 20% (1 in 5 patients)

4-5 points: **High risk** of positive penicillin allergy test, 50% (1 in 2 patients)

Trubiano JA, Vogrin S, Chua KYL, Bourke J, Yun J, Douglas A, Stone CA, Yu R, Groenendijk L, Holmes NE, Phillips EJ. Development and Validation of a Penicillin Allergy Clinical Decision Rule. JAMA Intern Med. 2020 May 1;180(5):745-752. doi: 10.1001/jamainternmed.2020.0403.

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