

Clinical Procedure



Health
Hunter New England
Local Health District

Antimicrobial Allergy De-Labelling Procedure - Penicillins

Sites where Clinical Procedure applies	District Wide
This Clinical Procedure applies to:	
1. Adults	Yes
2. Children up to 16 years	No
3. Neonates – less than 29 days	No
Target audience acting within scope of practice	Clinicians including pharmacy, medical, nursing, and allied health involved with allergy assessment and documentation for adult patients.
Description	This document contains standard operating procedures and processes for performing antimicrobial allergy screening, risk assessment, documentation, and referral.

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Keywords	Antibiotic, AMS, allergy testing, PENFAST, penicillin, allergy, antimicrobial stewardship, antimicrobial
Document registration number	HNELHD CP 24_12
Replaces existing procedure?	No district level document
Registration number and dates of superseded documents	(Note: JHH_0387)
Related Legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHS Standard) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics: <ul style="list-style-type: none"> • NSQHS Standard 3 • Antimicrobial Stewardship Clinical Care Standard • See Reference Section on page 6. 	
Prerequisites (if required)	Staff designation or competency level: RN; RM; NP; EN with Medication Endorsement; Pharmacist, Medical Officer, Dentist, Podiatrist Patient with a stated or labelled penicillin or any specific drug in penicillin class allergy
Procedure note	This document reflects what is currently regarded as safe and appropriate practice and requires mandatory compliance . If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their unit manager/delegate and document the variance in the patient's health record.
Position responsible for the procedure and authorised by	Director, Infection Prevention Service
Procedure contact person	Dr Sarah Browning sarah.browning@health.nsw.gov.au
Contact details	Bianca Mills, District Antimicrobial Stewardship Governance Pharmacist HNELHD-DistrictAMS@health.nsw.gov.au
Date authorised	16 August 2024
This document contains advice on therapeutics	Yes - Approval gained from HNE Quality Use of Medicines Committee on 30 September 2024
Issue date	2 October 2024
Review date	2 October 2027

Note: Over time links in this document may cease working. Where this occurs please source the document in the PPG Directory at: <http://ppg.hne.health.nsw.gov.au/>

SUMMARY - PURPOSE AND RISKS

This document contains standard operating procedures and process for performing antimicrobial allergy screening, risk assessment, documentation, and referral.

The risks associated with allergy risk assessment, testing and de-labelling include:

- Patient exposure to potential allergen.
- Patient may attribute subjective symptoms to antimicrobial.
- The potential for allergy label to be re-instituted.
- Psychological distress if patient strongly identifies with allergy label.

Risks to be mitigated by the procedures outlined in this document include:

- Promoting evidence-based risk stratification tool for assessment of antimicrobial allergies
- Standardise allergy testing procedures, observation, and referral pathways.
- Instructions on antibiotic allergy label modification and communication
- Provision of patient information that is consumer focused.
- Clear process for gaining consent and indications for when testing is appropriate.

Accurate assessment and documentation of patient allergy information is crucial to allow for optimal antimicrobial prescribing, allowing for the most appropriate and narrow spectrum antimicrobial possible, whilst ensuring that potential harms (such as anaphylaxis) are avoided. Allergy labelling is associated with suboptimal antimicrobial selection, greater treatment costs, prolonged length of stay, greater re-admission rates and higher prevalence of multi-drug resistant organisms.

Where an oral challenge with amoxicillin is completed as per this procedure using the tools provided, patients can safely have their allergy label removed for all agents within the penicillin class.

Risk Category: Clinical Care & Patient Safety

GLOSSARY

Acronym or Term	Definition
AAL	Antimicrobial Allergy Label
AMS	Antimicrobial Stewardship
CAP	Clinical Access Portal
DMR	Digital Medical Record
DRESS	Drug reaction with eosinophilia and systemic symptoms
GP	General Practitioner
HNELHD	Hunter New England Local Health District
ID	Infectious Diseases
iPM	Patient information management system
MedChart	Electronic Medication Management software
NSMC	National Standard Medication Chart (paper chart)
PEN-Fast	Antimicrobial allergy risk rating tool
SCAR	Severe cutaneous adverse reaction
SJS	Steven-Johnson Syndrome

TEN	Toxic epidermal necrolysis
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PROCEDURE

This procedure requires mandatory compliance.

CLINICAL PROCEDURE SAFETY LEVEL

Every clinician involved in the procedure is responsible for ensuring the processes for clinical procedure safety are followed. The following level applies to this procedure (click on the link for more information):

[Level 1 procedure](#)

Staff Preparation

It is mandatory for staff to follow relevant: “Five moments for hand hygiene”, infection control, moving safely/safe manual handling, documentation practices and to use HAIDET for patient/carer communication: **H**and hygiene, **A**cknowledge, **I**ntroduce, **D**uration, **E**xplanation, **T**hank you or closing comment.

Equipment Requirements*Stage 1 Procedure*

- Alcohol based hand rub
- Personal Protective Equipment
- PENFAST Antimicrobial Allergy Questionnaire

Stage 2 Procedure

- Observation area
- Amoxicillin 250 mg capsule (one only)
- Blood Pressure cuff
- Oxygen saturation monitor
- Patient thermometer
- Rapid Response Trolley

Patient Preparation

This procedure is only applicable where patients are:

- able to provide informed consent.
- aged ≥ 18 years of age
- identify (either self-identify, or via medical records) as having an antimicrobial allergy to any agent in the class of penicillins. Note this means a patient with e.g. a ‘dicloxacillin’ allergy can be safely assessed for de-labelling via this procedure, using amoxicillin as the test agent if applicable.

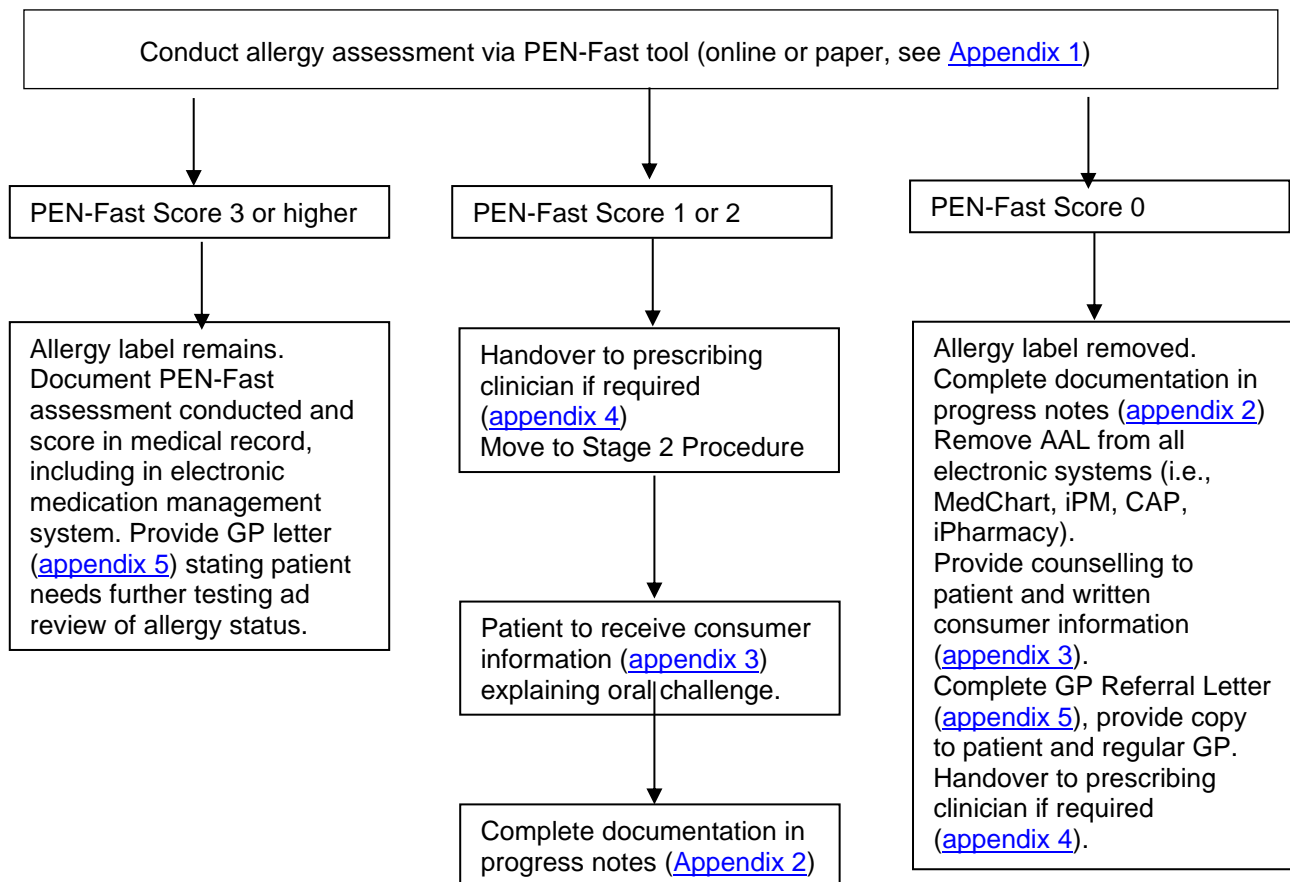
Pre-procedure

STOP and confirm the following before commencing the procedure:

- Patient identification using three core patient identifiers (Name – family and given names, date of birth and Medical Record Number - MRN)
- Procedure verification
- Allergy/adverse reaction check
- Verbal consent to be obtained, written consent is not mandatory. See [Policy \(nsw.gov.au\)](#)
- Ability to recognise and manage anaphylaxis, including access to a rapid response trolley.
- Provide patient with written information sheet ([Low risk penicillin allergies Oct 2020 SCV Aus.pdf \(wsimg.com\)](#))

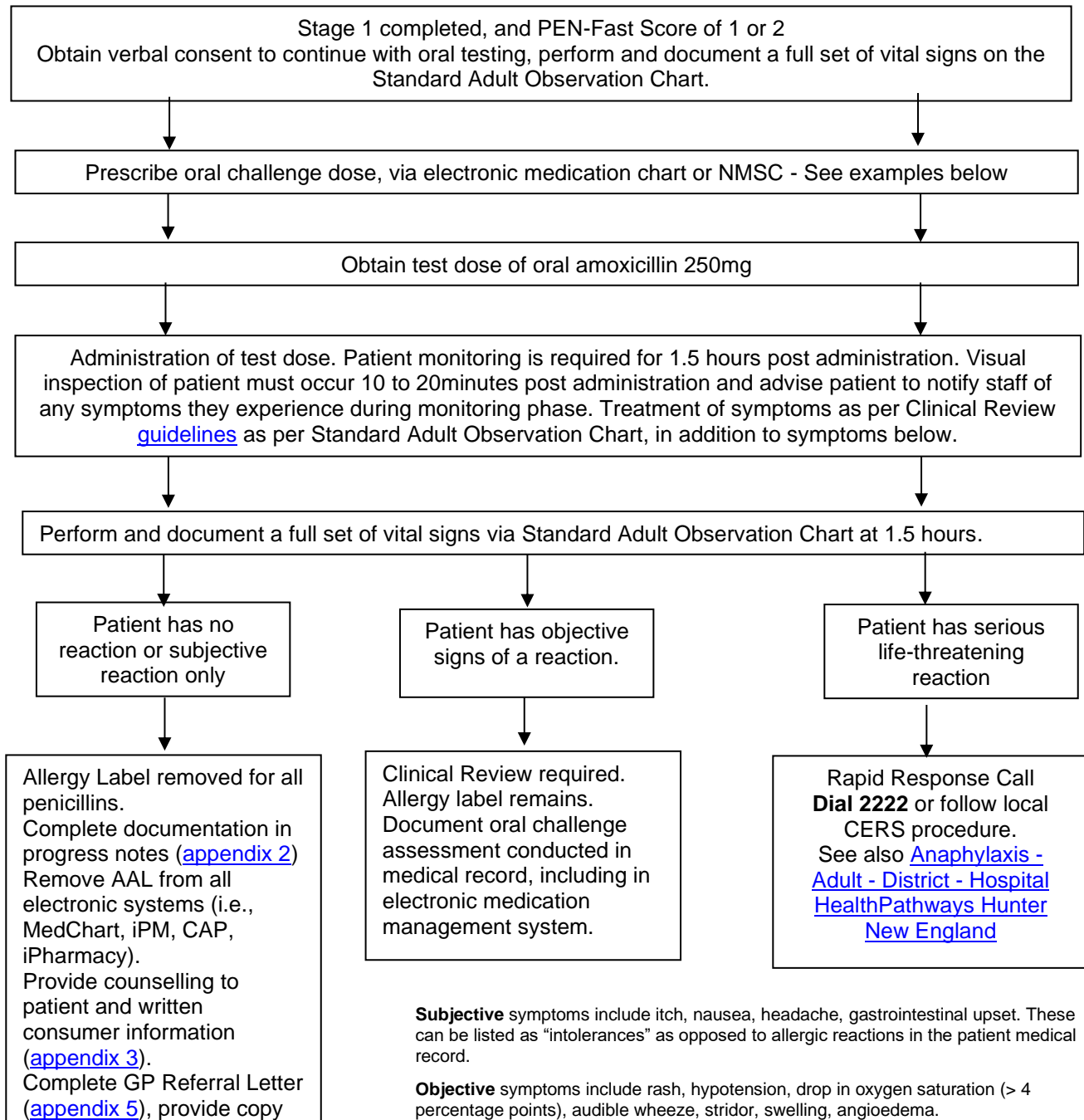
Procedure Steps**Stage 1 Procedure**

Stage 1 can be completed by any clinician as per the designation list at the beginning of this document, whilst working within their scope of practice.



Stage 2 Procedure

Stage 2 can only be completed by an authorised prescriber (medical officer, nurse practitioner)

**Sample MedChart documentation:**

	Medication	Date/Time Due	Route	Dose	Date/Time Given	
<input type="checkbox"/>	Amoxicillin (Amoxycillin) 250mg Capsule DOSE: 250 mg Oral Stat (12:58) Allergy de-labelling test dose Indication: Antimicrobial Allergy De-Labelling Test Dose 12/06/2024 Dr Testing Doctor2	12/06/2024 12:58				Source Not Assigned New Medication Order

Sample NMSC documentation:

Facility/service: Example Hospital
Ward/unit: General Ward

Medication chart number 1 of 1

Additional charts
☐ IV fluid ☐ BGL/insulin ☐ Acute pain ☐ Other
☐ Palliative care ☐ Chemotherapy ☐ IV heparin

Once only and nurse initiated medicines and pre-medications								
Date prescribed	Medicine (print generic name)	Route	Dose	Date/time of dose	Prescriber/Nurse Initiator (NI) Signature Print your name	Given by	Time given	Pharmacy
01/01/24	Amoxicillin	Oral	250 mg	01/01 10:00	A Prescriber A Prescriber			

IMPLEMENTATION AND MONITORING COMPLIANCE

- Communication to staff covered by this Procedure will be via the weekly email from Clinical Governance, and via the District Infection Prevention Committee and District Antimicrobial Stewardship Committee
- IMS+ of all clinical incidents and near misses directly relating to this procedure.
- Percentage of patients whose known adverse drug reactions are documented in MedChart is a KPI of the local Drug and Therapeutics Committee
- Antimicrobial allergy documentation data is captured at each inpatient facility via annual National Antimicrobial Prescribing Survey audits (NAPS, Surgical NAPS and Aged Care NAPS)

REFERENCES

1. Australian Commission on Safety and Quality in Health Care – [National Standard 3](#) – Antimicrobial Stewardship
2. Australian Commission on Safety and Quality in Health Care - [Antimicrobial Stewardship Clinical Care Standard](#)
3. Australian Commission on Safety and Quality in Health Care – [National Standard 4 – Adverse Drug Reactions Action 4.07, 4.08, 4.09](#)
4. Therapeutic Guidelines: Antibiotic, Therapeutic Guidelines, Melbourne, Victoria [Topic | Therapeutic Guidelines \(hcn.com.au\)](#)
5. Therapeutic Guidelines: Penicillin allergy assessment guide, Therapeutic Guidelines, Melbourne, Victoria [PenicillinAllergyAssessment_v6.pdf \(tg.org.au\)](#)
6. [NSW Health – Consent to Medical and Healthcare treatment Manual 2020](#)
7. NSW Health Policy Directive – [Medication Handling PD2022_32](#)
8. HNELHD – [Documentation of patient allergy and adverse drug reactions PD2022_32:PCP 53](#)
9. HNELHD – [Surgical Antibiotic Prophylaxis Hospital Health pathway \(link TBA\)](#)
10. HNELHD – [District Antimicrobial Stewardship Policy Pol 22_05](#)
11. HNELHD – [District Infectious Diseases Management Clinical Guideline CG22_12](#)
12. J. Trubiano, S. Vogrin, K. Chua, J. Bourke, J. Yun, A. Douglas, C. Stone, N. Holmes, E. Phillips, “PEN-FAST: A validated penicillin allergy clinical decision rule – Implications for prescribing”, International Journal of Infectious Diseases, vol 101, Supplement 1, 89, December 2020. [PEN-FAST: A validated penicillin allergy clinical decision rule – Implications for prescribing - International Journal of Infectious Diseases \(ijidonline.com\)](#)
13. J. Trubiano, S. Vogrin, K. Chua, J. Bourke, J. Yun, A. Douglas, C. Stone, N. Holmes, E. Phillips, R. Yu, L. Groenendijk, “Development and Validation of a Penicillin Allergy Clinical Decision Rule” JAMA Internal Medicine, vol 180 (5):1-9 May 2020. [Development and Validation of a Penicillin Allergy Clinical Decision Rule - PMC \(nih.gov\)](#)
14. K. G Blumenthal, J. G. Peter, J.A. Trubiano, and E. J. Phillips, “Antibiotic allergy,” Lancet, vol. 393, pp.183-198, 2019
15. Australasian Society of Clinical Immunology and Allergy. Anaphylaxis Resources [Anaphylaxis Resources - Australasian Society of Clinical Immunology and Allergy \(ASCIA\)](#)
16. Gonzalez-Estrada, A., Radojicic, C. Penicillin allergy: A practical guide for clinicians. Cleveland Clinic Journal of Medicine 82, 295–300, 2015.
17. Devchand, M., Kirkpatrick, C.M., Trubiano, J.A. Evaluation of a pharmacist-led penicillin allergy de-labelling ward round: A novel antimicrobial stewardship intervention. Journal of Antimicrobial Chemotherapy 74, 1725–1730. 2019
18. M. Devchand et al., “Pathways to improved antibiotic allergy and antimicrobial stewardship practice: The validation of a beta-lactam antibiotic allergy assessment tool,” J. Allergy Clin. Immunol. Pract., vol. 7, no. 3, pp. 1063-1065.e5, 2019.

Useful Links

1. MDCalc PEN-FAST Tool - [Penicillin Allergy Decision Rule \(PEN-FAST\) \(mdcalc.com\)](#)
2. QxMD – Calculate – PEN-FAST Tool - [Clinical version: PEN-FAST - Penicillin Allergy Risk Tool | QxMD](#)

FEEDBACK

Any feedback on this document should be sent to the Contact Officer listed on the front page.

APPENDICES

APPENDIX 1. PEN-FAST ASSESSMENT QUESTIONNAIRE

PEN	Penicillin allergy reported by patient	<input type="checkbox"/> If yes, proceed with assessment
F	Five years or less since reaction ^a	<input type="checkbox"/> 2 points
A	Anaphylaxis or angioedema	<input type="checkbox"/> 2 points
	OR	
S	Severe cutaneous adverse reaction ^b	
T	Treatment required for reaction ^a	<input type="checkbox"/> 1 point
		<input type="checkbox"/> Total points

Interpretation

Points	
0	Very low risk of positive penicillin allergy test <1% (<1 in 100 patients reporting penicillin allergy)
1-2	Low risk of positive penicillin allergy test 5% (1 in 20 patients)
3	Moderate risk of positive penicillin allergy test 20% (1 in 5 patients)
4-5	High risk of positive penicillin allergy test 50% (1 in 2 patients)

^aIncludes unknown.

^bForms of severe delayed reactions include potential Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis. Patients with a severe delayed rash with mucosal involvement should be considered to have a severe cutaneous adverse reaction.

Also available electronically at: [Penicillin Allergy Decision Rule \(PEN-FAST\) \(mdcalc.com\)](https://mdcalc.com/Penicillin-Allergy-Decision-Rule-PEN-FAST/)

[Clinical version: PEN-FAST - Penicillin Allergy Risk Tool | QxMD](#)

Antimicrobial Allergy De-Labelled for PEN-Fast Score 1 or 2 with oral challenge.

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APPENDIX 3. Consumer Information

CERTIFICATE OF UPDATED ALLERGY STATUS TEMPLATE



Health
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CERTIFICATE OF UPDATED ALLERGY STATUS

This certifies that

Has previously had an allergy label to:

☐

Penicillins

☐

Specific agent =

Allergy assessment and testing was performed using the following methods:

☐

Allergy de-labelling tool (PEN-FAST) – Risk rating:

☐

Oral Challenge – Did not react to:

and can safely be prescribed penicillins in the future.

This certificate is issued on behalf of the Hunter New England Local Health District. This de-labelling certificate is part of the District Antimicrobial Stewardship program. The purpose of this certificate is to clarify antimicrobial allergies to patients to optimise antimicrobial prescribing to patients.

Signature/Role

Date

Consumer information from the Clinical Excellence Commission:

[Do you have a true antibiotic allergy? Information for Patients and Carers \(nsw.gov.au\)](https://www.nsw.gov.au/antibiotic-allergy)



Leaflet: [Do you have an antibiotic allergy? \(nsw.gov.au\)](https://www.nsw.gov.au/antibiotic-allergy)





Consumer information from National Antibiotic Allergy
[Low risk penicillin allergies Oct 2020 SCV Aus.pdf](#)



Network:
[wsimg.com](https://www.wsimg.com)

APPENDIX 4. Handover of antimicrobial allergy de-labelling from non- prescribing clinician

 SMR050001	 NSW Health		GIVEN NAME _____		<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
	Facility: _____		D.O.B. ____/____/____ M.O. ____		
	PROGRESS / CLINICAL NOTES		ADDRESS _____		
			LOCATION / WARD _____		
			COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE		
Date and Time (use 24 hr clock)		Note: All entries must be legible, written in black pen and include the health care provider's printed name, designation and signature.			
Date: 01/01/24		Antimicrobial Allergy Label Assessment			
Time: 10:30		<u>Situation:</u> Patient, Mrs Brown has a current antimicrobial allergy label, documented as "Penicillin rash"			
		<u>Background:</u> An assessment of her allergy status was conducted, and her allergy history obtained. De-labelling of penicillin allergies will allow her more effective and appropriate treatment.			
		<u>Assessment:</u> A PEN-Fast allergy assessment was conducted, and Mrs Brown's score was 1. This places her at a low risk of a positive penicillin allergy test.			
		<u>Recommendation:</u> It is recommended Mrs Brown receive an oral challenge for antimicrobial allergy de-labelling during inpatient stay as per the HNE District Procedure. Patient amenable, team please review to prescribe.			
		Signed A Clinician #123456			

er AS2828.1: 2012
N - NO WRITING



Antimicrobial Allergy Assessment

Dear GP

Re: **Patient Name:**

DOB:

MRN:

This patient had an antimicrobial allergy assessment performed by:

As an inpatient/outpatient at:

Allergy Testing Details:

- Antimicrobial allergy to:
- Time of oral test:
- Agent received for oral test:
- Objective signs following test: **No objective signs.**
- Subjective signs following test: **No subjective signs.**

Clinical Summary:

Allergy history indicates this patient had features consistent with a low risk for future reaction to penicillin. Oral provocation testing was performed and there were no objective signs to indicate a significant reaction. This indicates a negative test to penicillin. This patient has had their allergy label removed and the record on our hospital electronic medical record system updated.

This assessment indicated that they can now receive penicillin for future indications.

Plan and Requested Actions:

Please remove allergy label on community records to ensure optimal first line antimicrobial therapy in accordance with guidelines for future indications.

Sincerely,



Antimicrobial Allergy Assessment

Dear GP

Re: **Patient Name:**

DOB:

MRN:

This patient had an antimicrobial allergy assessment performed by:

As an inpatient/outpatient at:

Allergy Testing Details:

- Antimicrobial allergy to:
- Time of assessment:
- Pen -FAST Tool used for assessment.
- Risk rating: 0

Clinical Summary:

Allergy history indicates this patient had features consistent with a very low risk for future reaction to penicillin. The PEN-FAST assessment tool was utilised and indicated a very low-risk rating for future reaction to penicillin. This patient has had their allergy label removed and the record on our hospital electronic medical record system updated.

This assessment indicated that they can now receive penicillin for future indications.

Plan and Requested Actions:

Please remove allergy label on community records to ensure optimal first line antimicrobial therapy in accordance with guidelines for future indications.

Sincerely,



Antimicrobial Allergy Assessment

Dear GP

Re: **Patient Name:**

DOB:

MRN:

This patient had an antimicrobial allergy assessment performed by:

As an inpatient/outpatient at:

Allergy Testing Details:

- Antimicrobial allergy to:
- Time of assessment:
- Pen -FAST Tool used for assessment.
- Risk rating: 3+

Clinical Summary:

Allergy history indicates this patient had features consistent with a moderate risk for future reaction to penicillin. The PEN-FAST assessment tool was utilised and indicated a moderate risk rating for future reaction to penicillin.

This assessment indicated that they require further review and assessment before they can receive penicillin for future indications.

Plan and Requested Actions:

Please review patient allergy label. This patient may benefit from further testing, or referral to an allergy/immunology clinic to ensure optimal first line antimicrobial therapy in accordance with guidelines for future indications. The John Hunter Hospital Immunology and Allergy Clinic can be contacted on (02) 4922 3912 Monday to Fridays, 8am to 4.30pm.

Sincerely,