



October 2022

Check Again

Breakthrough Series Collaborative

OFFICIAL

CHANGE PACKAGE

We aim to provide documents in an accessible format. If you're having problems accessing this document with you accessibility tools, please email Safer Care Victoria <u>email Safer Care Victoria</u> <info@safercare.vic.gov.au>

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

© State of Victoria, Australia, Safer Care Victoria, November 2023

ISBN 978-1-76131-658-6

Available at the <u>Safer Care Victoria website</u> https://www.safercare.vic.gov.au



Check Again Change Package

2 October 2022

OFFICIAL

What will our collaborative achieve?

By August 2023, we will increase access to comprehensive allergy assessment by 25%[^] for hospitalised Victorians^{*} with a penicillin allergy to ensure access to the safest and most appropriate antibiotics and enable the delabelling of low-risk penicillin allergies.

^from baseline data, *at participating sites

How to use this change package

A change package guides participants in a Breakthrough Series Collaborative to engage in improvement work at their health service. A change package provides information from literature, clinical practice guidelines and expert recommendations that can be considered and adapted within a local health care setting, for each change idea set out in the driver diagram. It is important to note, that it is not intended that teams will test all the change ideas, but for this document to provide a consolidated resource.

Driver Diagram

The driver diagram is used to conceptualise the issue and determine the changes which create a pathway towards achieving our aim. In this package, the driver diagram (Figure 1) is broken down into smaller, easy to use parts. Change ideas are set out for each element based on available evidence. To assist in navigating this document, hyperlinks have been embedded throughout the driver diagram.

AIM	PRIMARY		SECONDARY DRIVERS		CHANGE IDEAS				
	DRIVERS (P)		(S)		(C)				
By August 2023, we will increase access to comprehensive	D1 Decembra		S1. Program establishment	÷	 C1. Implement clinician training and support for use of an allergy assessment tool and delabelling C2. Design an appropriate model of care for pharmacy, nursing or medical led allergy assessment and delabelling including clear escalation pathways for clinicians C3. Identify oversight committee and integrate defined reporting line/ governance structures C4. Design and Implement penicillin allergy identification ward round C5. Choose allergy assessment tool(s) to consistently and safely identify patients with a low risk of penicillin allergy and confirm high risk allergies 				
allergy assessment by 25%^ for hospitalised Victorians* with a	P1. Recognition, safety and response		S2. On admission	←	 <u>C5. Choose allergy assessment tool(s) to consistently and safely identify patients with a low risk of penicillin allergy and confirm high risk allergies</u> <u>C6. Design a system to notify responsible team of patients admitted with penicillin allergy label</u> <u>C7. Design and implement protocol for direct delabelling of penicillin allergies and oral rechallenge</u> <u>C8. Design a proactive referral process to penicillin allergy team</u> 				
penicillin allergy to ensure access to the safest and			Ĺ	S3. Once infection identified requiring antibiotics	~	 <u>C5.</u> Choose allergy assessment tool(s) to consistently and safely identify patients with a low risk of penicillin allergy and confirm high risk allergies <u>C7.</u> Design and implement protocol for direct delabelling of penicillin allergies and oral rechallenge <u>C9.</u> Design referral process to penicillin allergy team at time of antibiotic prescription 			
most appropriate antibiotics and enable the delabelling of low		P2. Partnering with	S4. At the time of allergy assessment	←	C10. Co-design consumer information, videos and handouts C11. Co-design shared decision making tools and prompts to support patients to make an informed decision about their allergy C12. Tailored decision making process for individual team members/patients				
risk penicillin allergies. ^from baseline	<u>P2. Partnering with</u> consumers						$\left\{ \right.$	S5. Equity and access for people who speak languages other than English	←
data, *at participating sites			S6. Planning for and upon discharge and transition	←	C11. Co-design shared decision making tools and prompts to support patients to make an informed decision about their allergy C14. Co-design consumer information, videos and handouts in key languages C15. Develop discharge education material for patients in key languages C16. Develop discharge education material for patients C17. Design GP/Other specialists documentation/communication				

DEFINITION OF LEVELS OF EVIDENCE

Evidence to support the driver diagram for the assessment and delabelling of penicillin allergies is drawn from a variety of sources that provide strong empirical support for the primary and secondary drivers. Due to the range of definitions of what constitutes evidence for health care actions, the following are used with this work:

LEVEL 3: Highest level of evidence - very effective

- Published literature/resources that provides a clear description of actions and results within or across sites
 - Publication in healthcare peer reviewed journals or expert resources (from expert groups or organisations).

Experience with application in the field, demonstrated results, studied over time, with sustained results.

LEVEL 2: Indications of evidence - moderately effective

- Experience with application in the field, demonstrated results, sustained over time
- May have a shorter period of sustained results than Level 3
- May show strong evidence for alternate outcomes or processes e.g., processes for other disease states
- No major publication of this work

LEVEL 1: Emerging ideas worthy of trial by others - promising

- Early adaptors showing positive results
- Shorter trial in the field

LEVEL 0: No evidence

• A potentially good hypothesis worthy of testing

KEY PRINCIPLES UNDERPINNING THIS WORK

Embedding consumers in quality improvement

Involving consumers in the redesign of both the systems of care and their own care has been demonstrated to improve outcomes. <u>Co-design</u> brings consumers, patients, and stakeholders together to design new products, services, and policies. When patients and their caregivers/families contribute to the design and development of interventions with health care staff, local solutions to local problems are created, contextualized, and based on their needs. In this work, it is an expectation that individuals or carers that have lived experience of a penicillin allergy (or other appropriate allergy) are on quality improvement teams, patient advisory groups, and any other key working groups that are part of the improvement process.

Applying an equity lens first

Individuals from disadvantaged social groups, in general, experience poorer health outcomes than those from a non-disadvantaged social group. The greatest gains in a population can sometimes be made by considering who might be disadvantaged and starting improvement efforts there. When designing and testing changes, consider the perspective and experience of Aboriginal and Torres Strait Islanders, Culturally and Linguistically Diverse people, those from non-English speaking backgrounds, and others who may be disadvantaged.

Including people from a diverse range of backgrounds on the consumer panels, reduce the likelihood that improvement efforts will have cultural blind spots. The <u>Cultural responsiveness framework for Victorian Health</u> <u>Services</u> provides practical guidelines for improving cultural sensitivity in health services.

WHAT IS A CHANGE IDEA?

A change idea is an actionable, specific idea for changing a process. Change ideas can come from research, best practices, or from other organisations that have recognised a problem and have demonstrated improvement on a specific issue. Change ideas can be tested to determine whether they will result in improvement and are often revised as a result of these tests.

Teams test change ideas by running Plan-Do-Study-Act (PDSA) cycles: these are about learning what works and what does not in your efforts to improve your processes. Initially, these cycles are carried out on a small scale to see if they result in improvement. Teams can then expand the tests and gradually incorporate larger and larger samples until they are confident that the changes will result in sustained improvement.

HOW TO APPROACH THIS WORK?

Establishing a program to assess and delabel penicillin allergy requires individualised governance from each health service. To support participating teams to provide a safe and effective penicillin allergy assessment and delabelling program we have prioritised change ideas using a stepwise approach.

Whilst no team is expected to test **all** the listed change ideas, some change ideas and processes within this collaborative may need to be established sequentially. Validated improvement tools will assist teams to design and implement evidence based and tested processes appropriate to your local context in conjunction with your executive sponsor. Before progressing, sign off governance from your executive sponsor +/- specific committees depending on health service requirements will need to occur to minimise the risks within the program.

For change ideas that do not need to be completed sequentially, they can be considered a menu of options from which you may choose which are most appropriate for your health service. Each team will review their data, progress to date, organisational priorities, and select an area(s) to prioritise following the initial change ideas. For example, some may start with assessment items related to one driver. Others may choose to start by tackling assessment across both primary drivers. Choose an area that may lead to an easy win.

"While all changes do not lead to improvement, all improvement requires change."

PRIMARY DRIVER: RECOGNITION, SAFETY AND RESPONSE

Focusing on what can be done proactively and reactively to recognise and manage penicillin allergies to improve patient access to a safe and effective penicillin allergy assessment and delabelling program.

Program Establishment:

The first phase of the Check Again project requires health services to establish the foundations for the program. Health services need to identify the key team members for the initiative including the most appropriate ward or unit to commence testing change ideas. It is important to engage with a motivated and engaged team who will be able to test change ideas and excite colleagues about the impact of the program.

Improvement tools that will assist health service teams to establish the program include:

- 1. Process Mapping is a tool completed as a team to highlight the critical touchpoints for a patient with penicillin allergy within the health service. Examining the process map to establish opportunities for assessment and delabelling.
- 2. SWOT analysis stands for Strengths, Weaknesses, Opportunities and Threats and can be used to critically appraise the opportunities highlighted within your process map. This will ensure health services can establish a sustainable model of care that has been tailored specifically to the needs of your organisation.
- 3. Failure Mode and Effect Analysis is a systematic and proactive method to evaluate a process to identify where and how it may fail and assess the relative impact of such failures. Completing this analysis will enable sites to determine where processes, procedures or protocols may need to be established to minimise risk to patients, staff and the health service.

Penicillin Allergy Assessment

Prior to commencing a delabelling program it is important to have established a consistent and reliable penicillin allergy assessment process. The use of specific penicillin allergy assessment tool(s) and documentation processes are required with sign off from the executive sponsor or relevant oversight committee prior to proceeding to allergy delabelling.

Secondary driver	Change Idea	Explanation	Resources	Level of evidence (references)
S1. Program establishment	C1. Implement clinician training and support for use of an allergy assessment tool and delabelling	Implement processes to ensure clinicians undertaking penicillin allergy assessment and delabelling have sufficient training, support and supervision to enable them to safely, effectively and comprehensively assess and delabel penicillin allergies.	 <u>ASCIA e-training module</u> for penicillin allergies (For clinicians) <u>Penicillin Allergies</u> – NCAS (For clinicians) <u>CAAR videos</u> – education videos antibiotic allergy assessment (For clinicians) <u>Penicillin allergy: a practical approach to assessment and prescribing</u> – NPS (For clinicians) <u>The assessment of severe cutaneous adverse drug reactions</u> – NPS (For clinicians) <u>Penicillin Allergy Centre -</u> American Academy of Allergy, Asthma & Immunology (For clinicians) <u>Penicillin and Cephalosporin allergies</u> - SA Health (For clinicians) <u>Pathways to improved antibiotic allergy and antimicrobial stewardship practice: The validation of a beta-lactam antibiotic allergy assessment tool (For clinicians)</u> <u>Action 1.20 Australian Commission on Safety and Quality in Health Care (For clinicians)</u> 	3 (1-10)

51. Program establishment	C2. Design an appropriate model of care for pharmacy, nursing or medical led allergy assessment and delabelling including clear escalation pathways for clinicians	 Several clinical specialties have the skill set to lead a penicillin allergy assessment and delabelling program. These include: Pharmacy Nursing Medical teams Your health service will need to consider skill mix and resourcing to determine the most suitable approach for your health service. 	 <u>ASCIA e-training module</u> for penicillin allergies (For clinicians) <u>ASCIA Consensus Statement for the</u> <u>Assessment of Suspected Allergy to Penicillin</u> <u>Antibiotics</u> (For clinicians) <u>Albury Wodonga Health's protocol (Appendix</u> <u>A) (For clinicians)</u>
		Penicillin allergy assessment and delabelling is not without risk if it does not follow robust processes to determine the appropriate clinical pathway for patients.	 <u>Allergy Assessment Guide (Appendix B)</u> (For clinicians) <u>Quality Improvement Essentials Toolkit - IHI</u> (For clinicians)
		Participating sites will need to identify the tools, protocols, guides etc that they will use in their local penicillin allergy assessment +/- delabelling program.	 Penicillin Allergy Assessment and De-labelling St George Hospital, South Eastern Sydney (For clinicians) The Penicillin Allergy Delabeling Program: A
		Use Failure Modes and Effects Analysis and process mapping to identify risks, causes and potential gaps within the organisation and develop protocols and pathways to minimise risk to the patient.	Multicenter Whole-of-Hospital Health Services Intervention and Comparative Effectiveness Study (For clinicians) The Safety and Efficacy of an Oral Penicillin
	Utilising consistent documentation processes for penicillin allergy assessment will enable consistent allergy documentation within the medical record. Documentation of the active ingredient, date or length time since the reaction, nature and severity of the reaction are essential components to document from the assessment.	Challenge Program in Cancer Patients: A Multicenter Pilot Study (For clinicians) Effectiveness and Feasibility of Pharmacist- Driven Penicillin Allergy De-Labeling Pilot	
		Accurate documentation will assist with identifying low risk and no risk penicillin allergies that may be appropriate for direct delabelling or oral challenge.	Program without Skin Testing or Oral Challenges (For clinicians) Evaluation of a Pharmacist-Led Penicillin Allergy Assessment Program and Allergy Delabeling in a Tertiary Care Hospital (For
		Oral challenge documentation should include the dose, time of administration and any side effects or reactions encountered.	clinicians) Implementation of a pharmacist-led penicillin allergy de-labelling service in a public hospital (For clinicians)
			<u>Direct Challenges to Penicillin-Based</u> <u>Antibiotics in the Inpatient Setting</u> (For clinicians)

S1. Program establishment	C3. Identify oversight committee and integrate defined reporting line/governance structures	To manage clinical risk for patients and staff appropriate governance structures must be established. Governance should include an oversight committee, examples of this include infection control, Antimicrobial Stewardship (AMS) or medication safety committees and will be dependent on your health service. The committee will be responsible for the oversight of this program which may include review of protocols, adverse events and escalation pathways for clinicians. As part of the governance of this program sites should also consider reporting on whether the tools, protocols or guides they have chosen, are being used by the clinical staff.	• Action 3.01 Australian Commission on Safety and Quality in Health Care (For clinicians)	2
	C4. Design and implement a penicillin allergy identification ward round	Establishing a dedicated ward round for penicillin allergy will enable proactive assessment, consenting of patients for oral challenge and the delivery of patient education.	Evaluation of a pharmacist-led penicillin allergy de-labelling ward round: a novel antimicrobial stewardship intervention (For clinicians)	3 (21)
	C5. Choose allergy assessment tool(s) to consistently and safely identify patients with a low risk of penicillin allergy and confirm high risk allergies	 There are three standard allergy assessment tools that can be used by your health service to accurately and safely assess penicillin allergies. Allergy Assessment Tool PEN-FAST Therapeutic Guidelines Each tool has different strengths and it will be dependent on your model of care which would be the most appropriate for your organisation. To assist with deciding on the right tool(s) please refer to the Allergy Assessment guide (Appendix B). 	 Allergy Assessment Guide (Appendix B) (For clinicians) Diagnosis of antimicrobial hypersensitivity – Therapeutic Guidelines (For clinicians) Evaluation of a pharmacist-led penicillin allergy de-labelling ward round: a novel antimicrobial stewardship intervention (For clinicians) Development and Validation of a Penicillin Allergy Clinical Decision Rule (PEN-FAST) (For clinicians) A randomized evaluation of an antibiotic allergy assessment tool for supporting penicillin allergy de-labelling by non-allergists (For clinicians) Assessment of the validity of the beta-lactam antibiotic allergy assessment tool for use in the rural context, QLD (For clinicians) 	3 (4, 5, 7, 22- 24)

Secondary driver	Change Idea	Explanation	Resources	Level of evidence (references)
S2. On admission	C6. Design a system to notify responsible team of patients admitted with penicillin allergy label	Establishing a clear system to recognise, notify and inform the team of patients admitted with a penicillin allergy label. Examples of identification points include nursing, medical or pharmacy initial assessments or an automated alert in electronic medical records. You can test and design a system to meet health services individual needs. Some services may use an identification process that only notifies the responsible team of low risk or no risk penicillin allergies who may be appropriate for delabelling. Other services might choose to be notified about all patients with a penicillin allergy.	 <u>A Proactive Approach to Penicillin Allergy</u> <u>Testing in Hospitalized Patients</u> (For clinicians) <u>Penicillin Allergy Delabeling: A</u> <u>Multidisciplinary Opportunity</u> (For clinicians) <u>Inpatient Electronic Consultations (E-consults)</u> <u>in Allergy/Immunology (For clinicians)</u> <u>Addressing Inpatient Beta-Lactam Allergies: A</u> <u>Multi-Hospital Implementation (For clinicians)</u> 	3 (13, 25-28)
	C7. Design and implement protocol for direct delabeling of penicillin allergies and oral rechallenge	To maintain patient safety and minimise the risk of adverse events protocols should be established in accordance with hospital policy. Protocols should include eligibility and exclusion criteria for delabelling, dosage and drug recommendations for oral rechallenge, escalation pathways and how to respond if an adverse event occurs.	 <u>Albury Wodonga Health's protocol (Appendix</u> <u>A)</u> (For clinicians) <u>Antibiotic Allergy Oral Challenge Guideline</u> - Austin Health (For clinicians) <u>Recommendations for sites implementing an</u> <u>oral challenge program (Appendix C)</u> (For clinicians) <u>ASCIA's Antibiotic Allergy Challenges Consent</u> <u>Form (For clinicians)</u> <u>Direct oral penicillin challenge for penicillin</u> <u>allergy delabeling as a health services</u> <u>intervention: A multicenter cohort study (For</u> clinicians) <u>The Safety and Efficacy of an Oral Penicillin</u> <u>Challenge Program in Cancer Patients: A</u> <u>Multicenter Pilot Study (For clinicians)</u> <u>Single-step direct drug provocation testing is</u> <u>safe for delabelling selected non-low-risk</u> <u>penicillin allergy labels (For clinicians)</u> 	3 (11, 12, 15, 16, 29-33)

	8. Design a proactive referral process to penicillin allergy team	 The penicillin allergy team/service will be defined by local health services and could include pharmacists, AMS, specialist nurses, ID, immunology, or other medical specialties. Proactive assessment and delabelling of penicillin allergies requires a central process within your health service. The system may consist of: Electronic medical record referrals Identification of patient by the penicillin allergy team from medical records allergy alert Notification via phone call or page Manual referral systems The system will need to be communicated to the broader team to ensure that the referral pathways are clearly outlined. 	 <u>A Proactive Approach to Penicillin Allergy</u> <u>Testing in Hospitalized Patients (For clinicians)</u> <u>The Penicillin Allergy Delabeling Program: A</u> <u>Multicenter Whole-of-Hospital Health Services</u> <u>Intervention and Comparative Effectiveness</u> <u>Study</u> (For clinicians) 	3 (11, 25)
--	--	---	--	---------------

Secondary driver	Change Idea	Explanation	Resources	Level of evidence (references)
S3. Once infection identified requiring antibiotics	C9. Design referral process to penicillin allergy team at the time of antibiotic prescription	 The penicillin allergy team will be defined by local health services and could include pharmacists, AMS, specialist nurses, ID, immunology, or other medical specialties. Design and test a referral process to the penicillin allergy team prior to patient receiving antibiotics. The system may consist of: Electronic medical record referrals Identification of patient by the penicillin allergy team from medical records allergy alert Notification via phone call or page Manual referral systems The system will need to be communicated to the broader team to ensure that the referral pathways are clearly outlined. 	 <u>A Proactive Approach to Penicillin Allergy</u> <u>Testing in Hospitalized Patients (For clinicians)</u> <u>Implementation of a penicillin allergy</u> <u>screening tool to optimize aztreonam use (For clinicians)</u> 	3 (26, 34, 35)

PRIMARY DRIVER: PARTNERING WITH CONSUMERS

Ensuring consumers are included in and informed of decisions relating to their penicillin allergy is of utmost importance. For a penicillin allergy assessment and delabelling program to succeed we need to:

- Ensure one coordinated team: clinicians, patients, families, and carers working together.
- Ensure co-design principles are followed in the development of resources and tools to support shared decision-making and patient information
- Ensure that resources are available when needed and adapted to meet the diverse needs of the community

Secondary driver	Change Idea	Explanation	Resources	Level of evidence (references)
S4. At the time of allergy assessment	C10. Co-design consumer information, videos and handouts	Involve consumers in the development and design of information resources for penicillin allergy assessment and delabelling at your health service. Relabelling of penicillin allergies (following delabelling) by the patient or other health providers (who have access to old medical histories) is a common problem. Proactively design patient resources to help decrease the risks of penicillin allergy relabelling.	 Maintaining penicillin allergy delabeling: A quality improvement initiative (For clinicians) Antibiotic Allergy Challenges Frequently Asked Questions (FAQ) – ASICA (For consumers) Penicillin allergy – NCAS (For consumers) Do you have an antibiotic allergy? – CEC (For consumers) Penicillin Allergy – What do you need to know? - American Academy of Allergy, Asthma & Immunology (For consumers) NAAN resources - NAAN (For consumers) Always Use Teach Back! IHI - Institute for Healthcare Improvement (For clinicians) Teach-back (For clinicians) The Power of Four Words: "What Matters to You?" IHI - Institute for Healthcare Improvement (For clinicians) Action 4.11 Australian Commission on Safety and Quality in Health Care (For clinicians) 	3 (16, 36-38)

S4. At the time of allergy assessment	C11. Co-design shared decision- making tools and prompts to support patients to make an informed decision about their allergy	 Involve consumers in the development and design of shared decision-making tools and systems at your health service to ensure involvement of patients in decisions regarding their penicillin allergy. Without shared decision-making and the involvement of patients in their care, we are unlikely to see behaviour change and increasing the risk of penicillin allergy relabelling. Examples of how this could be done include the co-design of a penicillin allergy informed consent form. In addition, by using the 'teach back' technique throughout this process, clinicians will ensure that patients and carers understand the key concerns around penicillin allergy labels and the management of these. 		Shared decision making – Australian Commission on Safety and Quality in Health Care (For clinicians) Antibiotic Allergy Challenges Frequently Asked Questions (FAQ) – ASICA (For consumers) Penicillin allergy – NCAS (For consumers) Do you have an antibiotic allergy? – CEC (For consumers) NAAN resources – NAAN (For consumers) Penicillin Allergy – What do you need to know? - American Academy of Allergy, Asthma & Immunology (For consumers) Always Use Teach Back! IHI - Institute for Healthcare Improvement (For clinicians) Patient Priorities Care (For clinicians) Using plain language in health information (For clinicians) Easy English (For clinicians) The Power of Four Words: "What Matters to You?" IHI - Institute for Healthcare Improvement (For clinicians)	2 (37, 38)
	C12. Tailored decision-making process for individual team members/patients	Design and educate clinicians on importance of individualised pathways based on clinical reasoning to support patients and their communication needs. This will ensure a patient-centred penicillin allergy assessment and delabelling program.	•	Patient Priorities Care (For clinicians) My Health Priorities (For patients/carers) The Power of Four Words: "What Matters to You?" IHI - Institute for Healthcare Improvement (For clinicians) Action 5.14 Australian Commission on Safety and Quality in Health Care (For clinicians)	2

Secondary driver	Change ideas	Explanation	Resources Level of evidence (references)
S5. Equity and access for people who speak languages other than English	C13. Use of interpreter at time of allergy assessment	To ensure equity of care, patients who identify their primary language as other than English should have their allergy assessment undertaken with an interpreter present.	 <u>Patient Priorities Care</u> (For clinicians) <u>My Health Priorities</u> (For patients/carers) <u>Action 5.14 Australian Commission on Safety and</u> <u>Quality in Health Care (For clinicians)</u>
	C14. Co-design consumer information, videos and handouts in key languages	Involve consumers in the development and design of information resources for penicillin allergy assessment and delabelling at your health service. This information should be in a form that can be used and understood by patients and is sensitive to individual patients' needs (for example, culturally appropriate). Relabelling of penicillin allergies (following delabelling) by the patient or other health providers (who have access to old medical histories) is a common problem. Proactively design patient resources to help decrease the risks of penicillin allergy relabelling.	 Shared decision making – Australian Commission on Safety and Quality in Health Care (For clinicians) Always Use Teach Back! IHI - Institute for Healthcare Improvement (For clinicians) Teach-back (For clinicians) Patient Priorities Care (For clinicians) My Health Priorities (For patients/carers) Hemingway App (For clinicians) The Power of Four Words: "What Matters to You?" IHI - Institute for Healthcare Improvement (For clinicians)
	C15. Develop discharge education material for patients in key languages	Being in hospital can be overwhelming. The provision of education and materials for patients on discharge will empower them to change their behaviour and if patients have been delabelled, prevent the relabelling of a penicillin allergy. This information should be in a form that can be used and understood by patients and is sensitive to individual patients' needs (for example, culturally appropriate).	 <u>Always Use Teach Back! IHI - Institute for Healthcare</u> <u>Improvement (For clinicians)</u> <u>Teach-back (For clinicians)</u> <u>The Power of Four Words: "What Matters to You?" </u> <u>IHI - Institute for Healthcare Improvement (For clinicians)</u> <u>Patient Priorities Care (For clinicians)</u> <u>My Health Priorities (For patients/carers)</u> <u>Using plain language in health information (For clinicians)</u> <u>Easy English (For clinicians)</u> <u>Hemingway App (For clinicians)</u> <u>Action 4.11 Australian Commission on Safety and Quality in Health Care (For clinicians)</u>

Secondary driver	Change ideas	Explanation	Resources	Level of evidence (references)
S6. Planning for and upon discharge and transition	C16. Develop discharge education material for patients	Being in hospital can be overwhelming. The provision of education and materials for patients on discharge will empower them to change their behaviour and if patients have been delabelled, prevent the relabelling of a penicillin allergy. Creating an environment where patients can receive the most appropriate and safest antibiotics both in hospital and the community.	 <u>Always Use Teach Back!</u> <u>IHI - Institute for Healthcare</u> <u>Improvement</u> (For clinicians) <u>Teach-back</u> (For clinicians) <u>The Power of Four Words: "What Matters to You?"</u> <u>IHI - Institute for Healthcare Improvement</u> (For clinicians) <u>Patient Priorities Care</u> (For clinicians) <u>My Health Priorities</u> (For patients/carers) <u>Hemingway App</u> (For clinicians) <u>The Power of Four Words: "What Matters to You?"</u> <u>IHI - Institute for Healthcare Improvement</u> (For clinicians) <u>The Power of Four Words: "What Matters to You?"</u> <u>IHI - Institute for Healthcare Improvement</u> (For clinicians) <u>Action 4.11</u> [Australian Commission on Safety and <u>Quality in Health Care</u> (For clinicians) 	3 (38-40)
	C17. Design GP/ other specialist documentation and communication	 Designing communication for distribution to general practitioners and other key specialists on discharge will enable patients to receive the safest and most appropriate antibiotics both in hospital and in the community. Consider distributing this information to: General Practitioners Community Pharmacy Dentists Specialist doctors Information on the patient's penicillin allergy assessment +/- delabelling could be included in the patient's discharge summary. This change idea will also assist to prevent the relabelling of penicillin allergies in patients have been delabelled or had their allergy history clarified. 	 <u>Antibiotic Allergy Alert Card</u> – NAAN (For clinicians) <u>GP Letter Post Antibiotic Allergy Reconciliation or testing</u> – NAAN (For clinicians) <u>Antibiotic Allergy Challenges Frequently Asked Questions (FAQ)</u> – ASICA (For consumers) <u>NAAN resources</u> - NAAN (For consumers) <u>Penicillin Allergy – What do you need to know? -</u> American Academy of Allergy, Asthma & Immunology (For consumers) 	3 (38-40)

References

1. Berger RE, Singh HK, Loo AS, Cooley V, Osorio SN, Lee JI, et al. Improving Antibiotic Stewardship for Inpatients with Reported Beta-Lactam Allergies and Limited Access to Penicillin Skin Testing. Jt Comm J Qual Patient Saf. 2022;48(3):147-53.

2. Blumenthal KG, Shenoy ES, Hurwitz S, Varughese CA, Hooper DC, Banerji A. Effect of a Drug Allergy Educational Program and Antibiotic Prescribing Guideline on Inpatient Clinical Providers' Antibiotic Prescribing Knowledge. The Journal of Allergy and Clinical Immunology: In Practice. 2014;2(4):407-13.

3. Husband AK, Lloyd C, AJ W, DM S. Practice and development audit. International Journal of Pharmacy Practice. 2007;15(Supplement_2):B73-B93.

4. Devchand M, Urbancic KF, Khumra S, Douglas AP, Smibert O, Cohen E, et al. Pathways to improved antibiotic allergy and antimicrobial stewardship practice: The validation of a beta-lactam antibiotic allergy assessment tool. The journal of allergy and clinical immunology In practice. 2019;7(3):1063-5 e5.

5. English KR, Knight K, Radke A, Sammells B, Walter C, Halliday D. Assessment of the validity of the beta-lactam antibiotic allergy assessment tool for use in the rural context, QLD. Aust J Rural Health. 2022;Epub ahead of print.

6. Staicu ML, Soni D, Conn KM, Ramsey A. A survey of inpatient practitioner knowledge of penicillin allergy at 2 community teaching hospitals. Annals of Allergy, Asthma & Immunology. 2017;119(1):42-7.

7. Owens R, Sandoe J, Whyte AF, Wilcock M, West R, Stonell R, et al. A randomized evaluation of an antibiotic allergy assessment tool for supporting penicillin allergy de-labelling by non-allergists. Clin Exp Allergy. 2021;51(9):1246-9.

8. Devchand M, Trubiano JA. Penicillin allergy: a practical approach to assessment and prescribing. Aust Prescr. 2019;42(6):192-9.

9. Copaescu AM, Trublano JA. The assessment of severe cutaneous adverse drug reactions. Aust Prescr. 2022;45(2):43-8.

10. Shenoy ES, Macy E, Rowe T, Blumenthal KG. Evaluation and Management of Penicillin Allergy: A Review. JAMA. 2019;321(2):188-99.

11. Chua KYL, Vogrin S, Bury S, Douglas A, Holmes NE, Tan N, et al. The Penicillin Allergy Delabeling Program: A Multicenter Whole-of-Hospital Health Services Intervention and Comparative Effectiveness Study. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2021;73(3):487-96.

12. Trubiano JA, Smibert O, Douglas A, Devchand M, Lambros B, Holmes NE, et al. The Safety and Efficacy of an Oral Penicillin Challenge Program in Cancer Patients: A Multicenter Pilot Study. Open Forum Infect Dis. 2018;5(12):ofy306.

13. Staicu ML, Vyles D, Shenoy ES, Stone CA, Banks T, Alvarez KS, et al. Penicillin Allergy Delabeling: A Multidisciplinary Opportunity. The journal of allergy and clinical immunology In practice. 2020;8(9):2858-68.e16.

14. Anstey KM, Tsao L, Otani IM. Drug Allergy Delabeling Programs: Recent Strategies and Targeted Populations. Clin Rev Allergy Immunol. 2022;62(3):484-504.

15. Trubiano JA, Vogrin S, Copaescu A, Nasra M, Douglas A, Holmes NE, et al. Direct oral penicillin challenge for penicillin allergy delabeling as a health services intervention: A multicenter cohort study. Allergy. 2022;77(3):1038-42.

16. Australasian Society of Clinical Immunology and Allergy (ASCIA). Drug (Medication) Allergy. Australia 2022 [cited 2022 March].

17. Turner NA, Wrenn R, Sarubbi C, Kleris R, Lugar PL, Radojicic C, et al. Evaluation of a Pharmacist-Led Penicillin Allergy Assessment Program and Allergy Delabeling in a Tertiary Care Hospital. JAMA Network Open. 2021;4(5):e219820-e.

18. du Plessis T, Walls G, Jordan A, Holland DJ. Implementation of a pharmacist-led penicillin allergy de-labelling service in a public hospital. Journal of Antimicrobial Chemotherapy. 2019;74(5):1438-46.

19. Ramsey A, Mustafa SS, Holly AM, Staicu ML. Direct Challenges to Penicillin-Based Antibiotics in the Inpatient Setting. The journal of allergy and clinical immunology In practice. 2020;8(7):2294-301.

20. Song YC, Nelson ZJ, Wankum MA, Gens KD. Effectiveness and Feasibility of Pharmacist-Driven Penicillin Allergy De-Labeling Pilot Program without Skin Testing or Oral Challenges. Pharmacy (Basel). 2021;9(3).

21. Devchand M, Kirkpatrick CMJ, Stevenson W, Garrett K, Perera D, Khumra S, et al. Evaluation of a pharmacist-led penicillin allergy de-labelling ward round: a novel antimicrobial stewardship intervention. The Journal of antimicrobial chemotherapy. 2019;74(6):1725-30.

22. Trubiano JA, Vogrin S, Chua KYL, Bourke J, Yun J, Douglas A, et al. Development and Validation of a Penicillin Allergy Clinical Decision Rule. JAMA Intern Med. 2020;180(5):745-52.

23. Therapeutic Guidelines [digital]. Melbourne: Therapeutic Guidelines Limited; 2022. Available from: <u>https://www.tg.org.au.acs.hcn.com.au</u>.

24. W. Covington E, B. Wingler MJ, Jayakumar RA, White CW. Strategies for Clarifying Penicillin Allergies When Skin Testing Is Not an Option. Pharmacy. 2019;7(2):69.

25. Chen JR, Tarver SA, Alvarez KS, Tran T, Khan DA. A Proactive Approach to Penicillin Allergy Testing in Hospitalized Patients. The journal of allergy and clinical immunology In practice. 2017;5(3):686-93.

26. Chen JR, Khan DA. Evaluation of Penicillin Allergy in the Hospitalized Patient: Opportunities for Antimicrobial Stewardship. Curr Allergy Asthma Rep. 2017;17(6):40.

27. Mustafa SS, Staicu ML, Yang L, Baumeister T, Vadamalai K, Ramsey A. Inpatient Electronic Consultations (E-consults) in Allergy/Immunology. The journal of allergy and clinical immunology In practice. 2020;8(9):2968-73.

28. Blumenthal KG, Shenoy ES, Wolfson AR, Berkowitz DN, Carballo VA, Balekian DS, et al. Addressing Inpatient Beta-Lactam Allergies: A Multihospital Implementation. The journal of allergy and clinical immunology In practice. 2017;5(3):616-25.e7.

29. Jani YH, Williams I, Krishna MT. Sustaining and spreading penicillin allergy delabelling: A narrative review of the challenges for service delivery and patient safety. British journal of clinical pharmacology. 2020;86(3):548-59.

30. Li J, Cvetanovski V, Fernando S. Single-step direct drug provocation testing is safe for delabelling selected non-low-risk penicillin allergy labels. Annals of allergy, asthma & immunology : official publication of the American College of Allergy, Asthma, & Immunology. 2021;127(2):232-5.

31. Rose MT, Slavin M, Trubiano J. The democratization of de-labeling: a review of direct oral challenge in adults with low-risk penicillin allergy. Expert Rev Anti Infect Ther. 2020;18(11):1143-53.

32. Torda A, Chan V. Antibiotic allergy labels-the impact of taking a clinical history. Int J Clin Pract. 2018;72(3):e13058.

33. Savic L, Ardern-Jones M, Avery A, Cook T, Denman S, Farooque S, et al. BSACI guideline for the set-up of penicillin allergy de-labelling services by non-allergists working in a hospital setting. Clin Exp Allergy. 2022;Epub ahead of print.

34. Staicu ML, Brundige ML, Ramsey A, Brown J, Yamshchikov A, Peterson DR, et al. Implementation of a penicillin allergy screening tool to optimize aztreonam use. Am J Health-Syst Pharm. 2016;73(5):298-306.

35. Estep PM, Ferreira JA, Dupree LH, Aldridge PJ, Jankowski CA. Impact of an antimicrobial stewardship initiative to evaluate beta-lactam allergy in patients ordered aztreonam. Am J Health Syst Pharm. 2016;73(5 Suppl 1):S8-13.

36. Brown M, Uzoma J, Vansice R, Mahan K, Conn KM, Ramsey A, et al. Examining the impact of a penicillin allergy skin testing brochure on inpatient perceptions: A pre-post intervention study. The journal of allergy and clinical immunology In practice. 2021;9(4):1736-7.e3.

37. Jannic A, Servy A, Chevalier X, Colin A, Chosidow O, Ingen-Housz-Oro S, et al. Self-diagnosed drug allergies: the belief of patients. J Eur Acad Dermatol Venereol. 2017;31(12):e524-e6.

38. Lutfeali S, DiLoreto FF, Alvarez KS, Patel SV, Joshi SR, Tarver SA, et al. Maintaining penicillin allergy delabeling: A quality improvement initiative. The journal of allergy and clinical immunology In practice. 2021;9(5):2104-6.e2.

39. McDanel D, Hosch L, Pham KD, Schwery A, Seiler K, Dowden AM. Relabeling of penicillin drug allergy after evaluation in a drug allergy clinic. The journal of allergy and clinical immunology In practice. 2022;10(1):346-8.

40. Harper HM, Sanchez M. Review of Pharmacist Driven Penicillin Allergy Assessments and Skin Testing: A Multi-Center Case-Series. Hosp Pharm. 2022;57(4):469-73.

Appendix A - Albury Wodonga Health's procedure

PENICILLIN ALLERGY DELABELING PROCEDURE



Definition / Description:

This procedure is designed to provide instructions on the process of investigating and removing the penicillin allergy label in patients who have been previously been labelled as having a penicillin allergy. Delabeling false penicillin allergies is particularly beneficial for patients with a probable need of antibiotic therapy, as penicillins are first-line agents for many infections. However, delabeling is beneficial for all patients as the rate of antibiotic prescriptions increases with ageing. Approximately 50% of patients with a listed penicillin allergy are able to have their penicillin allergy removed or delabeled by assessment and/or allergy testing. ^[1] ^[2] ^[3] ^[4] Those with a penicillin allergy label requiring antibiotic treatments are more likely to have worse clinical outcomes, increased medication error and delays to antibiotic therapy, increased hospital duration and costs, increased antimicrobial resistance and increased mortality. ^[1] Direct oral challenges have been demonstrated to be safe and effective in patients who are identified as having low-risk penicillin allergy histories. ^[2] ^[5] ⁽⁶⁾

Personnel Able to Perform or Assist with Procedure:

- AMS team (Infectious diseases (ID) registrar, ID consultant or AMS Pharmacist)
- Medical officer responsible for patient care
- Registered nurse

Expected Outcomes:

It is expected the majority of patients with a low risk penicillin allergy will be able to have their penicillin allergy removed or delabeled by either assessment and/or direct oral challenge. This will allow for patients previously thought to be penicillin allergic to be treated with these antibiotics when they are required.

Equipment:

- Adrenaline 1:1,000 (1mg/1mL) amps
- Depending on the patients allergy history either: phenoxymethylpenicillin 250mg or amoxicillin 250mg or flucloxacillin 250mg

Process Standards:

Utilise <u>Antibiotic Allergy Assessment Tool MR1072</u> to determine if the patient is a low risk for a penicillin allergy. Only low risk patients are to be challenged as part of this procedure.

Utilise Antibiotic Allergy Inpatient Challenge MR1073 to assist with this procedure

Patients who report only Type A adverse drug reactions (such as nausea, vomiting, diarrhoea and headache) to penicillins can have their allergy delabeled without the need to undergo a direct oral penicillin challenge.

Inclusion criteria for oral penicillin challenge:

- Age > 18 years
- The patient scored as low-risk using the Antibiotic allergy assessment tool (AAAT) (<u>see MR1072</u>). Low risk is defined as scoring "green" or "white". This includes:
 - Unknown reaction > 10 years ago or date cannot be recalled ("many years ago");

PRO1855 - V1.0, 20 APR 2022

Page 1 of 6



- Type A adverse drug reactions (reaction documented is an expected side effect), where the patient won't accept direct delabeling;
- History of an unspecified childhood rash, localized injection site reaction only, or maculopapular exanthem (MPE) greater than 10 years prior

Exclusion criteria for oral penicillin challenge:

- Pregnancy.
- Allergy history unavailable due to patient cognitive impairment.
- Moderate or severe allergy history. "Orange" or "red" using the AAAT.
- History of any anaphylaxis or idiopathic urticaria/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).
- Concurrent use of antihistamines or of prednisolone at a dose of 10mg or greater (or equivalent corticosteroid dose).

Preparation:

- A member of the AMS team (ID consultant, ID registrar or AMS pharmacist) must be notified and agree that the patient is suitable for an oral challenge prior to proceeding with oral challenge.
- Medical officer present on ward throughout the procedure (not necessary to be with the patient the whole time).
- Adrenaline 1:1,000 (1mg/1mL) amps available on the ward.
- Have the antibiotic for direct oral challenge available.

Direct oral challenge procedure:

- Only to be performed on Monday to Friday between 9am and 3pm. Coordinate timing of oral challenge with the AMS team.
- 2. Patient to be consented by a member of the AMS team or medical officer.
- Obtain agreement from the treating / parent medical unit that the challenge procedure is clinically appropriate.
- 4. Notify the ward nursing staff looking after the patient and the ward in-charge nurse.
- Drug order (single dose penicillin VK 250mg or amoxicillin 250mg or flucloxacillin 250mg) to be charted as a stat order by ID registrar, ID consultant or medical registrar:
 - a. If reported allergy is to penicillin VK or benzylpenicillin -give phenoxymethylpenicillin VK 250mg
 - b. If reported allergy is to amoxicillin or ampicillin give amoxicillin 250mg.
 - c. If the reported allergy is to flucloxacillin give flucloxacillin 250mg
 - d. If the reported allergy is to "penicillin unspecified" and occurred prior to the widespread use of amoxicillin in 1972, give phenoxymethylpenicillin VK 250mg



- If the reported allergy is to "penicillin unspecified" and occurred after 1972, give amoxicillin 250mg
- f. If reported allergy is to Augmentin (amoxicillin + clavulanic acid) give amoxicillin 250mg. If no reaction occurs, the patient will be delabeled to amoxicillin only. The allergy label to clavulanic acid will remain
- If the reported allergy is to piperacillin/tazobactam, ticarcillin/clavulanate, or dicloxacillin do not perform challenge.
- h. NOTE: If the reported reaction is a Type A allergic drug reaction only with no other features consistent with an allergy and with a clear patient history, and beta-lactam therapy is required, the penicillin allergy label can be removed, and administration of a full treatment dose of penicillin can proceed without test dose.
- 6. Adrenaline 1:1,000 (1mg/1mL) amps available on the ward but PRN prescription not required.
- Medical officer to be available during 2 hour oral challenge observation period and available thereafter to attend patient immediately if required.
- 8. Nursing requirements:
 - a. Immediately prior to challenge perform baseline patient observations (HR, BP, Sats & RR)
 - Administer orally either a single dose of penicillin VK 250mg or amoxicillin 250mg or flucloxacillin 250mg
 - c. Perform half hourly observations for 2 hours post oral challenge
- Follow up visit by the AMS team immediately after post oral challenge to inform the patient of the outcome of the challenge procedure. This step is important to ensure that the patient understands the outcome and is more likely to accept future use of penicillin.
- If a history of delayed maculopapular exanthem (MPE) and no current antibiotic requirements, testing with a 5 day low dose oral challenge (penicillin VK 500mg bd or amoxicillin 500mg bd) or flucloxacillin 500mg bd) to exclude delayed hypersensitivity may be offered to the patient.
- 11. If no evidence of reaction, AMS team or medical team to remove penicillin allergy from patient drug chart and alert sheet immediately post challenge. A letter will be sent to the patient's other treating clinicians and GP and given to the patient to notify them of the allergy label removal.

Reactions from the test dose:

- If anaphylaxis occurs, administer 500 microgram (0.5 mL of 1:1,000 adrenaline) of adrenaline 1:1,000 (1mg/1mL) as per AWH adrenaline drug protocol. Then follow the AWH adrenaline drug protocol.
- If a reaction takes place and the antibiotic is being administered by nursing staff, the treating
 medical team must be notified immediately and the event documented in the patient record.
- For mild dermatological reactions (eg. maculopapular exanthem and localised itch), administer 1x Loratadine 10mg PO.
- The detail of the reaction is to documented/updated on patient's allergy alert. The patient is NOT to be delabeled.



Documentation of allergy delabeling:

If the patient has no adverse reaction after the first exposure to the test antibiotic, the AMS team or treating medical team will notify the patient that they do not have an antibiotic allergy to the test antibiotic.

Delabeling actions:

- Allergy label for the tested antibiotic can be removed from the patients drug chart and alert sheet – AMS team member responsible
- The delabeling procedure is to be documented in the patient's discharge summary and medical record – medical officer responsible
- A written document should be provided to the patient and the patient's GP, other treating
 physicians and local pharmacy AMS team member responsible
- Data to be recorded in the Austin Hospital's REDCap database AMS team member responsible
- Antibiotic Allergy Assessment Tool MR1072 and Antibiotic Allergy Inpatient Challenge MR1073 to be filed in the patients notes (nurse responsible) and scanned into patient's medical record.



Annexes:					
Related AWH Documents:	Antibiotic Allergy Assessment Tool MR1072				
	Anti	biotic Allergy Inpatient Challenge MR1073			
Accreditation Standards:					
Other Relevant Information:					
References:	1.	Blumenthal K, Peter J, Trubiano J, Phillips E. Antibiotic			
		Allergy. Lancet 2019 Jan 12;393 (10167):183-198. doi:			
		10.1016/S0140-6736(18)32218-9			
	2.	Chua, K., Vogrin, S., Bury, S., Douglas, A., Holmes, N.,			
		Tan, N., Brusco, N., Hall, R., Lambros, B., Lean, J.,			
		Stevenson, W., Devchand, M., Garrett, K., Thursky, K.,			
		Grayson, M., Slavin, M., Phillips, E. and Trubiano, J.,			
		2020. The Penicillin Allergy Delabeling Program: A			
		Multicenter Whole-of-Hospital Health Services Intervention			
		and Comparative Effectiveness Study. Clinical Infectious			
		Diseases.			
	3.	Trubiano JA, Adkinson NF, Phillips EJ. Penicillin allergy is			
		not necessarily forever. JAMA 2017; 318:82-3.			
	4.	Trubiano J, Phillips E. Antimicrobial stewardship's new			
		weapon? A review of antibiotic allergy and pathways to			
		"de-labeling." Curr Opin Infect Dis 2013;26:526-37.			
	5.	Banks TA, Tucker M, Macy E. Evaluating penicillin			
		allergies without skin testing. Curr Allergy Asthma Rep			
		2019; 19:27.			
	6.	Mustafa SS, Conn K, Ramsey A. Comparing direct			
		challenge to penicillin skin testing for the outpatient			
		evaluation of penicillin allergy: a randomized controlled			
		trial. J Allergy Clin Immunol Pract 2019; 7:2163–70.			



- Devchand et al., J Allergy Clin Immunol Pract. 2019 Mar;7 (3):1063-1065.e5. doi: 10.1016/j.jaip.2018.07.048. PMID: 30172019
- Chua et al., Clin Infect Dis. 2020 Aug 5;ciaa 653. doi: 10.1093/cid/ciaa653. PMID: 32756983.

Contact Point

In consultation with:

TITLE / POSITION:
Geoff Mackay (AMS Pharmacist)
Dr Justin Jackson (ID consultant)
Dr John Burston (ID consultant)
Dr Kyra Chua (Austin Hospital) & Associate Professor Jason Trubiano (Austin Hospital)

CHANGES FROM PREVIOUS DOCUMENT:

New Document

THIS SECTION FOR CORPORATE RECORDS OFFICE USE ONLY				
Approved by Executive / Delegate:	Date Approved:	SharePoint Location:		
Medication Safety Committee	20 April 2022	Procedures		
Responsible Department:	Date for Review:	Linked Documents:		
Medication Safety Committee	20 April 2025			
Version No:	Original Approval Date:	Previously Named As:		
1.0	20 April 2022	Same		

Penicillin Allergy Assessment Tools

Background:

Comprehensive penicillin allergy assessment allows for the determination of the severity of the allergy, the timing of the reaction and an understanding of which antibiotics the patient has tolerated since the penicillin reaction occurred. Understanding the severity of a patient's penicillin allergy label enables clinicians to stratify the risk of using alternative beta-lactam antibiotics and improve antibiotic prescribing appropriateness for patients with a penicillin allergy.

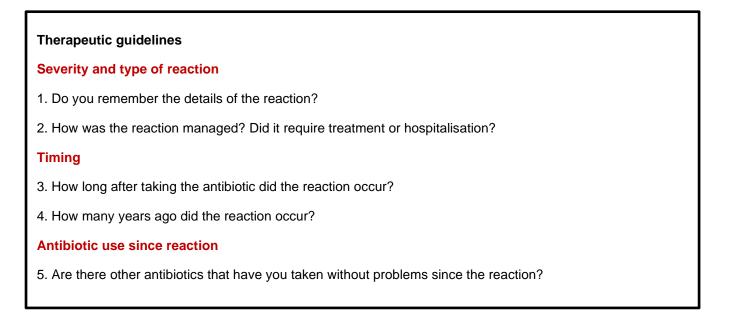
There are multiple published options available to assist in the penicillin allergy assessment process. To ensure safe and reliable penicillin allergy assessment for patients, Safer Care Victoria (SCV) recommends that health service sites select, adapt and use the following assessment tools:

- 1. Therapeutic Guidelines Antibiotic Allergy Assessment Questions,
- 2. An amended version of the Antibiotic allergy assessment tool,
- 3. PEN-FAST a Penicillin Allergy Clinical Decision Rule

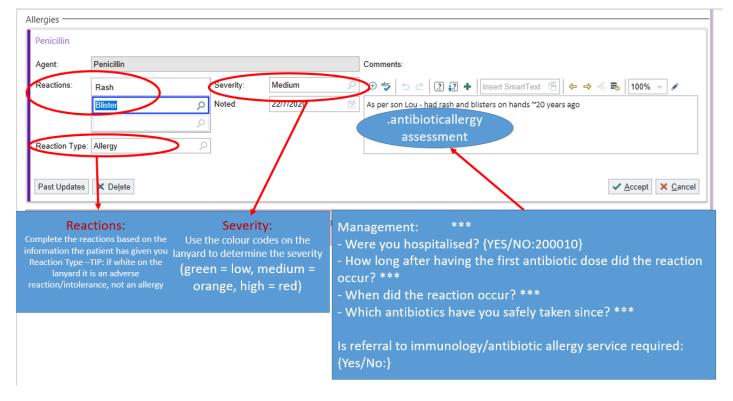
These tools are all readily assessable by health services, and different tools may be used at different stages of the assessment process. An explanation about the tools can be found below.

1. Therapeutic Guidelines Antibiotic Allergy Assessment Questions (23)

The Therapeutic Guidelines endorses the use of a comprehensive list of questions to understand a patient's penicillin allergy. This list is particularly useful in an electronic medical records environment to integrate into the electronic system and identify patients who may meet the criteria for a low-risk penicillin allergy. These questions can be adapted by health care services to formalise a process to assess penicillin allergies.



Example of an EMR form (Epic) based off the Therapeutic Guidelines questions:



Source: Peter MacCallum Cancer Centre 2022

Example of an EMR form (Cerner) based off the Therapeutic Guidelines questions:

	Allergies & Sensitivities	
O Lacknowledge that by clicking "Mark All as Reviewed", I ha	ve assessed and/or updated the patient Allergy status	
Mark All as Reviewed Add Modify No Known Allergies	Reverse Allergy Check Display All	•
D. Substance Category Reactions	Seve I Type C. Reaction	n S Updated By
Peanuts Drug Hives	Severe Allergy Cance	lled 09/09/2020 Quality, Brenda Mrs RN
✓ penicillins Drug Rash	Mod 🔍 Allergy Active	19/11/2020 Devchand, Misha - Pharmacist
No Known All Drug	Allergy Cance	lled 19/11/2020 Devehand, Misha Pharmaeist
•	III	•
	Penicillin Allergy Assessment	
Is the patient allergic to Penicillin antibiotics	Y O Yes O No Ampicil	cludes Amoxicilin, Amoxicilin/Clavulanic acid (Augmentin), n, Benzylpericilin, Dicloxacilin, Flucloxacilin, ymethylpenicilin, Piperacilin/Tazobactam (Tazocin)
How long ago did the reaction occur?	O Less than 5 years O 5 · 10 years O	Greater than 10 years C Unknown
How long after taking the first or second dose of antibiotic did the reaction occur?	C Less than or equal to 2 hours C Greater than 2 hour	s O Unknown
Did the patient have treatment for the reaction?	O Yes O No O Unknown	
How was the reaction managed? Tick all the boxes that apply	O Hospitalisation O Adrenaline O Antihist	amine O Cream/Dintments O Unknown
What is the Penicillin Allergy Severity? If the patient of	describes MULTIPLE MANIFESTATIONS default to t	he higher corresponding severity
Mild	Moderate	Severe
 Childhood exanthem (mild rash with no severe symptoms) Diffuse rash or localised rash/swelling with no other symptoms Mild hepatic or renal impairment Gastrointestinal symptoms (nausea, vomiting or diarrhoea) 	Angioedema (lip, facial or tongue swelling) Generalised swelling (outside of angioedema) Urticaria (wheals and hives) Laxyngeal or respiratory compromise (shortness of breath, hoarse voice or throat tightness)	Bistering/desquamating rash or mucosal ulceration (skin shedding, mouth, eye or genital ulcers) Any blood count abnormality Severe renal injury, failure or AIN Severe liver injury, failure or DILI
 Mild neurological manifestation (headache, depression, mood disorder) Unknown reaction greater than 10 years or family history of allergy 	- Severe neurological manifestation (seizure or psychosis) - Anaphylactoid/infusion reactions (i.e. red man syndrome) - Unknown reaction less than or equal to 10 years	Fever (not explained by infection) Anaphylaxis or unexpected collapse

ALL information obtained during PENICILLIN allergy assessment must be entered into Cerner Allergy Box (including allergy severity)

Source: Austin Health 2021.

2. Antibiotic allergy assessment tool (amended version)⁽⁴⁾

The antibiotic allergy assessment tool utilises patient-reported symptoms and signs associated with an index betalactam allergy to assign an accurate phenotype to the allergy and management recommendation for the allergy. This tool can be used by any health professional (i.e. doctor, pharmacist or nurses) and was validated by junior doctors, senior doctors, pharmacists, specialist nurses and haematology/oncology nurses.

D	ermatologi	cal		Respiratory	or Sy	stemic	Unknow	n	
Skin manifes	ation		commendation & ultant allergy type	Clinical manifestation		commendation & ultant allergy type	Clinical manifestation		Recommendation & Resultant allergy type
Childhood exanthem Mild rash with no severe	· · /		Unlikely to be significant (non-severe)	Laryngeal involvement		Immediate	Unknown reaction ≤ 5 years ago		Unknown (non-severe)
Immediate diffuse ra ("itchy immediate rash") <2 hours post dose	ısh		Immediate hypersensitivity (non-severe)	("throat tightness" or "hoarse voice")		hypersensitivity (severe)	Unknown reaction > 5 years ago or family history of penicillin allergy only		Unlikely to be significant (non-severe)
Diffuse rash or localized rash/swelling	> 5 years ago; or unknown		Delayed hypersensitivity (non-severe)	Respiratory compromise ("shortness of breath")		Immediate hypersensitivity (severe)	Renal		
with no other symptoms (non-immediate or unknown timing)	≤5 years ago		Delayed hypersensitivity (non-severe)	Fever ("high temperature") Not explained by infection		Delayed hypersensitivity (severe)	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)
Angioedema ("lip, facial or tongue sw	elling")		Immediate hypersensitivity (severe)	Anaphylaxis or unexplained collapse		Immediate hypersensitivity (severe)	Mild renal impairment (Does not meet criteria in box above)		Unlikely immune mediated (non-severe)
Generalized swelling (outside of angioedema)	;		Immediate hypersensitivity (severe)	Haemat	ologi	cal	Liver		
Urticaria ("wheals and hives")			Immediate hypersensitivity	Low platelets < 150 x10 ⁹ /L or unknown		Potential immune mediated (severe)	Severe liver injury, failure or DILI (\geq 5x upper limit of normal (ULN) for ALT or AST, or \geq 3x ULN for ALT with \geq 2x ULN for bilirubin, or \geq 2x ULN for ALP, or transplant)		Potential immune mediated (severe)
*isolated childhood urtic challenged on a case-by-			(non-severe)	Low neutrophils < 1x10 ⁹ /L or unknown		Potential immune mediated (severe)	Mild hepatic enzyme derangement (Does not meet criteria in box above)		Unlikely immune mediated (non-severe)
Mucosal ulceration ("mouth, eye or genital u	llcers")		Delayed hypersensitivity (severe)	Low haemoglobin < 100 g/L or unknown		Potential immune mediated (severe)	Gastrointestinal, Neurologic	al or	Infusion-related
Pustular, blistering o	r		Delayed	Eosinophilia		Delayed hypersensitivity	Gastrointestinal symptoms ("nausea, vomiting, diarrhoea")		Unlikely immune mediated (non-severe)
desquamating rash ("skin shedding")			hypersensitivity (severe)	(>0.7 x 10 ⁹ /L or unknown)		(severe)	Mild neurological manifestation ("headache, depression, mood disorder")		Unlikely immune mediated (non-severe)
Appropriate for supervis	ed direct oral rec	:hallen	ge (or direct de-label	ling)		🗆 Low risk	Severe neurological manifestation		Unknown or unclear
Appropriate for supervis	ed direct oral rec	hallen	ge			🗆 Low risk	("seizures or psychosis")		mechanism
May be appropriate for	referral for specia	alized s	kin testing			Moderate risk	Anaphylactoid/infusion reaction		Unknown or unclear
May be appropriate for	referral for specia	alized s	kin testing			🗆 High risk	(e.g. red man syndrome)		mechanism

3. PEN-FAST - a Penicillin Allergy Clinical Decision Rule⁽²²⁾

PEN-FAST is a clinical decision rule that accurately identifies low-risk penicillin allergies that do not require formal allergy testing. A PEN-FAST score of less than 3, is able to exclude a severe penicillin allergy and can identify patients who are appropriate to undergo an oral penicillin challenge. The PEN-FAST rule requires the user to have some drug allergy knowledge i.e. allergists, specialist nurses, infectious diseases clinicians with allergy training, or specialist pharmacists with allergy knowledge. For accessibility, there is also an <u>online calculator</u> that can also be used to calculate a PEN-FAST score.

Customise: Sites may choose to use a PEN-FAST score of 0, 0 - 1 or 0 - 2 to indicate patients appropriate for challenge.

PEN	Penicillin allergy reported by patient	If yes, proceed with assessment
F	Five years or less since reaction ^a	2 points
A	Anaphylaxis or angioedema	
s	OR Severe cutaneous adverse reaction ^b	2 points
-		
Т	Treatment required for reaction ^a	1 point
		Total points
	Interpretati	on
Points		
0 1	ery low risk of positive penicillin allergy test <	1% (<1 in 100 patients reporting penicillin allergy)
[1-2] L	ow risk of positive penicillin allergy test 5% (1	in 20 patients)
3 N	oderate risk of positive penicillin allergy test	20% (1 in 5 patients)

^a Includes unknown.

^b Forms 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. Acute interstitial nephritis, drug induced liver injury, serum sickness and isolated drug fever were excluded phenotypes from the derivation and validation cohorts.

Recommendations for sites implementing an oral penicillin challenge program

Background

The safety of performing direct oral penicillin challenges has been extensively demonstrated in the literature and these programs have been shown to improve appropriate antibiotic prescribing. However, there is no standardised approach to setting up an inpatient low-risk oral penicillin challenge program. This document aims to give evidence and expertbased recommendations on considerations when health care services set up a penicillin oral challenge program. (11, 12, 15, 16, 29-33)

1. Assessment

Consider: Who is notified of patients potentially appropriate for an oral challenge? How are they notified?

See Appendix B – penicillin allergy assessment tools

2. Eligibility

Consider: Who is eligible for an oral challenge? (Include: comorbidities, other medications, stability, location [i.e. on ward]) What does your site define to be a low risk penicillin allergy?

Recommended eligibility criteria from the Check Again faculty:

- Low risk penicillin allergy (to be defined by each site) See Appendix B
 - Possible definition of a low risk penicillin: Type A ADR (pharmacologically predictable reactions i.e. nausea, vomiting, diarrhoea etc), family history, rash > 5-10 years (non-severe), unknown reaction > 10 years
- Age: 16 100 (pregnant patients are currently excluded from the Check Again collaborative)
- Allergy History: Either the patient, the patient's family/carer/key contact or the patient's GP must be able to give a reliable allergy history. Exclude patients with a history of antibiotic-associated anaphylaxis, history of antibiotic-associated Severe Cutaneous Adverse Reactions (SCAR) or history of acute kidney injury or severe liver impairment associated with antibiotic therapy.
- **Stability**: No MET calls in past 24 hours, has been out of ICU for > 48 hours. Patient should be haemodynamically stable. Neutrophils > 0.5.
- Location: Not in ICU, on ward
- **Medications**: Exclude if the patient is currently prescribed: prednisolone > 25 mg daily (or equivalent), systemic vasoconstrictors including terlipressin or H1-antagonist antihistamines
- Comorbidities: Exclude if patient's reason for admission is exacerbation of asthma or cardiac in nature

3. Safety

Consider: Risk management plan – how to manage the patient if they have a reaction during the oral challenge? Will your hospital governance require a doctor to be present on the ward for the oral challenge and observation period? Does ICU need to be aware of any oral challenges taking place in the hospital?

Recommendations from the Check Again faculty:

• Consider undertaking oral rechallenges within regular business hours to ensure availability of staff to monitor and review the patient

4. Oral challenge

Consider: Who will consent the patient? Where and how will the consent be documented? What patient education processes and resources will be used prior to the oral challenge? Which drugs should be used for the oral challenge? What patient observations are required and for how long?

Recommendations from the Check Again faculty:

Drugs to be used for the oral challenge

- Single dose: phenoxymethylpenicillin 250 mg or amoxicillin 250 mg or flucloxacillin 250 mg
 - o If reported allergy is phenoxymethylpenicillin or benzylpenicillin give phenoxymethylpenicillin
 - o If reported allergy is amoxicillin or ampicillin give amoxicillin
 - o If reported allergy is flucloxacillin give flucloxacillin
 - If reported allergy is "unknown penicillin" give amoxicillin.
- 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

Observations

- Immediately prior to oral challenge, perform baseline patient observations (Heart Rate, Blood Pressure, Oxygen saturation, Respiratory Rate)
- Perform 30 minutely observations for 1.5 hours post administration of oral penicillin challenge

All patients who undergo an oral penicillin challenge should receive written information including

- Written information regarding potential health impacts of a penicillin allergy
- Written information regarding the oral challenge procedure and what happens or what to do if an adverse drug reaction occurs

5. Post Oral Challenge

Consider: Who will educate and provide written information to the patient if the oral penicillin challenge is successful/not successful? Who will update the allergy section of the patient's medical record? Who will ensure this information is included in the discharge summary and communicated to the patient's regular GP, pharmacy and other specialists?

Recommendations from the Check Again faculty:

Processes that should occur post an oral challenge

- Post oral challenge instructions regarding potential delayed adverse drug reaction and what to do if that occurs
- Verbal education of patient and/or carer of challenge outcome
- Written information of the challenge outcome (already written here)
- Removal of allergy label from patient chart (EMR, Med Chart and/or Alerts)
- Communication of the penicillin allergy delabelling to primary healthcare providers, and other health professionals including in the discharge summary