Safer Care Victoria

100,000 LIVES

February 2024

Check Again

Breakthrough Series Collaborative

OFFICIAL

PROJECT TOOLKIT

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Check Again toolkit

Who is this toolkit for?

This resource is for services that are planning improvement work to improve the assessment of penicillin allergies and implement delabelling strategies for low-risk penicillin allergies.

What is the toolkit?

This toolkit contains learnings from the Check Again project and improvement theory developed for the Check Again project.

The toolkit includes:

- Background information on the Check Again project
- A Clinician Toolkit
- An Improvement Toolkit

Extra resources available online include:

- the Check Again project charter – *contains information about the timeline of this project*
- the Check Again change package – *contains resources to support your work*
- the Check again evaluation summary report – *contains the summary of the results from the Check Again project*

Background

What did we set out to achieve in the Check Again project?

Patient reported antibiotic allergies or antibiotic allergy labels (AALs) have been an increasing public health issue both in Australia and internationally. More than two million Australians report an allergy to antibiotics, with the most commonly reported allergy being to penicillins (up to 10% of hospital inpatients) (Chua, et al., 2021; Devchand & Trubiano, 2019). Studies have shown that in more than 95% of cases, these penicillin allergy 'labels' are incorrect (Chua, et al., 2021; Copaescu, et al., 2022).

AALs are associated with an increased use of restricted or suboptimal antibiotics, increased rate of readmission, increased risk of surgical site infections, increased length of stay and increased mortality.

The Check Again project was established by Safer Care Victoria (SCV) with an aim to:

> 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 **At participating sites*

To find more information about findings of the Check Again project please see here.

The Check Again story

The Check Again Collaborative was built off the success of the *Antibiotic allergy delabelling program* (supported by the Better Care Victoria Innovation Fund). In 2019, the pilot program safely delabelled 97% of low-risk penicillin allergies following a negative oral penicillin challenge or direct delabelling (Chua, et al., 2021). The program showed significant improvements across health economics, patient experiences and medication safety with sustained gains across the project lifecycle (Chua, et al., 2021).

The Check Again collaborative was 10-month collaborative which ran from October 2022 to July 2023. 12 sites chose to participate and test change ideas to improve the assessment of penicillin for hospitalised Victorians. In addition, sites could choose to add a direct delabelling and/or oral challenge (test dose) component for low-risk penicillin allergies.

The Check Again project had lots of successes considering that only two of the 12 sites, were actively testing and delabelling low-risk penicillin allergies prior to the collaborative. By the end of the collaborative, 11 sites were actively delabelling low-risk penicillin allergies. Over the course of the collaborative, 148 patients had their penicillin allergy label removed following allergy assessment alone, and 63 patients had their penicillin allergy label removed following an oral challenge.

"... discussions with other health services .. helped us to encourage each other, learn from wins and obstacles and build camaraderie. " (Learning Session 2 Feedback, ID10, Metropolitan health service)

We now have a protocol/program set up for the initiative that we were involved in. This was a big achievement "(Summative Survey, ID 13, Pharmacist, Rural Health Service).

"Without the project, it is unlikely that these allergy checking and delabelling procedures would have been put in place." (Summative Survey, ID 20, Consumer)

1. Clinical Toolkit

This Clinical Toolkit was based on the feedback from the Check Again faculty. When starting a penicillin allergy assessment and delabelling program, consider three levels when designing and implementing your program:

1. Hospital level – governance and models of care

- Project governance
  - Consider who is responsible from a governance perspective. Sites who had an engaged executive sponsor, or executive support were able to overcome barriers in a timelier manner than those without.
  - Have clear flowcharts on the testing and implementation phases of the project and clear lines of accountability.
- Model of care at the health service:
  - Use a standardised approach, that is consistent across the Health Service.
  - Ensure clear ownership/accountability for each stage of the model of care.
  - Ensure that the model of care if multi-disciplinary and at a minimum should include: Pharmacy, Infectious Diseases/Antimicrobial Stewardship and Nursing. Additional teams to consider including are quality/improvement and allergy/immunology if available.

2. Clinician level – risk assessment and protocol development

Consider risks associated with the project and risk mitigation strategies (both patient safety and overall project risks). It is also important to consider which tool(s) your health service will use and to keep them consistent throughout the health service.

- Assessment tools
  - For the Check Again project, three assessment tools (**Appendix A**) were recommended to be used. Sites chose to use one tool alone or a combination of the tools. A majority of the sites in the Check Again collaborative used the Antibiotic Allergy Assessment Tool.
- Protocol development
  - This was a time-consuming process for the Check Again sites, consider starting this early, and engaging with hospital leadership to help support this process. To support the development of a local protocol, the Check Again faculty developed the protocol template (see **Appendix B**), which could be customised for the health care service. This template was adapted by rural regional and metropolitan health services.

3. Patient level – consumer engagement, feedback and information

- Engage with consumers early! Ensure they are part of the project team and continue to engage throughout the project.
- Some online consumer information is available online: consider using or adapting locally (see the International Antibiotic Allergy Network website for more information).

Key Learnings from the Check Again Collaborative

Models of Care:

The models of care that were the most successful and sustainable were those that embed the Check Again work within the role of the Antimicrobial Stewardship team, so that the ownership/governance of this program sat across multiple teams (Infectious Diseases and Pharmacy) with a multi-departmental structure already in place.

Patients that were more likely to progress to oral challenge and benefit from the program were those who were immunocompromised patients, surgical patients or those with an acute infection. Therefore, the project found that sites that used a targeted approach (focusing on high-risk patient groups i.e. surgical patients, or immunocompromised patients) were more successful than those that trialled hospital wide programs.

Governance:

From a governance perspective, sites that progressed rapidly needed Pharmacy, Infectious Diseases and Allergy/Immunology (if applicable) leadership engaged from the start and hospital executive involvement. Teams that had this support, were able to have their protocols/guidelines approved in a timely manner. However, even with this support, it took a majority of sites most of the collaborative to get these documents approved.

2. Improvement Toolkit

Using the model for improvement

Your step-by-step guide

This guide brings together foundational quality improvement methods, the Model for Improvement, and information from the Check Again project. Guided by simple but effective improvement science principles, the Model for Improvement helps us deliver results-based outcomes and support improvement in healthcare.

The Model for Improvement asks you to respond to three questions as you plan and undertake improvement work and it includes the plan-do-study-act (PDSA) cycle as the engine for developing, testing and implementing change in your system. Thoughtful, collaborative consideration of the three questions enables deep understanding of the problem or opportunity for improvement, identification of high-quality change ideas, and construction of an effective measurement strategy to capture learning and track progress.

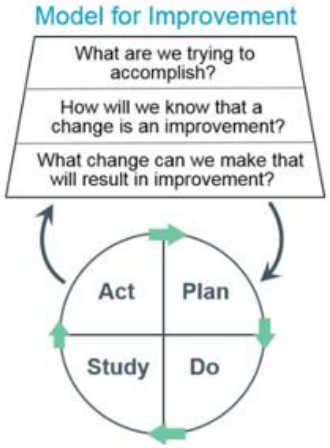


Figure 1. Model for improvement

1. Build your team

Improvement teams

Effective improvement in our complex healthcare system requires a team approach to share the work and to provide diverse knowledge and experience. Ideally, your team will include:

- a team leader who will be responsible for coordinating and driving the work (i.e. Antimicrobial Stewardship (AMS) Pharmacist, Nursing, Infectious Diseases and/or an Allergy clinician etc)
- at least one consumer with lived experience of your system
- someone with quality improvement knowledge and experience
- multidisciplinary representation, e.g. consider nursing staff, medical staff, administration staff (if appropriate)
- a senior sponsor

From the Check Again Collaborative it was found that teams that included a pharmacy executive and a representative from the AMS team developed more sustainable programs and were able to progress their programs rapidly (when compared to teams without these representatives). Therefore, it is recommended that these groups be included in the project team.

Senior sponsor

Support from your health service leadership is critical to enable your access to time, resources, and organisational commitment. Your senior sponsor is also essential in championing your work and helping you sustain will and energy throughout the work.

Partnering with consumers

Involving consumers in the redesign of the systems of care and the care they receive can improve outcomes. When patients, caregivers and families contribute to the design and development of interventions, local solutions to local problems are created based on their needs. If you are unsure where to start with consumer recruitment, reach out to the Consumer liaison service in your health service or see further guidance from Safer Care Victoria for partnering with consumers.

Partnering for Diversity

When forming your team, consider how you will attract diverse perspectives and experiences. Including a diverse range of people can ensure solutions work across the population.

Helpful tools:

- SCV Partnering in healthcare framework
- SCV Partnering for Quality Improvement
- Cultural responsiveness framework – Guidelines for Victorian health services
- SCV training opportunities for quality improvement
- Designing for Diversity
- Institute for Healthcare Improvement (IHI) Achieving health equity

2. Explore your opportunity for improvement

What does the data tell you?

Measures set out in the table below were used by participating services. You may wish to use these to understand your system's current performance, collecting data across all measures to form a baseline before beginning to test changes.

Remember the equity lens: the segmentation of data by social groupings can help target improvement efforts to those who may be most disadvantaged.

Table 1. Check Again measures (next page)

Measure Type	Measure	Measure definition
Outcome	% of patients with a no risk penicillin allergy that have their allergy directly delabelled [1]	**Numerator:** Number of patients who are assessed and found to have a no risk penicillin allergy following comprehensive allergy assessment and have their allergy label directly removed **Denominator:** Number of patients who undergo comprehensive allergy assessment and are found to have a no risk penicillin allergy label.
	% of patients with a low risk penicillin allergy that have their allergy delabelled following an oral challenge1	**Numerator:** Number of patients who are assessed and found to have a low risk penicillin allergy following comprehensive allergy assessment and have their allergy label removed following an oral challenge **Denominator:** Number of patients who undergo comprehensive allergy assessment and are found to have a low risk penicillin allergy label.
	% of patients with a penicillin allergy who correctly identify their allergy status post delabelling1	**Numerator:** Number of patients with a penicillin allergy who correctly identify their allergy status post delabelling **Denominator:** Number of patients who underwent penicillin allergy delabelling and then participated in the survey/phone call/follow up questions
Process	% of patients with a penicillin allergy that have the following information completed in the allergy section of their medical record (the active ingredient, the date/how long ago the reaction was, nature and severity of the reaction) ***(contributes to EIIF outcomes)***	**Numerator:** Of the denominator, the number of patients that have all four information points (the active ingredient, the date or how long ago the reaction was, nature and severity of the reaction) completed. **Denominator:** Total number of patients with a penicillin allergy documented in their medical record
	% of patients who list their primary language as other than English with a penicillin allergy that have the following information completed in the allergy section of their medical record (the active ingredient, the date/how long ago the reaction was, nature and severity of the reaction)	**Numerator:** Of the denominator, the number of patients who list their primary language as other than English that have all four information points (the active ingredient, the date or how long ago the reaction was, nature and severity of the reaction) completed. **Denominator:** Total number of patients who list their primary language as other than English with a penicillin allergy documented in their medical record
	% of patients who have the allergy section of their medical record updated following penicillin allergy delabelling1	**Numerator:** Number of patients with a penicillin allergy that have the allergy section of their medical record updated following penicillin allergy delabelling **Denominator:** Number of patients with a penicillin allergy had their penicillin allergy delabelled (either directly delabelled or following an oral challenge)
Balancing	Number of patients with a documented penicillin allergy who had an adverse reaction to a penicillin during their current hospital stay	**Numerator:** Number of patients who have a documented penicillin allergy, receive a penicillin during their inpatient stay and have an adverse reaction to that penicillin. **Denominator:** Number of patients who have an adverse reaction to a penicillin during their inpatient stay
	% of patients who have an adverse drug reaction during the monitoring period following an oral penicillin challenge1	**Numerator:** Number of patients who have an adverse drug reaction in the monitoring period following the penicillin challenge **Denominator:** Number of patients who undergo an oral challenge

	% of patients with a penicillin allergy who receive a penicillin following either comprehensive penicillin allergy assessment or delabelling	*Option 1:* **Numerator:** Number of patients who receive a penicillin post a comprehensive penicillin allergy assessment **Denominator:** Total number of patients who have had their penicillin allergy assessed *Option 2:* **Numerator:** Number of patients who receive a penicillin post penicillin allergy delabelling **Denominator:** Total number of patients who had their penicillin allergy delabelled

What do you know about the processes driving current practice?

Understanding your system involves knowing all the steps in the process and the factors affecting experiences and outcomes. Detailed understanding of this will help you and the team identify where there are inconsistencies, gaps, duplications, or delays.

Helpful tools/activities:

- Process mapping or patient journey map Can we use the IHI Flowchart info sheet?
- Affinity mapping What Is An Affinity Map?
- Cause and effect (fishbone/Ishikawa) analysis What is a Fishbone Diagram? Ishikawa Cause & Effect Diagram | ASQ
- SCV's Family of Measures

3. What will you try to accomplish?

What are the specific, measurable, achievable, relevant, and timely (SMART) goals for your team? How much do you want to improve by? How can you set a goal that will energise and motivate, without seeming too far out of reach or too easy?

What is your timeframe? Is it a realistic match for how much you want to improve by and the complexity of your system? Is there a particular part of your service you want to focus on? For example, your aim might be:

By August 2023, we aim to increase the number of inpatients with comprehensive penicillin allergy documentation across X Hospital to 85 % and de-label 20% of inaccurate penicillin allergy labels through direct de-labelling or oral penicillin challenges to improve antibiotic use.

Helpful tools:

- IHI Setting Aims

4. What will you focus on?

In quality improvement work, the ideas and potential solutions we want to test in our system are known as change ideas. A change idea is an actionable, specific idea for changing a process. It can come from research, best practice, 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 because of these tests. In the Check Again project driver diagram (**Appendix C**), you will see change ideas down the right-hand side. A driver diagram is a visual representation of the theory of change and the relationship between the aim of the project and the change ideas. Change ideas in the collaborative came from research work undertaken and services participating in the collaborative.

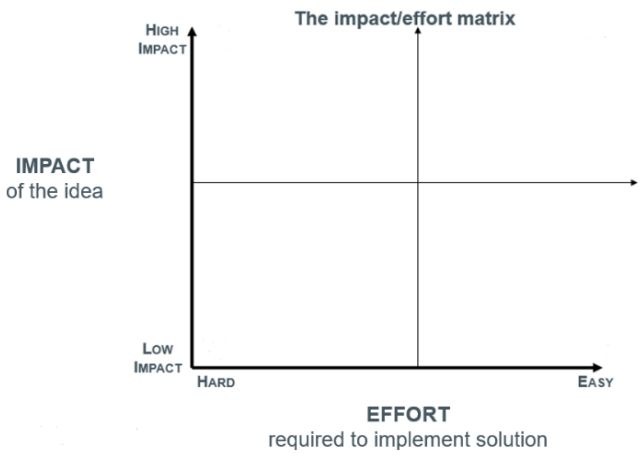


Figure 2. Impact vs effect

No team is expected to test **all** the change ideas included in this toolkit. Consider a menu of options from which you can choose. Your data, understanding of current practice and organisational priorities will guide how you prioritise ideas. Some teams may start with one driver. Others may choose to start by tackling one idea across all three drivers. Many teams find it helpful to start with easy wins to build belief in the work.

Helpful tools:

- IHI Changes for improvement
- Prioritising change ideas: impact/effort matrix (Figure 2).
- See the Check Again change package

5. How will you know that change is an improvement?

Measurement is essential to help learn about the impact you are having as you test changes in a wide range of conditions, whether changes are leading to improvement and what the next steps could be. You and your team will collect and learn from data in real time, using annotated run charts to understand your impact, adjust your hypotheses along the way, and see progress towards your aim.

A family of measures

- A small family of measures will help track your progress:

You may wish to use measures from the Check Again collaborative (**Table 1**) or develop measures to suit your context.

Collecting data: when and how much?

You will need to collect just enough data to learn whether your changes are having an impact on your system. Too much and all your time will be taken up with data collection. Too little and you won't learn effectively. A good place to start is to sample 20 patient records per week, noting that your data collection opportunities

will vary depending on your service size. Consider joining the International Network of Antibiotic Allergy Nations (iNAAN) which utilises a point-of-care smartphone device which was adapted from the published Antibiotic Allergy Assessment Tool and PEN-FAST to provide clinicians with a platform to easily collect penicillin allergy phenotypic data and enable a resultant risk-assessment. This project has Austin Health Ethics (HREC) approval (HREC/78719/Austin-21) and the focus of this project is to collect penicillin allergy data to inform national guidelines, policy and AMS practice.

Making sense of your data

Displaying your data on run charts will help you understand the impact of your changes, assess progress, and communicate progress with stakeholders. A run chart is a line graph of data over time, demonstrating performance of a process and enabling you to determine between expected (common cause) and unexpected (special cause) variation. Annotating your run charts to show when tests of change happen will increase your understanding of how these changes are influencing practice.

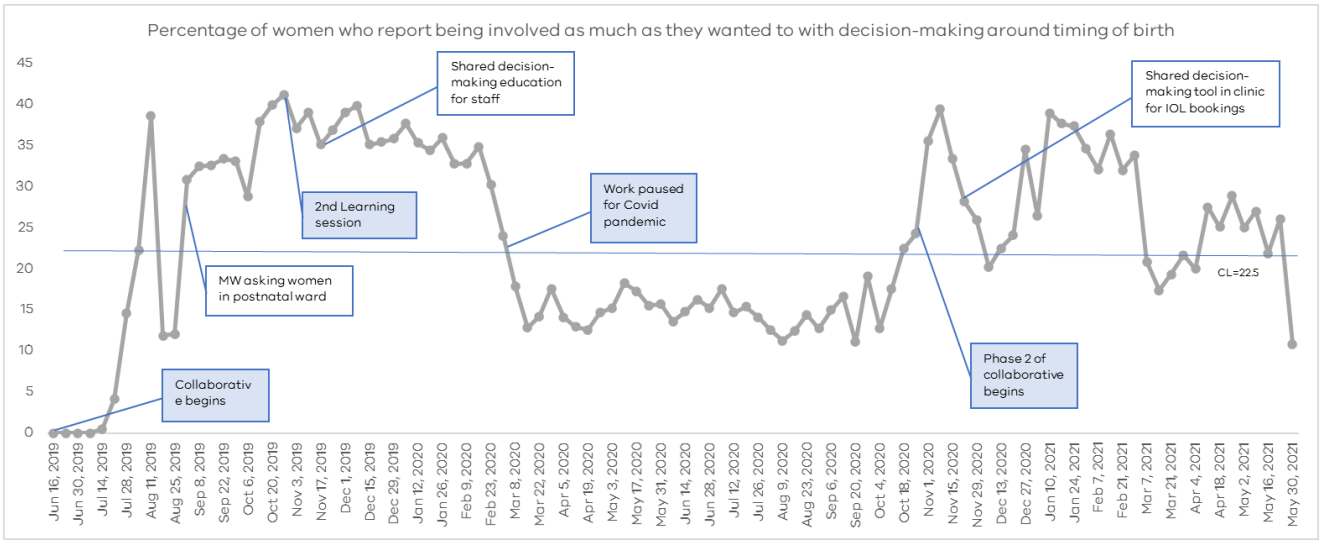


Figure 3. Run chart example: Process measure

Helpful tools:

- IHI Measurement for improvement
- SCV's Family of Measures

Introducing changes into your system

Testing change using PDSA enables teams to learn what works and what does not in their efforts to improve processes. Initially, cycles are carried out on a small scale to see if they result in improvement, e.g. one patient on one day. Teams then expand tests and gradually incorporate larger and larger samples until they are confident that changes will result in sustained improvement.

It is important to attend rigorously to each of the four stages of a PDSA cycle:

- **Plan** – be clear about what you are trying to learn with this PDSA cycle, note the questions you have and make predictions about what will happen, and document details of the test (who, what, when, where and how)
- **Do** – carry out the plan, observe and measure (that is, collect data) what happens. Take notes of what went well and what didn't
- **Study** – analyse and compare data, check your observations against your predictions, summarise lessons learnt
- **Act** – decide on what will happen next: will you adapt the change and test again, adopt the change, or abandon it and try something different with your next PDSA cycle.

Helpful tools:

- IHI's Plan-do-study-act (PDSA) form
- SCV's Plan Do Study Act Cycles

6. Building and sustaining will through stories

Document your local lived experience experts' stories to compliment your improvement data and share them within the organisation. It is a great way to continue to motivate your Health Service.

7. Sustainability

It is important to plan for the long-term sustainability from the start of a project, this will help to set your project up for success. Consider using the MOCHA tool to help guide these discussions:

- Measurement
- Ownership
- Communication & training
- Hardwiring the change
- Assessment of Workload

Helpful tools:

- Sustainability Planning Worksheet

Additional information

Information about this project can be found online including the Project Summary. In addition, for more information on the project or content mentioned in this toolkit please email: 100klives@safercare.vic.gov.au.

References

Chua, K., Vogrin, S., Bury, S., Douglas, A., Holmes, N., Tan, N., . . . Trubiano, J. (2021). The Penicillin Allergy Delabeling Program: A Multicenter Whole-of-Hospital Health Services Intervention and Comparative Effectiveness Study. *Clin Infect Dis.*, 487-496.

Copaescu, A., James, F., Vogrin, S., Rose, M., Chua, K., Holmes, N., . . . Trubiano, J. (2022). Use of a penicillin allergy clinical decision rule to enable direct oral penicillin provocation: an international multicentre randomised control trial in an adult population (PALACE): study protocol. *BMJ Open*.

Devchand, M., & Trubiano, J. A. (2019). Penicillin allergy: a practical approach to assessment and prescribing. *Australian Prescriber*, 192-193.

Appendices

Appendix A: Assessment Tools:

a) Therapeutic Guidelines Antibiotic Allergy Assessment Questions

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.

Therapeutic guidelines

Severity and type of reaction

1. Do you remember the details of the reaction?

2. How was the reaction managed? Did it require treatment or hospitalisation?

Timing

3. How long after taking the antibiotic did the reaction occur?

4. How many years ago did the reaction occur?

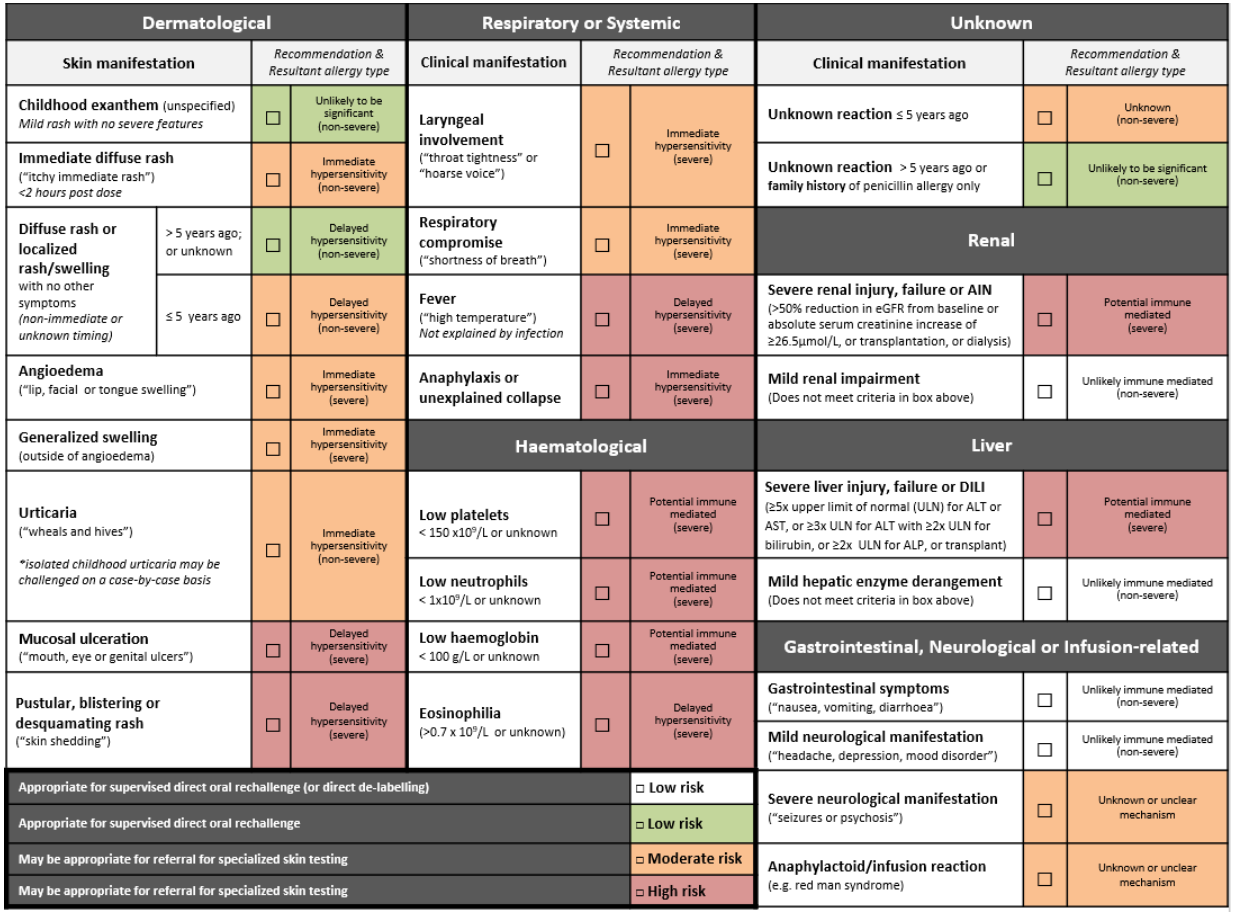
Antibiotic use since reaction

5. Are there other antibiotics that have you taken without problems since the reaction?

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

b) Antibiotic allergy assessment tool (amended version)

The antibiotic allergy assessment tool utilises patient-reported symptoms and signs associated with an index beta-lactam 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.



Dermatological				Respiratory or Systemic			Unknown		
Skin manifestation		Recommendation & Resultant allergy type		Clinical manifestation	Recommendation & Resultant allergy type		Clinical manifestation	Recommendation & Resultant allergy type	
Childhood exanthem (unspecified) *Mild rash with no severe features*		☐	Unlikely to be significant (non-severe)	**Laryngeal involvement** ("throat tightness" or "hoarse voice")	☐	Immediate hypersensitivity (severe)	**Unknown reaction** ≤ 5 years ago	☐	Unknown (non-severe)
Immediate diffuse rash ("itchy immediate rash") *<2 hours post dose*		☐	Immediate hypersensitivity (non-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 with no other symptoms *(non-immediate or unknown timing)*	> 5 years ago; or unknown	☐	Delayed hypersensitivity (non-severe)	**Respiratory compromise** ("shortness of breath")	☐	Immediate hypersensitivity (severe)	**Renal**		
	≤ 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 swelling")		☐	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)	**Haematological**			**Liver**		
Urticaria ("wheals and hives") **isolated childhood urticaria may be challenged on a case-by-case basis*		☐	Immediate hypersensitivity (non-severe)	**Low platelets** < 150 x10^9/L or unknown	☐	Potential immune mediated (severe)	**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)
				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 ulcers")		☐	Delayed hypersensitivity (severe)	**Low haemoglobin** < 100 g/L or unknown	☐	Potential immune mediated (severe)	**Gastrointestinal, Neurological or Infusion-related**		
Pustular, blistering or desquamating rash ("skin shedding")		☐	Delayed hypersensitivity (severe)	**Eosinophilia** (>0.7 x 10^9/L or unknown)	☐	Delayed hypersensitivity (severe)	**Gastrointestinal symptoms** ("nausea, vomiting, diarrhoea")	☐	Unlikely immune mediated (non-severe)
							Mild neurological manifestation ("headache, depression, mood disorder")	☐	Unlikely immune mediated (non-severe)
Appropriate for supervised direct oral rechallenge (or direct de-labelling)			☐ Low risk				**Severe neurological manifestation** ("seizures or psychosis")	☐	Unknown or unclear mechanism
Appropriate for supervised direct oral rechallenge			☐ Low risk						
May be appropriate for referral for specialized skin testing			☐ Moderate risk				**Anaphylactoid/infusion reaction** (e.g. red man syndrome)	☐	Unknown or unclear mechanism
May be appropriate for referral for specialized skin testing			☐ High risk						

Source: 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

c) PEN-FAST - a Penicillin Allergy Clinical Decision Rule

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 online calculator 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	
	OR	☐ **2 points**
S	Severe cutaneous adverse reaction[b]	
T	Treatment required for reaction[a]	☐ **1 point**
		☐ **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)

[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.*

Source: 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

Appendix B: Oral Challenge Protocol template:

1. Assessment

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

See penicillin allergy assessment tools in **Appendix A.**

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)
    - 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
    - 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.
- 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

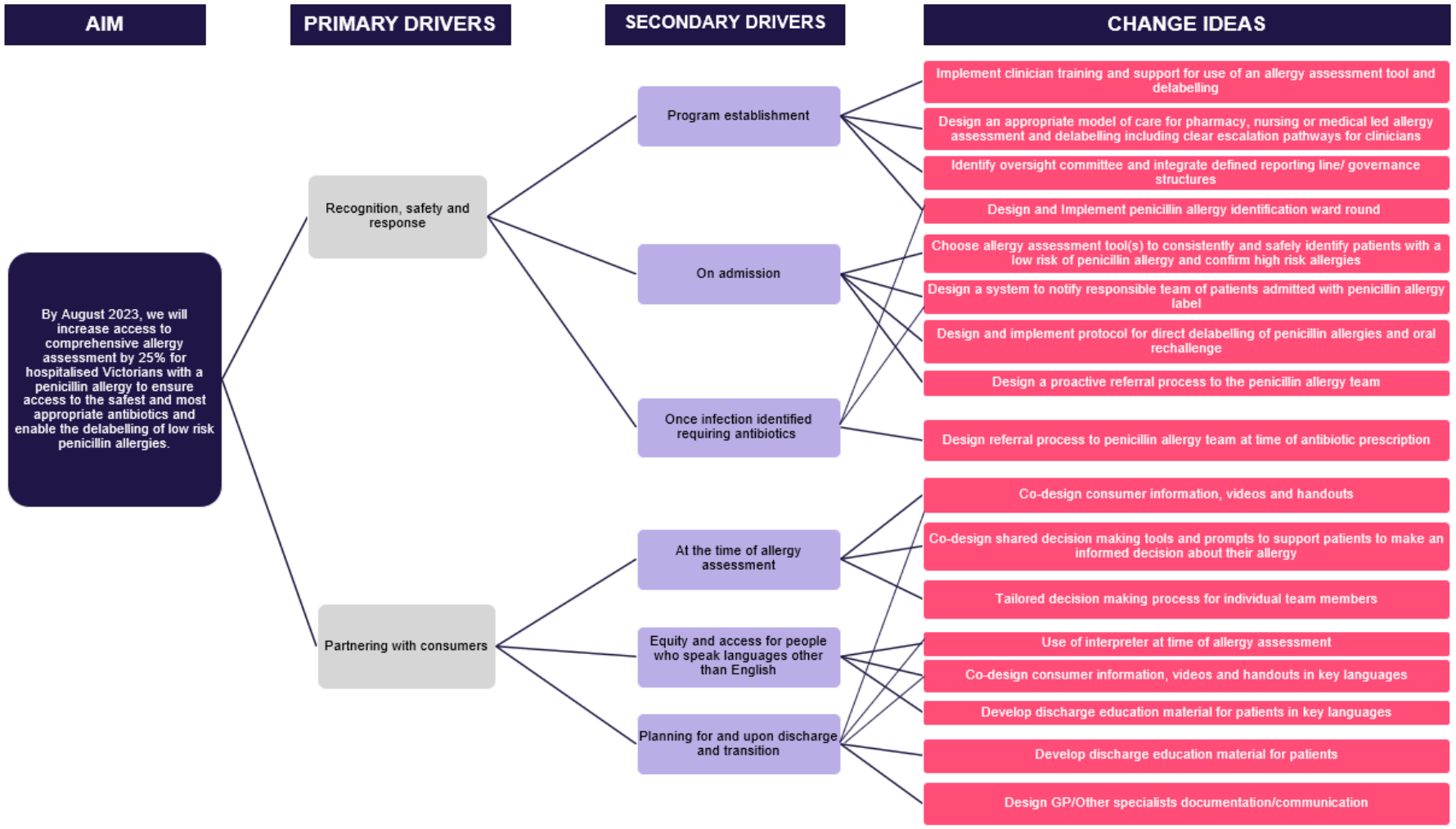
Consider: Who will educate and provide written information to the patient if the oral penicillin challenge is successful/not successful? Who will update the allergy section of the patient's medical record? Who will ensure this information is included in the discharge summary and communicated to the patient's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

Appendix C: Driver Diagram



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