

# Check Again Breakthrough Series Collaborative

## Project Charter

OFFICIAL

### Background information

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)<sup>1,2</sup>. However, studies have shown that in 85% of cases, these allergy 'labels' are inaccurate due to an incorrect diagnosis at the time of the "reaction" or because the patient has grown out of the allergy over time<sup>3</sup>.

AALs create barriers to the optimal prescribing of antibiotics, leading to increased use of restricted antibiotics, increased rates of readmission, increased risk of surgical site infections, increased length of stay and increased mortality. In the long-term, lack of access to penicillins may lead to antimicrobial resistance, where infections become increasingly challenging to treat<sup>1,2</sup>.

The "Check Again" initiative builds off the success of the 2019 Better Care Victoria delabelling program which safely delabelled 97 % of low-risk penicillin allergies after a negative oral penicillin challenge. The pilot program showed significant improvements across health economics, patient experiences and medication safety with sustained gains across the project lifecycle<sup>1</sup>.

This initiative aims to improve inpatient access to antibiotic allergy assessment and testing for low-risk penicillin allergies and open the door for health services to offer more effective and safer treatment options.

### What are we trying to accomplish?

By August 2023, we will increase access to comprehensive allergy assessment by 25%<sup>^</sup> 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.

<sup>^</sup> From baseline

\* At participating sites

More specifically, Check Again seeks to:

- Increase the consumer's access to essential antibiotics they may need both now, and in the future - improving outcomes and reducing harm.
- Upskill healthcare professionals on how to assess all penicillin allergies and delabel low-risk penicillin allergies.
- Build improvement capability within the healthcare sector.

The National Safety and Quality Health Service (NSQHS) Standards, Antimicrobial Stewardship Clinical Care Standard – Quality Statement 3, ensures the accurate assessment and documentation of penicillin allergies to allow for optimal antimicrobial prescribing. This means using the most appropriate and narrow-spectrum

antimicrobial possible, while ensuring that potential harms (such as anaphylaxis) are avoided. Check again aligns with this clinical standard and supports health services in its implementation.

The scope of the Check Again initiative will include health services and teams from:

- Metropolitan, rural or regional
- Subacute or acute
- Private or public
- Adult or paediatric

Due to the complexity of this project, maternity and critically ill patients will be excluded at this stage.

### How are we going to achieve this together?

Safer Care Victoria (SCV), in conjunction with the Institute for Healthcare Improvement, will partner with health services to use the Model for Improvement (MFI)<sup>4</sup> to accelerate their work in assessment and, if appropriate, delabelling of penicillin allergies. A breakthrough series (BTS)<sup>5</sup> collaborative structure (Figure 1) will be used to test and implement evidence-based change ideas to accomplish a common aim.

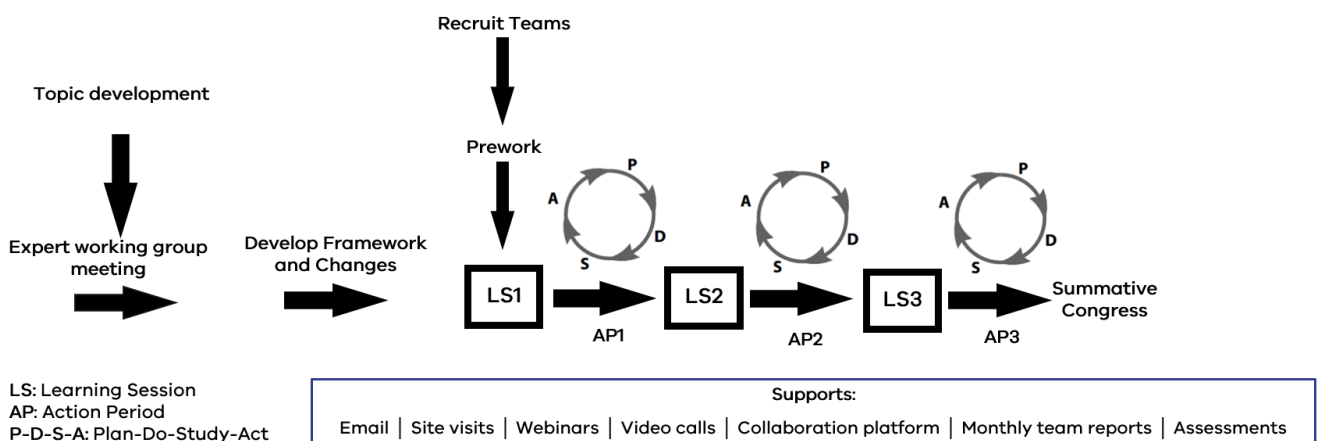
This opportunity involves:

- 3 in-person collaborative learning sessions (or equivalent virtual sessions), where teams will learn exchange ideas; and
- 3 health service-based action periods, where teams are supported by SCV to test, adapt, adopt or abandon changes (see Table 1 for further detail).

Teams will continue to collaborate with each other and SCV through dynamic and engaging web calls, online discussions, email, and monthly progress reports.

The collaborative will run from **Tuesday 6 September 2022 to Tuesday 29 August 2023**.

**Figure 1: The breakthrough series collaborative model**



**Table 1: Collaborative activities**

Activity	Description
<p><b>Team recruitment process</b></p>	<ul style="list-style-type: none"> <li>• Expressions of interest close <b>11:59pm Thursday 25 August 2022</b></li> <li>• Teams who have submitted an EOI will be notified of the outcome on <b>Tuesday 30 August 2022.</b></li> </ul>
<p><b>Kickstart webinar and pre-work</b>  <b>Tuesday 6 September 2022</b>  <b>12:30pm – 2:00pm</b></p>	<ul style="list-style-type: none"> <li>• A <b>Kickstart webinar</b> will provide participating teams with the opportunity to meet each other, hear more about the collaborative and support teams to prepare for the pre-work before learning session 1.</li> <li>• Pre-work will be provided to participating health services so that they come prepared for Learning Session 1. This will include confirming local team structures and collecting baseline data for measures.</li> <li>• This is an optional meeting for health services. We would recommend that at least one person from your team attends if able.</li> </ul>
<p><b>Learning sessions (LS)</b>  <b>LS 1:</b>  <b>Monday 3 October &amp; Tuesday 4 October 2022</b>  <b>LS 2:</b>  <b>Monday 6 February and Tuesday 7 February 2023</b>  <b>LS 3:</b>  <b>Monday 3 April and Tuesday 4 April 2023</b></p>	<ul style="list-style-type: none"> <li>• Learning sessions are face-to-face or virtual meetings, where teams come together with each other and the expert faculty to exchange ideas and learn. At the first Learning Session, SCV and the faculty will present on the program to assess and delabel penicillin allergies. It will include specific changes, called a Change Package, that when applied locally will significantly improve the system’s performance. Teams learn from an Improvement Advisor (IA). The MFI that enables teams to test these change ideas locally, and then reflect, learn, and refine these tests.</li> <li>• At the second and third Learning Sessions, team members learn even more from one another as they report on successes, barriers, and lessons learned in general sessions, workshops, storyboard presentations, and informal dialogue and exchange. Formal academic knowledge is bolstered by the practical voices of peers who can say, “I had the same problem; let me tell you how I solved it.”</li> </ul>
<p><b>Action periods (AP)</b>  Between learning sessions</p>	<ul style="list-style-type: none"> <li>• During Action Periods, teams test, refine and implement changes in their local settings—and collect data to measure the impact of the changes. They submit monthly progress reports for the entire collaborative to review and are supported by web-conference calls and site visits that enable them to share information and learn from each other. The aim is to build collaboration and support teams as they try out new ideas, even at a distance.</li> </ul>
<p><b>Summative congress</b>  <b>Tuesday 29 August 2023</b></p>	<ul style="list-style-type: none"> <li>• Once the collaborative is complete, the work is documented, and teams present their results and lessons learned to each other at a half-day event called a summative congress.</li> </ul>

## How will we know that a change is an improvement?

A measurement strategy including outcome, process and balancing measures has been developed (see Table 2). These measures will continue to be tested and refined as a part of the collaborative and will help teams evaluate the impact of the changes and interventions being tested. These measures will be used to assess progress toward the collaborative aim of ensuring Victorians with a penicillin allergy have access to a comprehensive allergy assessment and subsequent delabelling of low-risk penicillin allergies if indicated. A detailed measurement strategy will be made available along with the guide.

In the lead up to Learning Session 1, we are recommending for sites to provide up to 4 weeks of baseline data. This data collection will be discussed in more detail at the Kickstart Call.

Beginning after Learning Session 1, we will request each team to report data on a weekly or monthly basis depending on the measure (see Table 2 for frequency of data collection). Further information will be provided in the Kickstart Call on Tuesday 6 September 2022.

**Table 2: Family of Measures**

Outcome measures		Frequency
1	% of patients with a no risk penicillin allergy that have their allergy directly delabelled**	Weekly
2	% of patients with a low risk penicillin allergy that have their allergy delabelled following an oral challenge**	Weekly
3	% of patients with a penicillin allergy who correctly identify their allergy status post delabelling**	Monthly
Process Measures		
4	% 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)	Weekly
5	% 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)	Weekly
6	% of patients who have the allergy section of their medical record updated following penicillin allergy delabelling**	Weekly
Balancing measures		
7	Number of patients with a documented penicillin allergy who had an adverse reaction to a penicillin during their current hospital stay	Monthly
8	% of patients who have an adverse drug reaction during the monitoring period following an oral penicillin challenge**	Monthly
9	% of patients with a penicillin allergy who receive a penicillin following either comprehensive penicillin allergy assessment or delabelling	Monthly

\*\*These measures will only be used by health services who implemented the delabelling component of this collaborative.

## What changes can we make that will result in an improvement?

In this collaborative, teams will focus on testing and implementing evidence-based change ideas that have been identified as being key to the assessment and delabelling of penicillin allergies. To ensure governance processes are embedded throughout the collaborative lifecycle, a step-wise approach will be followed. This will ensure that change activities are introduced in a staged manner. The change package will outline priority pieces which must be done to ensure governance and safety are considered from the commencement of the project.

These change ideas relate to two primary drivers: **Recognition, Safety and Response** and **Partnering with consumers** (See Appendix 1 for a detailed driver diagram)

- **Recognition, Safety and Response:** Health services will be prepared to execute a safe and robust penicillin allergy assessment and delabelling program by establishing safety processes, designing appropriate models of care and implementing program governance. These processes will enable healthcare providers to identify patients with penicillin allergy and undertake accurate assessment of allergy risk.

Strategies to increase recognition, safety and response will include:

- Implementing multidisciplinary training and site-specific models of care for allergy assessment and delabelling
  - Developing, testing and implementing safety protocols, defining clear escalation pathways for clinicians
  - Defining and obtaining site-specific governance
  - Implementing processes to ensure clinicians consistently and safely identify patients suitable for allergy assessment +/- delabelling both on admission and at time of antibiotic prescription
  - Designing a referral pathway system which incorporates notification of allergy status to both penicillin allergy team and home team
  - Implementing protocols for the direct delabelling of penicillin allergies and oral challenge
- **Partnering with consumers:** Consumer partnership in care will be enhanced by the co-design of consumer documents to facilitate shared decision making and improve the patient and healthcare worker experience. Equity and access for people who speak languages other than English will be prioritised.

Strategies to improve partnering with consumers will involve:

- Co-design of consumer-facing documents
- Adopting a tailored decision-making process with consideration to individual needs of consumer and clinician
- Development of discharge and clinician communication documents in key languages to facilitate safe transitions of care.

## How will Safer Care support you?

Safer Care Victoria and the collaborative faculty will:

- Provide a Collaborative Lead, Improvement Advisor and coaching support in addition to faculty who have expertise in the subject matter and improvement methods.
- Provide information on subject matter, application of that subject matter, and methods for process improvement, both during and between Learning Sessions.
- Provide an SCV-endorsed comprehensive change package which will include evidenced-based resources to enable sites to tailor their theory of change to their site-specific clinical context.

- Support knowledge management of promising changes and action toward results through collaborative models (i.e. driver diagram, comprehensive change package, measurement strategy, and evidence-based tools and resources).
- Provide communication strategies to keep teams connected to the collaborative faculty and colleagues.
- Provide access to an online system for data reporting, access to collaborative resources and communication.
- Review team reports and analyse data providing guidance and feedback, including overall collaborative learning and development.
- Foster growth and development of improvement capability and capacity.

## What will participation involve?

Participating organisations are expected to:

- Designate a senior leader as an executive sponsor who will:
  - Connect the goals of the collaborative to a strategic collaborative in their organisation.
  - Support the core team to attend learning sessions (3x two-day in person sessions or virtual equivalent) and monthly coaching calls.
- As this is a spread and scale project, consider which settings would be the most appropriate place to start at your health service. You will need to nominate a unit(s) or ward(s) that are engaged in participating in this project at your site including a collaborative lead.
- If you or your Health Service are interested in participating in Check Again but unable to commit to the full collaborative, please contact us and we can discuss flexible options for joining the project and specific components that you and your site can choose to be involved in.
- Collaboratives work best when the workload is shared within a health service, this could consist of a multidisciplinary team approach with 3-5 people. You and your health service can choose the approach that is most appropriate for you.
- In our experience, optimal results are achieved when teams share the workload to:
  - Complete a health service charter, setting aims and goals for the project team
  - Hold weekly team meetings
  - Test changes using rapid Plan-Do-Study-Act cycles
  - Collect data and plot results over time
  - Complete and share reports for monthly calls and Learning Sessions
  - Contribute to monthly collaborative online meetings and site visits

**Your multidisciplinary team could include:**

Role	Responsibility	Key event attendance
Executive sponsor	<ul style="list-style-type: none"> <li>Accountable for your organisation’s participation in the collaborative, ensuring it aligns with organisational values and strategic plan, and the delivery of project outcomes (ongoing).</li> <li>Visible champion of the project with the management team and is the ultimate decision-maker, with final approval on all phases, deliverables and project scope changes.</li> </ul>	<p>Kickstart call: (optional)</p> <p>Tuesday 6 September 2022 12:30-2pm</p> <p>Learning Session 2 – Executive Sponsor Session (highly recommended)</p> <p>Monday 3 February &amp; Tuesday 4 February 2023 full day events</p> <p>They may also attend any other learning sessions.</p>
Collaborative lead at health service	<ul style="list-style-type: none"> <li>Clinical leader who works effectively with clinicians, leaders and other technical experts within the organisation to spread and scale the collaborative i.e. allergy nurse, pharmacist, medical consultant</li> <li>This person will lead the project at your service and is responsible for managing the team involved in the collaborative</li> </ul>	<p>Kickstart call:</p> <p>Tuesday 6 September 2022 12:30-2pm</p> <p>All learning sessions (see planned key dates)</p>
Team member with improvement knowledge	<ul style="list-style-type: none"> <li>This person supports the quality improvement, improvement methodology, measurement strategy and data collection.</li> <li>This person, and the rest of the team, will be supported in developing their capability in improvement methodology by SCV and IHI Improvement Advisors.</li> </ul>	<p>Kickstart call: (highly recommend)</p> <p>Tuesday 6 September 2022 12:30-2pm</p> <p>All learning sessions</p>
Clinical champions (relevant medical, nursing, allied health staff including pharmacy).	<ul style="list-style-type: none"> <li>These individuals may include a physician, medical staff, nurse, pharmacist, nurse practitioner, clinical nurse specialist, and/or others who will play a pivotal role in the assessment and if indicated delabelling of penicillin allergies at your site.</li> <li>We strongly encourage interprofessional representation on your team and urge you to enlist more than one clinical champion.</li> <li>There should be representation from the setting (ward or unit) that you have chosen to commence the collaborative at your service</li> <li>These champions should have good working relationships with colleagues and be interested in driving change to improve assessment and care for patients with penicillin allergies.</li> <li>You will need 3-5 clinical champions to achieve the best outcomes.</li> </ul>	<p>Kickstart call: (highly recommend)</p> <p>Tuesday 6 September 2022 12:30-2pm</p> <p>All learning sessions</p>



Consumer representative/lived experience leader	<ul style="list-style-type: none"> <li>We recommend each team partner with a minimum of one person with lived experience.</li> </ul>	<p>Kickstart call: (highly recommend)</p> <p>Tuesday 6 September 2022 12:30-2pm</p> <p>All learning sessions</p>
Wider team members	<ul style="list-style-type: none"> <li>Influencers in the organisation who can drive commitment and attention to the work and support the frontline clinicians to test and measure changes. These members do not need to be registered. You will need 6-12 wider team members to achieve the best outcomes</li> </ul>	n/a

**\*Team members may hold more than one role.**

The advantage to this team approach is that improvements are designed and implemented by local, frontline teams involved in the day-to-day work to achieve sustainability.

### **Terms of Use and Data Restriction Disclaimer – Safer Care Victoria**

Check Again involves the collection of data from participating ‘health service entities’ (Data Contributors) into a database held by Safer Care Victoria (SCV), through its contractor Team Assurance. The data is not intended to include personal or health information of individuals and is collected for quality and safety purposes in concordance with the Health Records and Privacy and Data Protection act. Data Contributors will be able to view information contributed from other Data Contributors but will only be able to edit their own data.

Safer Care Victoria have entered into a contract with Team Assurance Pty Ltd which requires them to keep these details confidential and not provide them to others.

Your access to Team Assurance is voluntary and you are not required to provide consent for disclosure of your information to Team Assurance Pty Ltd. However, if you do not consent, you will not be able to access the Team Assurance database.

In accessing the Team Assurance database, you acknowledge and agree that:

- You will comply with the Privacy and Data Protection Act 2014 (Vic), Health Records Act 2001 (Vic) and Health Services Act 1988 (Vic) in relation to your participation in the project;
- You will keep your unique log-in details secret;
- You have been nominated as an Authorised System User by a participating Health Service or by Safer Care Victoria;
- You will not attempt to re-identify any statistical information made available to you on Team Assurance;
- You will not publish (or make publicly available) any data you obtain through Team Assurance;
- You will use the data obtained through Team Assurance only for the project;
- Your personal information may be used Safer Care Victoria for audit of your activity in Team Assurance;
- You will comply with any terms of use provided by Team Assurance Pty Ltd;
- You will notify Safer Care Victoria of any suspected data breach and will work with Safer Care Victoria and Team Assurance Pty Ltd to contain the breach and investigate its origin; and
- Your access to Team Assurance will be terminated if you cease to work for the Health Service or Safer Care Victoria advises your assistance is no longer required (whichever is relevant), you use Team Assurance in a manner inconsistent with the terms of use, or you are in breach of any of the acknowledgments set out above.

You may gain access to the personal information held by SCV about you by contacting us at:

[100klives@safercare.vic.gov.au](mailto:100klives@safercare.vic.gov.au)

### **The National Inpatient Penicillin Allergy Database (optional)**

In addition to collecting and reporting data to Safer Care Victoria (as outlined in the Terms of Use and Data Restriction Disclaimer – Safer Care Victoria section above), sites will be given the opportunity to collect additional data for a separate network, the National Antibiotic Allergy Network (see Appendix 2). Participation in the National Antibiotic Allergy Network’s National Inpatient Penicillin Allergy Database is **optional** and not a requirement to be involved in the Check Again collaborative.

## Planned key dates

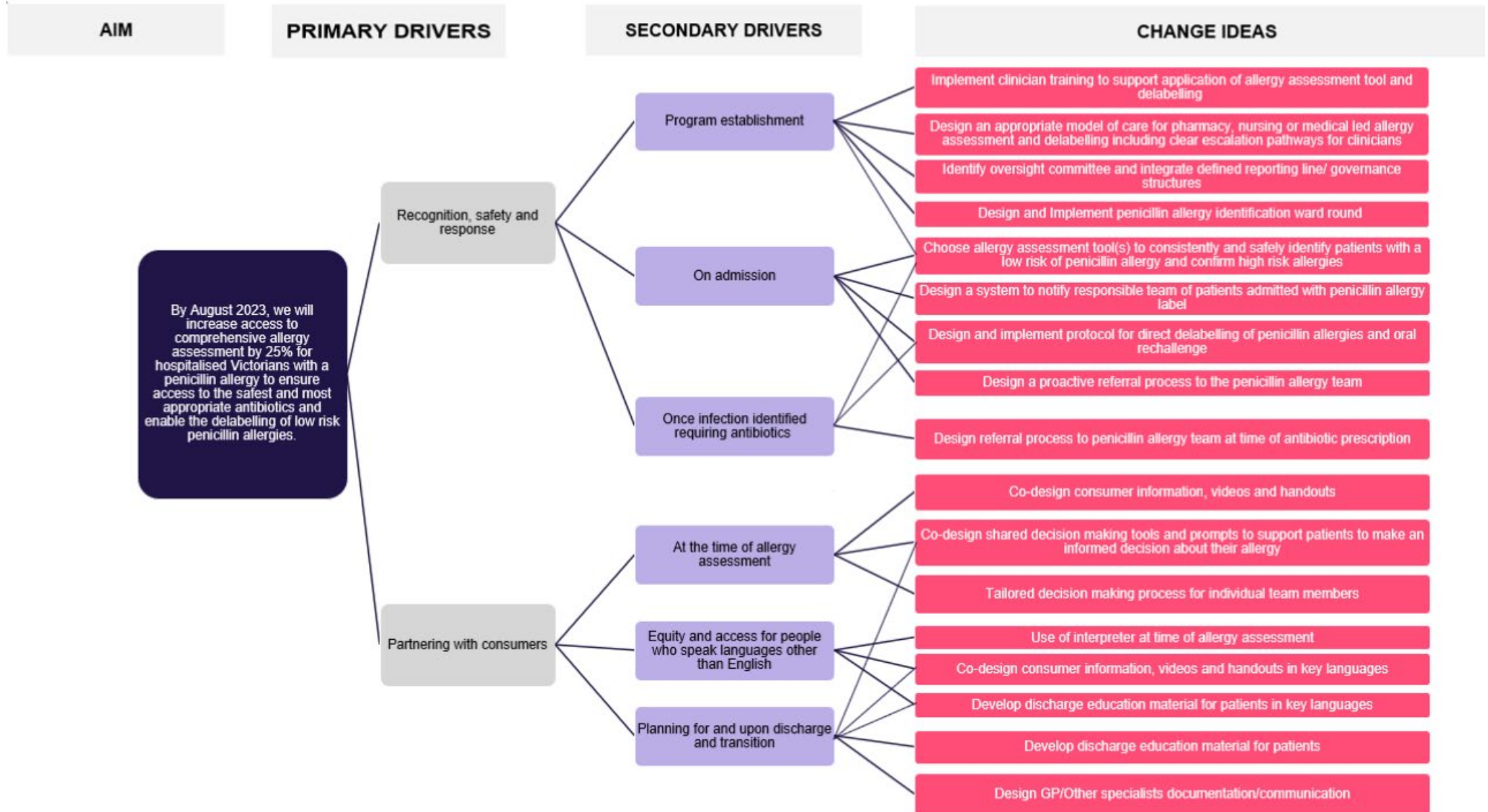
Activity	July 2022	Aug 2022	Sep 2022	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	July 2023	August 2023
Expression of Interest Open	4													
Optional information session	19													
Expression of Interest Closed		25												
Health Service Notification		30												
Kickstart call			6											
Learning Session 1				3-4										
Action Period 1 (AP1)				5				5						
Penicillin Allergy Education Webinar (optional)				12										
<b>AP1 Online Meetings</b>				25	29	-	17							
Learning Session 2								6-7						
Action Period 2 (AP2)								8		2				
<b>AP2 Online Meetings</b>								14	14					
Learning Session 3										3-4				
Action Period 3 (AP3)										5		28		
<b>AP3 Online Meetings</b>											2	6		
AP3 Holding the gains online meeting														29
Summative Conference														29



## References:

1. 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. *Clin Infect Dis*. 2021 Aug 2;73(3):487-496. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8326579/>>
2. Devchand M, Trubiano JA. Penicillin allergy: a practical approach to assessment and prescribing. *Aust Prescr* 2019;42:192–9.3.
3. 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 Nov;18(11):1143-1153. doi: 10.1080/14787210.2020.1792775. Epub 2020 Jul 19. PMID: 32662696.
4. Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance* (2nd edition). San Francisco: Jossey-Bass Publishers; 2009.
5. Institute for Healthcare Improvement. *The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement*. IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2003.

## Appendix 1: Check Again Driver Diagram



### Background

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The National Antibiotic Allergy Network (NAAN) is a multidisciplinary, collaborative group of clinicians with a focus on antibiotic allergy, who represent each Australian state and territory, and numerous allergy and antimicrobial stewardship societies and research centres. The NAAN strives to improve and integrate antibiotic allergy practice into antimicrobial stewardship (AMS) programs in accordance with the National Safety and Quality Health Service (NSQHS) standards. A key component of NAAN is the development of a national database of oral penicillin allergy assessment and challenge that enables sites to self-audit their programs whilst contributing data that will inform national policy. We are inviting sites participating in the **Safer Care Victoria (SCV) collaborative, Check Again**, to contribute data to this research collaborative. This is **voluntary** and sites can still participate in the Check Again collaborative without contributing data to NAAN.

### The National Inpatient Penicillin Allergy Database

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A key objective of this database is to collect and analyse penicillin allergy data in both adult and paediatric healthcare settings. An inpatient penicillin allergy assessment database, including outcomes from direct oral challenge, has the potential to identify the national impact penicillin allergy has on antimicrobial prescribing, antimicrobial resistance, and medication safety. Subsequent findings have the ability to significantly change AMS practice and impact health policy.

**Data collection:** Penicillin allergy assessment and/or direct oral challenge data that is performed as part of the SCV Check Again collaborative can be easily collected via a simple, point-of-care iOS application on a phone or iPad. De-identified data is securely transmitted to the national penicillin allergy database. Please note that sites will be required to enter measures data for the Check Again collaborative into a separate web-based database.

**Time commitment:** Collection of data is a simple and efficient process via the point-of-care iOS app. Data may be entered by any clinician involved in formal antibiotic allergy assessment e.g: doctor, pharmacist or nurse. The app is designed to be incorporated into existing AMS and/or antibiotic allergy processes, thus any time commitment in contributing data is expected to be minimal.

### Why participate?

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- Contribute your local penicillin allergy assessment and/or direct oral challenge data to a national inpatient penicillin allergy database.
- Sites will continue to retain access to their own local penicillin allergy assessment and direct oral challenge data and will also be provided with monthly reports. These reports can be used by individual sites for the purposes of local audit, accreditation and research.
- Ethics approval has been obtained. Individual sites will require governance approval, however this process will be supported by the NAAN project team.
- There is no cost associated with being involved in the program and data support is provided by the Centre for Antibiotic Allergy and Research.

### Further information

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Please don't hesitate to contact A/Prof Jason Trubiano for further information.

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