



October 2022 – August 2023

Check Again Evaluation Report

Breakthrough Series
Collaborative

Executive Summary

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Acknowledgements

Safer Care Victoria (SCV) partnered with the Institute for Healthcare Improvement (IHI) to design and deliver the Check Again - Breakthrough Series Collaborative ('the Check Again Collaborative').

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To the 13 sites that dedicated their time to improving care for patients in their service, your time and energy has made all the difference, thank you.

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The project team was also supported by an expert faculty Error! Reference source not found.comprised of clinical and lived experience experts, who contributed to the design of the Check Again Collaborative and participated in learning sessions and action period calls to support the teaching and coaching of teams in improvement science.

We would like to acknowledge the lived experience experts who shared their stories with the Check Again Collaborative teams working to improve their wellbeing and reminded us why this work matters.

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Authors & Contributors: Misha Devchand, Robert Forsythe

Reviewed and endorsed by SCV and IHI delegates

Acronyms used in this document

AMS	Antimicrobial Stewardship
IHI	Institute for Healthcare Improvement
MHR	My Health Record
PMCC	Peter MacCallum Cancer Centre
SCV	Safer Care Victoria

Background

More than two million Australians have reported an allergy to antibiotics, with the most commonly reported allergy being 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). Antibiotic allergy labels are associated with an increased use of restricted or suboptimal antibiotics (Trubiano, et al., 2016), increased rate of hospital readmission (Knezevic, et al., 2016), increased risk of surgical site infections (Blumenthal, et al., 2018), increased length of hospital stay (Macy & Contreras, 2014) and increased mortality (Charneski, Deshpande, & Smith, 2011; Rose MT, 2020).

The accurate assessment and documentation of penicillin allergies has been recognised by the Australian Commission on Safety and Quality in Health Care Antimicrobial Stewardship (AMS) Clinical Care Standards, as a key component of AMS programs. Quality Statement 3 in the [AMS Clinical Care Standards](https://www.safetyandquality.gov.au/publications-and-resources/resource-library/antimicrobial-stewardship-clinical-care-standard-2020) <<<https://www.safetyandquality.gov.au/publications-and-resources/resource-library/antimicrobial-stewardship-clinical-care-standard-2020>> recommends healthcare services "ensure the accurate assessment and documentation of patient adverse reaction information [i.e. antibiotic allergies] to allow for optimal antimicrobial prescribing." A comprehensive allergy assessment involves collecting and documenting a full set of data (four items) about the nature of the allergy. This includes: (1) the active ingredient of the medication that the allergy has been attributed to, (2) how long ago the allergy occurred, (3) what the nature of the reaction was, and (4) its severity. Clinicians may use multiple information sources to complete a comprehensive allergy assessment including patient/carer interview and records from health professionals.

The Check Again – Breakthrough Series Collaborative (the 'Check Again Collaborative') was established by SCV in partnership with the Institute for Healthcare Improvement (IHI) to address this. The Check Again Collaborative was a world first program, which implemented penicillin allergy assessment and delabelling (for low-risk allergies) as a state-wide collaborative.

The Check Again Collaborative was built off the success of the *Antibiotic allergy delabelling pilot 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 challenge¹ or direct delabelling² (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).

¹ An oral penicillin challenge is when a dose of penicillin is administered to someone suspected of having an allergy in a medically supervised environment.

² Direct Delabelling is when the penicillin allergy label is removed following a clinical risk assessment process that suggests the risk of allergy is very low.

Consumer story – Tracey

The Check Again Collaborative is dedicated to enhancing patient access to penicillin allergy assessments. This medically supervised testing process, endorsed by patient Tracey, is one that she wholeheartedly recommends to others.

"I would encourage people to consider it," she shared. "It takes place in a safe, controlled environment, and it might reveal that you are no longer allergic to penicillin, or that what you believed was a reaction wasn't one at all."

Reflecting on her experience with the penicillin allergy assessment, Tracey explained that she opted for the testing because she was uncertain about her allergy to penicillins (a class of antibiotics). "About a decade ago, I developed a rash after taking medication. I was unsure if it was ... an allergic reaction or not," she recalled.

During a recent visit to the Peter MacCallum Cancer Centre (PMCC) for surgery, when asked about her allergies, Tracey found herself uncertain, reflecting on the time she had the rash years earlier and questioning whether or not it was an allergic reaction. "I was informed that I could be tested to conclusively rule it out," Tracey recounted. "I decided that was the right course of action."



The staff at PMCC explained the allergy testing process, which took place in an environment to ensure the testing was controlled and Tracey was closely monitored for any adverse effects. The results revealed that Tracey did not have an allergy to penicillins. Now armed with this knowledge, Tracey can confidently consider using penicillin for future infections, following consultations with her healthcare providers.

Tracey also strongly encourages other eligible patients to undergo similar testing to gain a clearer understanding of any specific allergies they may or may not have. Additionally, Tracey commended the professionalism, understanding, and informativeness of the staff at the PMCC, encouraging other healthcare providers to consider implementing a similar service.

What did we want to accomplish?

The Collaborative set out to achieve the following aim:

By August 2023, we will increase access to comprehensive allergy assessment by 25%³ for hospitalised Victorians⁴ with a penicillin allergy to ensure access to the safest and most appropriate antibiotics and enable the delabelling of low-risk penicillin allergies.

This aim was supported by the following objective:

By upskilling clinicians and implementing antibiotic allergy assessment tools, in conjunction with inpatient oral penicillin challenges, there will be a reduction in the number of hospitalised Victorians with a penicillin allergy. The Check Again Collaborative will demonstrate the feasibility and utility of such a service across a variety of healthcare settings, and support further spread.

What approach did we take?

Health service teams were invited to participate in a 10-month project which used a Breakthrough Series (BTS) Collaborative design. This design employs a collaborative model where multiple organisations come together to learn and implement best practices within a structured framework.

The process begins with identifying a significant healthcare issue and assembling expert panels to develop evidence-based change ideas. These ideas are then tested through Plan-Do-Study-Act (PDSA) cycles in real-world settings. The impact of changes that have been tested is evaluated using measures that help participating services determine whether the changes are making a difference. The measurement approach used in the Check Again Collaborative is described in [Appendix A](#).

Participating organisations share their experiences, data, and results in regular learning sessions and action period calls, fostering a culture of collective learning and rapid iteration.

In total 13 teams signed up to participate in the Check Again Collaborative which started on 3 October 2022, with one health service attending learning session one and then choosing to leave the Collaborative. 12 teams attended the Summative Event on 29 August 2023.

What changes did we make?

The key focus areas for the Collaborative were:

1. Identifying changes that could be made both proactively and reactively to recognise and manage penicillin allergies as well as improve patient access to a safe and effective penicillin allergy assessment and delabelling.
2. Partnering with consumers to develop allergy assessment processes that are person centred.

³ From baseline

⁴ At sites participating in the Collaborative

The change theory was developed following an extensive scoping period. This period included undertaking detailed literature reviews and targeted collaboration with lived experience experts, clinicals experts and formation of an expert working group to clearly define objectives and project scope. Specific and actionable evidence-based change ideas were defined in response to the two priority focus areas ([Table 1](#)).

Table 1. High-level change theory for the Check Again Collaborative, presented as a driver diagram⁵

AIM	PRIMARY DRIVERS	SECONDARY DRIVERS
<p>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.</p> <p><i>^ From baseline</i> <i>*At participating sites</i></p>	<p>P1. Recognition, safety, and response</p>	<p>S1. Program establishment</p>
		<p>S2. On admission</p>
		<p>S3. Once infection identified requiring antibiotics</p>
	<p>P2. Partnering with consumers</p>	<p>S4. At the time of allergy assessment</p>
		<p>S5. Equity and access for people who speak languages other than English</p>
		<p>S6. Planning for and upon discharge and transition</p>

Primary driver 1: Recognition, safety and response

This focused on what could 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 establishment:

To have a reliable program in which reported penicillin allergies can be comprehensively assessed and responded to (e.g. allergy testing and/or delabelling), health services needed to establish a model of care that. This included deciding which existing functions in the organisation would share responsibility for the program (e.g., the AMS team, infectious diseases, pharmacy department) and the staff roles and responsibilities within the model of care.

⁵ A driver diagram is a visual display of a theory of what “drives,” or contributes to, the achievement of a project aim.

Penicillin allergy assessment:

Prior to commencing a delabelling program it was important for teams to have established a consistent and reliable penicillin allergy assessment process. The use of specific penicillin allergy assessment tool(s) and documentation processes were required to be signed off by the health service executive sponsor and/or relevant oversight committee prior to proceeding to allergy delabelling.

Penicillin allergy testing/delabelling:

For no risk allergies (allergies that are a side effect to a penicillin for example, nausea, diarrhoea, and not an immune mediated reaction), or if a patient has safely tolerated a penicillin since their initial allergy, sites could choose to implement a direct delabelling program. This is where a patient's penicillin allergy is discussed with the patient and removed from their medical record without allergy testing.

For low-risk penicillin allergies (as assessed by the penicillin allergy assessment tools), patients are offered a single test dose of penicillin during their hospital stay to disprove and safely delabel their penicillin allergy. Patients are monitored after this test dose to ensure that they have not had a reaction. For patients that tolerate the test dose, the allergy is removed from their medical record.

Primary driver 2: Partnering with consumers

Primary driver 2 focused on ensuring consumers were included and informed of decisions relating to their penicillin allergy. For a penicillin allergy assessment and delabelling program to succeed, teams need to ensure that:

- They had one coordinated team: clinicians, patients, families, and carers working together.
- Co-design principles were followed in the development of resources and tools to support shared decision-making and patient information.
- Resources were available when needed and adapted to meet the diverse needs of the community.
- Patients understood the process of penicillin allergy assessment with or without delabelling (to avoid the relabelling of allergies inadvertently).

What impact did we have?

Key outcomes

Quantitative and qualitative evidence showed that all health services developed a Model of Care to assess penicillin allergies. In addition, a majority of sites also set up a delabelling program for low-risk penicillin allergies. The outcome measures demonstrate a trend toward improvement by the end of Check Again. At the start of the Check Again Collaborative only two sites were actively assessing and delabelling appropriate penicillin allergies and by 30 August 2023, 11 sites were delabelling appropriate penicillin allergies.

What did we learn?

- The Models of Care that were the most successful and sustainable were those that embedded the Check Again Collaborative work within the role of the AMS team. This meant that the

ownership/governance of this work sat across multiple teams (Infectious Diseases and Pharmacy) and was able to align to a multi-departmental structure that was already in place. This structure was used by nine of the 12 participating sites in the Check Again Collaborative. Two of the other sites used an immunology led model (both sites are currently on hold since the Check Again Collaborative ended, primarily due to reliance on a single staff member to drive the work) and the third site was a rural site that was led by the Quality team in conjunction with Infection Control team.

- Sites that used a targeted approach - focusing on high-risk patient groups such as surgical patients or immunocompromised patients - were more successful than those that trialled hospital wide programs. In these high-risk patient groups, there is a clear advantage to the immediate patient journey for removing inaccurate allergy labels e.g., an immunocompromised patient will be at a disadvantage if the number of available antibiotics that can be administered is diminished. There was lower uptake of oral challenges in general medical units; this is likely due to the medical complexity of this patient group and difficulties obtaining a reliable allergy history.
- Improving access to penicillin allergy assessment and delabelling for Victorians aligned with strategic priorities for most participating health services.
- Feedback from Collaborative participants suggested that lived experience expertise played a pivotal role in propelling improvement across participating health services. However, health services were still learning the best way to engage with consumers at a local level. Consumers were engaged as project faculty and contributed to the creation of consumer videos and stories.
- Sites that made swift progress had active Pharmacy leadership involvement from the outset, along with engagement from hospital executives. Teams with this support, managed to have their protocols and guidelines for direct delabelling and oral challenge approved promptly. Nonetheless, despite this backing, the majority of sites required most of the duration of the Collaborative to gain approval for these documents. Notably, smaller rural or regional hospitals were more able to secure swift approval, likely due to reduced layers of organisational sign off. It is recommended that future initiatives consider the time needed for health service governance processes to occur and leave sufficient time for this to be completed prior to the active testing period.
- Throughout the Check Again Collaborative, participating teams consistently identified the functionality of electronic medical record systems, and My Health Record (MHR), as obstacles to penicillin allergy documentation. Safety concerns were voiced regarding MHR, particularly the inability of hospital clinicians to manually update allergy records to remove outdated allergies or add supplementary information to the record.
 - Engagement with participating services gets better when the Collaborative's content matches the audiences' needs. As the Check Again Collaborative progressed, changes were made, for example making learning sessions shorter, simplifying how improvement science is taught, and giving examples in teaching that were more relevant to the participants.
 - The data burden of manually collecting measures and then entering into the data collection platform (Team Assurance) was problematic for many teams within their available resources. It is recommended that future initiatives take steps to minimise the burden of manual data collection where possible.

Limitations of the Check Again Collaborative

When reviewing the results of the Check Again Collaborative there are several limitations to consider:

- The 10-month time frame of the Check Again Collaborative was too short for many teams to fully test and establish their processes. Some Covid-19 pandemic restrictions remained in place during the first half of the Collaborative which impacted the ability for teams to meet in-person and for health service staff to participate, particularly AMS professionals who also had duties in pandemic response.
- The period of active testing for some health services was additionally shortened due to the time required for approval of procedures relating to direct delabelling and oral rechallenge.

Conclusion

Overall, the Check Again Collaborative resulted in 11 of 12 teams implementing a penicillin allergy assessment and delabelling program. Teams enjoyed their experience of being involved and have observed process changes within their health services. These changes will support future improvement work.

Passion and engagement by the project teams was demonstrated throughout the Collaborative. Quantitative and qualitative evidence showed that all health services that completed the Collaborative implemented a model of care to assess penicillin allergies and either directly delabel or oral challenge appropriate allergies. The removal of inaccurate penicillin allergies labels is likely to have long-term positive impacts for all patients as it ensures access to a range of first line treatment options when those patients develop an infection in the future. Evidence also demonstrates that many of these process changes have been embedded into everyday practice to support their sustainability.

Executive support and engagement from the health service project teams were key enablers for success. It is also important to consider organisational readiness and protocol/guideline development pathways when attempting future improvement work. Access to people with lived experience of penicillin allergy and their stories also helps build will for change amongst health service stakeholders. Health services provided ongoing feedback during the Collaborative that the most valuable component was the sharing of experiences between teams, and availability of expert clinical faculty. Access to people with lived experience of penicillin allergy and their stories also helps build will for change amongst health service stakeholders. This is an important lesson for future projects in the AMS area and is reflected in the recommendation to create a Check Again Network to help sustain this work.

Next steps

SCV will use these learnings and recommendations to develop the next phase of the Check Again Collaborative and future projects. As the sharing and networking opportunities were highly valued by the participating health services, SCV will establish a Check Again Network in June 2024. The objective of the Check Again Network will be to continue this important work with existing teams and to promote further scale and spread to additional Victorian health services. The Check Again Network will partner with the International Network of Antibiotic Allergy Nations and will be supported by SCV's Medicines Team to ensure a sustainable model, that can continue after the 100,000 Lives Program has concluded.

The importance of appropriate functionality in electronic health care systems (for example, My Health Record) was emphasised by participating teams, and SCV will advocate for changes to support the usage of these systems across Victoria.

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Appendix A - How did we measure improvement?

Measurement strategy

Measurement is a critical part of testing and implementing changes: measures tell a team whether the changes they are making lead to improvement. Determining if improvement has really happened and if it is lasting requires observing patterns over time.

Participating teams used a measurement strategy (see [Table 1](#)) during the Check Again Collaborative to determine whether the changes they were making were leading to improvement.

The measurement strategy was developed in consultation with subject matter experts and the IHI, bringing together the best available evidence to create a comprehensive measurement plan that created minimal burden on the participating teams.

The measurement strategy included three outcome measures, three process measures and three balancing measures. Outcome measures relate to the overall outcome the project is aiming to influence, while process measures refer to improvement in the parts of a system/service. Balancing measures refer to the unintended (either positive or negative) impacts of outcomes and/or process changes.

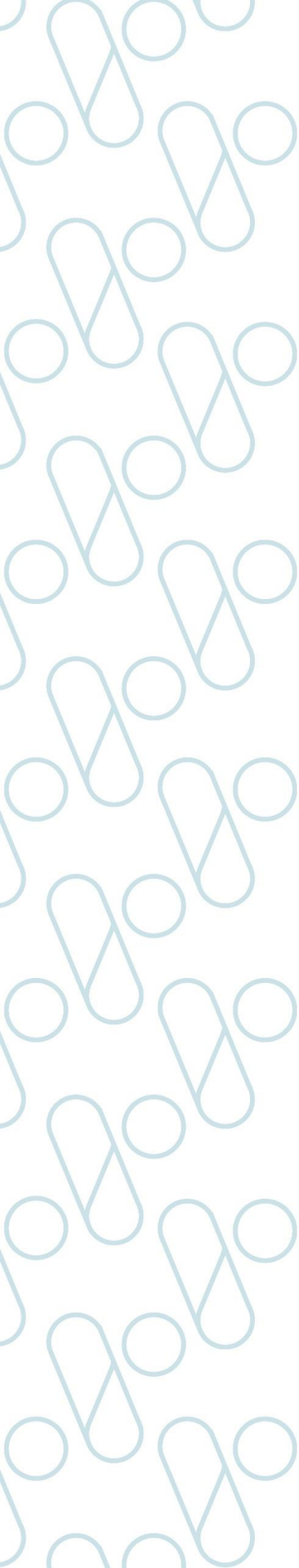
Convenience sampling was employed as the data was used longitudinally for improvement. The aim of this work was not to generate research findings but to ascertain if improvement had occurred in participating services. Teams reported their data on TeamAssurance, a cloud-based collaborative platform that supports the tracking of data for real-time, rapid improvement.

Table 2. Summary of measurement strategy

Measure Type	Measure
Outcome	% of patients with a no risk penicillin allergy that have their allergy directly delabelled ⁶
	% of patients with a low-risk penicillin allergy that have their allergy delabelled following an oral challenge ⁶
	% of patients with a penicillin allergy who correctly identify their allergy status post delabelling ⁶
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)
	% 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)

⁶This measure will only be used by health services that have implemented a program to delabel penicillin allergies as one of their change ideas.

Measure Type	Measure
	% of patients who have the allergy section of their medical record updated following penicillin allergy delabelling ⁶
Balancing	Number of patients with a documented penicillin allergy who had an adverse reaction to a penicillin during their current hospital stay
	% of patients who have an adverse drug reaction during the monitoring period following an oral penicillin challenge ⁶
	% of patients with a penicillin allergy who receive a penicillin following either comprehensive penicillin allergy assessment or delabelling



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