

**National Allergy Strategy  
Drug allergy project  
Funding request  
31/01/19**

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## Key issues

To ensure patient safety and effective use of medications, there are two key issues that need to be addressed with regards to drug allergy:

1. **Patients with documented severe drug allergies must never receive the drug.** Appropriate education, communication and patient record systems need to be in place to ensure patient safety.
2. **Patients are often labelled as a drug allergy when they are not allergic to the drug.** If an appropriate health professional determines that the patient is not allergic to the drug, appropriate education, communication and patient record systems need to be in place to ensure the patient is no longer inappropriately and unnecessarily avoiding the drug.

## Fast facts – drug allergy

- Antibiotic allergies affect people of all age groups, from infants to the elderly.
- Many patients may be inappropriately and unnecessarily avoiding drugs:
  - Self-reported antibiotic allergy is common in Australian patients. The overall self-reported antibiotic allergy rate for all hospital patients is 18% for adults (1,2) and 24% reported for general medical inpatients in a multi-centre study in Victoria (1,3).
  - In the general population (South Australian survey data), 22% of adults consider themselves allergic to one or more drugs, 13% allergic to an antibiotic, and 9.3% allergic to penicillin. Self-reported drug allergy is more common in females and increases with age (4).
  - Importantly, 90% of patients with an unconfirmed antibiotic allergy label are not allergic and can safely tolerate the antibiotic after undergoing validated drug allergy assessment (5). This over labelling results in inappropriate prescribing and increased use of broad spectrum antimicrobials, poor patient outcomes and a financial impact on the health system
  - Systematic evaluation of antibiotic allergies in Australia is a key public health strategy, to improve anti-microbial stewardship in our hospitals and benefit patients, especially those who are most vulnerable (5).
- Documentation and communication regarding drug allergies needs to be improved:
  - Currently, antibiotic allergies are poorly documented and communicated, and this is associated with prescribing errors (i.e. contraindicated antibiotics administered in 6% of adult patients with reported allergy to penicillin) (1).
  - Drug allergy is the most common cause of fatal anaphylaxis in Australia.
  - Delay in the diagnosis and management of severe reactions to drugs may occur as the reactions have not been recognised
- Unnecessary avoidance of antibiotics impacts health and antimicrobial stewardship:
  - There is a higher readmission rate at 4 weeks and 6 months in adult Australian patients with reported antibiotic allergy (28%, 48%) compared to those with no antibiotic allergy (17.5%, 37%) (1).
  - Broad spectrum antibiotics are used more frequently in patients with antibiotic allergy labels (1,2), and more frequent use of broad spectrum antibiotics contributes to antimicrobial resistance (6).
  - 11% of adult patients have an antibiotic allergy label to more than one class of antibiotics, which significantly restricts their anti-microbial choices (1).
  - A penicillin allergy label is associated with an increased risk of Methicillin-resistant *Staphylococcus aureus* (MRSA) and *C difficile*, due to the increased use of  $\beta$  lactam alternative antibiotics (7).

The purpose of this submission is to seek funding to implement a comprehensive drug allergy project as this has been identified by the National Allergy Strategy as requiring urgent attention.

## National Allergy Strategy progress

Allergic diseases are amongst the fastest growing chronic health conditions, affecting 1 in 5 Australians, resulting in increased costs of care (1). To address these issues, the Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA), as the leading medical and patient organisations for allergy in Australia, have developed a National Allergy Strategy in collaboration with key stakeholder organisations. ASCIA and A&AA are progressing with the implementation of the National Allergy Strategy and have made the following progress.

### National Allergy Strategy projects funded by the Australian government

- In July 2016 the National Allergy Strategy received funding from the Australian government for the following projects that were all completed in July 2017 as per the contract:
  - 250K website - a hub for the 250,000 teens and young adults in Australia with severe allergies ([www.250K.org.au](http://www.250K.org.au)).
  - All about Allergens online training for food service – this free online course includes videos and interactive activities ([www.foodallergytraining.org.au](http://www.foodallergytraining.org.au)). Supporting resources have also been developing including a free downloadable booklet and templates as well as a resource hub for authorised officers developed in partnership with Environmental Health Australia.
  - Scoping work regarding improving drug allergy management to reduce deaths in hospitals.
- In May 2017, the National Allergy Strategy received funding from the Australian government for the food allergy prevention project (Nip Allergies in the Bub) which is currently being piloted in preparation for national implementation in July 2019.
- In June 2018, the National Allergy Strategy received funding from the Australian government to continue to progress the youth project (250K), food service project and scope a shared care model for Allergy.
- In August 2018, the National Allergy Strategy received confirmation of sustainability funding for a further 4 years (June 2019 to July 2023).

### National Allergy Strategy projects funded by non-government sources

- A partnership has been developed with the Western Australian Primary Health Alliance (WAPHA) to assess and update existing allergy HealthPathways and develop new allergy HealthPathways for allergic conditions across both metropolitan and rural areas of Western Australia. Once these HealthPathways are published in Western Australia, they will be available to all Primary Health Networks (PHNs) across Australia.
- Piloting of a shared care model program in the Kimberley region in Western Australia to determine the education and resource needs to improve regional management of allergic conditions.
- A food allergy menu assessment tool has developed in partnership with the Dietitians Association of Australia (DAA) to improve food allergy meal service to vulnerable populations.
- Food allergy policy and audit tool templates have been developed to improve food allergy management in hospitals and other institution type facilities.
- Consultation regarding the development of an anaphylaxis register for Australia is currently being undertaken.

### Where is Australian government support now urgently required?

Untreated or poorly managed allergic diseases result in preventable morbidity and unnecessary hospital admissions. Quality and appropriate clinical care is essential for the diagnosis and management of allergic diseases, and to ensure optimal patient outcomes.

There are several issues regarding drug allergy that require urgent attention which will improve patient outcomes and reduce the use of more expensive antibiotic medications.

The details of these projects and funding requests are detailed in the Budget Request section in this submission.

## What cost savings can be achieved?

Many patients are considered to be allergic to one or more drugs, most commonly antibiotics, usually because they have had adverse symptoms or a reaction whilst taking the drug. In some cases, this is valid, and the drug should be avoided. However, in many cases the patient is not truly allergic because the symptoms were not actually caused by the drug, but rather the illness they had at the time (e.g. virus). Furthermore, the perception of allergy might be based on childhood reactions that are no longer relevant, or on entirely spurious information (e.g. the wrong drug, or a family member with allergy).

When the healthcare provider documents that a person has a drug allergy, we refer to them as having a **drug allergy 'label'**. When a person has been tested and confirmed as not being allergic to the drug, we refer to this as '**de-labelling**' the person's drug allergy status.

Drug allergy 'de-labelling' saves costs by allowing basic, safe and cheaper drugs (particularly antibiotics) to be used, which might otherwise be avoided unnecessarily. It prevents complications, results in shorter hospital stays, reduces readmissions and reduces the rate of bacterial antimicrobial resistance (in the case of antibiotics) in the community.

The development of national guidelines for drug allergy 'de-labelling' would allow more patients to be safely 'de-labelled' and will therefore contribute to cost savings for both the health sector and for consumers.

## What is the current government policy?

The Australian Government recognises the burden of chronic diseases and is working to address this through the National Strategic Framework for Chronic Conditions.

Since 2016, the Australian government has engaged with ASCIA and A&AA to discuss the National Allergy Strategy and fund specific projects (see page 3), in recognition that allergic diseases are important chronic diseases.

## Overview

In 2016-17 with funding from the Australian Government, the National Allergy Strategy sought to scope the development of a database and clinical education requirements to improve drug allergy management and reduce drug allergy deaths in hospitals.

To ensure patient safety and effective use of medications, there are two key issues that need to be addressed with regards to drug allergy:

1. **Patients with a documented severe drug allergy must never receive the drug.** Appropriate education, communication and patient record systems need to be in place to ensure patient safety.
2. **Patients are often labelled as a drug allergy when they are not allergic to the drug.** If an appropriate health professional determines that the patient is not allergic to the drug, appropriate education, communication and patient record systems need to be in place to ensure the patient is no longer inappropriately and unnecessarily avoiding the drug.

### **Poor documentation and communication of drug allergy places patients at risk from the inadvertent administration of a drug that they are known to be allergic to.**

Documentation of allergy is designed to protect the patient from harm by alerting healthcare providers to avoid prescribing a drug that will result in a life-threatening reaction. A recent Australian study showed poor documentation and communication of patients' antibiotic allergy status as well as prescribing errors and inappropriate antibiotic re-challenges in 6% of adult patients documented as having a penicillin allergy (1).

A review of coronial findings for drug allergy deaths in Australia has identified the following problems in relation to the patient's drug allergy status:

- There was a failure to check medical records, medical alert jewellery or a failure to ask the patient about any drug allergies.
- There was a failure of staff to pass on important information about drug allergies.
- There was a failure to have the patient prominently labelled as having a drug allergy (e.g. with a red patient alert band).
- There was a failure to have notes available at time of patient contact.

The rate of reported antibiotic allergy in hospitals is high. On average 18% of all hospital patients report an antibiotic allergy (1,3). Overall, the documentation of these drug allergies is poor. It has been published that the majority of drug allergy entries in the notes and on the medications are incomplete and vague (8). Furthermore, Australian studies have found prescribing errors (i.e. contraindicated antibiotics administered) in 6% of adult patients with reported allergy to penicillin (1). A recent review of national medication charts reveals incomplete entries in the majority of cases (8).

When addressing drug allergy and preventable deaths from drug allergy, we need to consider:

- The importance of accurate patient records, including the ability to identify a patient's true allergy status;
- How electronic health records (e.g. My Health Record, electronic hospital patient record systems) and electronic prescribing software work together to ensure safety checks and medical alerts are in place, to ensure patients do not receive a drug they are allergic to; and
- Improving the management of drug allergy in the community setting, as allergic reactions to drugs can also occur outside of healthcare settings, and some may require hospitalisation.

This importantly requires not only appropriate patient record infrastructure and information sharing, but also evidence-based health professional education. Health professionals need to be able to:

- Correctly identify true drug allergy and refer the patient to a clinical immunology/allergy specialist appropriately;
- Correctly record/document a patient's drug allergy to ensure the patient's current drug allergy status is accurately communicated (the patient is 'documented or labelled' as being drug allergic);
- Successfully remove the patient's drug allergy 'label' ("de-labelling") once the patient has undergone a drug allergy challenge and it has been confirmed by a clinical immunology/allergy specialist that the

patient is not allergic to the drug. De-labelling patients will enable patients whose drug allergy was dismissed after assessment to receive the most appropriate drug for their medical condition without restriction.

To protect patients with confirmed life-threatening allergies, a drug allergy registry should be created, similar to drug allergy registries in New Zealand and Europe. There are several reasons why a drug allergy registry would be beneficial with the greatest value being an improvement in patient safety. A drug allergy registry allows us to capture information about the frequency of drug allergy and the types of adverse drug reactions that are occurring. If we are not able to capture this information in a consistent and meaningful way, it becomes impossible to generate substantial evidence that a drug is causing repeated adverse drug reactions and should be used with caution or not at all. Further to this, a drug allergy registry would help to improve clinician knowledge regarding which drugs are specifically implicated and which risk factors for an allergy are relevant.

### **Inappropriate and unnecessary avoidance of safe and useful drugs in patients who have been incorrectly 'labelled' as being allergic to a drug can impact on patient health**

Studies have shown that up to 90% of patients who report an allergy to penicillin, the most commonly reported antibiotic allergy, can actually safely tolerate the drug (9). This erroneous attribution of allergy ('labelling' the patient as being allergic), has been shown to adversely affect patient care in both children and adults for penicillin allergy 'labels' directly by:

- limiting the selection of antibiotics for any given infection;
- indirectly by increasing costs associated with alternative and restricted antibiotic choices; and
- increased hospital admissions and longer length of stay in hospital, in Western Australia and other countries (10).

Furthermore, antibiotic resistance has emerged as a significant public health issue world-wide and is associated with the avoidance of what are known as narrow-spectrum antibiotics (e.g. penicillin). The consequences of incorrectly 'labelling' a patient as being allergic to an antibiotic are far-reaching, as an antibiotic allergy 'label' acquired in childhood is most often carried through to adulthood unless the patient has been assessed by a clinical immunology/allergy specialist. In the context of chronic disease management, which today would include many cancers and other conditions which affect the immune system, antibiotic resistance can increase morbidity, mortality and has significant economic consequences. Therefore, an antibiotic allergy 'de-labelling' strategy has an important role to play in increasing patient safety and reducing antimicrobial resistance in all patients including the elderly.

Health consumers must be closely engaged with the proposed strategy as antibiotic allergy 'labels' are largely self-reported and associated with a drug intolerance rather than true allergy. Therefore, antibiotic allergy 'de-labelling' initiatives must be accompanied by both health professional (including primary health care professionals) and consumer education strategies to ensure that clinical interventions are effective in the long term.

With regards to antibiotic allergy management, we propose implementation of a strategy whereby low risk antibiotic allergy-labelled patients are 'de-labelled' during admissions and in primary care. In-patients with an antibiotic allergy 'label' should be assessed and have effective 'de-labelling' or verification of the antibiotic allergy during their stay, thus preventing the long-term consequences of carrying an unnecessary antibiotic allergy label.

Overall, to address the key issues with drug allergy management, we need to develop a Model of Care for drug allergy for patients of all ages. The Model of Care should address antibiotic allergies as well as all other drug allergies which impact clinical care - most commonly opiate allergies, non-steroidal medications, contrast agent allergy, reactions to anti-cancer agents and anaesthetic allergies. To combat the poor documentation and prescribing errors, better education and mandatory training regarding drug allergy and clinical alert policies is also required.

# Recommendations and resource outcomes from the drug allergy scoping project (2016-17)

## Drug allergy database

It has become evident through our consultations with health professionals and the ASCIA Drug Allergy Working Party, that to improve drug allergy management in hospitals, hospital staff require access to an accurate patient record which clearly documents whether they have a suspected drug allergy (allergy label). Therefore, a patient's medical history outside of the hospital needs to be accessible to hospital staff. For example, if a patient has seen a private clinical immunology/allergy specialist who has verified/confirmed their penicillin allergy, this information should be accessible to the emergency department hospital staff that attend to the unconscious patient after an accident. My Health Record (MHR) has the potential to provide access to a patient's complete medical history in almost every region in Australia. However, MHR in its current form does not allow for the most current or accurate allergy information to be easily identified and accessed.

### Recommendations:

1. Allergy information in MHR must be prominent such as an alert type mechanism (this is important for drug and food allergy).
2. Consumers need to be educated about the clinical risks of hiding allergy information.
  - a. Allergy information in MHR should not be able to be hidden by consumers, to ensure that allergy information, particularly drug allergy information (including drug allergy de-labelling information), can be accessed by health professionals at all times. This also relates to food allergy and many of the changes required for drug allergy can also accommodate food allergy.
3. Standardised Adverse Drug Reaction (ADR) nomenclature should be used in all hospitals in Australia.
  - a. SNOMED CT provides clinical descriptions at a range of levels and specificity (e.g. descriptions reflecting the subtle differences in a diagnosis).
  - b. We recommend different reference sets of SNOMED-CT appropriate to the clinician's skill level (e.g. basic level for general practitioners and an advanced level for specialists) be developed.
  - c. Clinical education regarding drug allergy coding is required, to ensure accurate entry of current information.
4. It is recommended that the standards set by the Australian Digital Health Agency (ADHA) for state and territory digital health platforms to interact with MHR allow for:
  - a. All data being shared with MHR, whether it is from a hospital, general practice, pharmacy, dietitian or other health provider, should be shared as dynamic data rather than having to open disparate documents (e.g. shared health summaries and discharge summaries).
  - b. All health professionals should be able to access MHR. If MHR is agreed to be opt out, we recommend a concurrent strategy to maximise clinician connectivity and usage is undertaken.
  - c. Allergy alerts every time a health professional accesses a patient's MHR.
  - d. Resurrection alerts in case an allergy is re-entered after successful de-labelling. This will allow an additional check to ensure that 're-labelling' a person's drug allergy or their food allergy, is appropriate.
  - e. Inclusion of out-patient medical information.
  - f. Integration of medicine and dispensing data within MHR.
5. It is recommended that there is a coordinated process to prevent unnecessary duplication of data entry. Duplication is not only time wasting but can increase the risk of data entry error and confusion about most current information/allergy status.
6. Private and public hospitals need to meet the ADHA standards to share patient data with MHR. States and territories may need additional resources.
7. Hospital electronic health systems should have a system for alerts that are triggered when a clinician intends to change a patient's drug allergy alert status.

- a. There should be a safety check to ensure a patient's drug allergy status is not changed erroneously (e.g. pop-up information that indicates a patient was de-labelled to penicillin last year comes up when someone tries to enter in an alert for penicillin allergy in their electronic health record). This will help prevent patients being erroneously re-labelled with a drug allergy. This should also be applied to a patient's food and latex allergy status.
8. An effective, nationally standardised drug allergy de-labelling guideline needs to be developed to ensure patient safety in de-labelling, reduce unnecessary antibiotic allergy labels, and reduce use of second line antibiotics.
  - a. The Australian Commission of Safety and Quality in Health Care (ACSQHC) have agreed to work in partnership with the National Allergy Strategy to develop a national guideline for drug allergy de-labelling.
9. MHR needs to have the capacity to effectively de-label patients. That is, once a patient has undergone a drug allergy challenge and has been confirmed to no longer be allergic to the drug, MHR needs to allow for the 'de-labelled drug allergy status' to remain for that medication.
10. State-based electronic health records need to have the capacity to effectively de-label patients.

## Clinical education requirements

Patient safety is paramount and appropriate management of patients with drug allergy requires health professionals to have a good understanding of ADRs, drug allergy labels and the consequences of administering a drug to a patient with drug allergy. Further to this, a patient's clinical information is only useful if the information is accurate and most current. Incorrect clinical records can result in harm to the patient if they are given a medication they are allergic to or if they are unnecessarily avoiding a medication. Over diagnosis of drug allergy, particularly penicillin allergy, can have an ongoing impact on the patient's health, as avoiding first line antibiotics results in longer hospital stays, more hospital re-admissions and contributes to antimicrobial resistance.

### Recommendations:

1. Standardised clinical education on how to complete the Australian Commission for Safety and Quality in Health Care standard medication chart.
2. Standardised clinical education is required for all emergency department staff, including junior doctors, anaesthetists, nurses, members of Medical Emergency Team (MET) call staff/first responders, in regards to prompt recognition of drug allergy, search for medical identification jewellery and anaphylaxis recognition and treatment. Staff education should be compulsory and include the following:
  - a. How to classify a drug reaction (requires knowledge of ADR classifications)
  - b. How to investigate drug allergy
  - c. How to accurately document drug allergy
  - d. Alert signs/symptoms for severe drug reactions
  - e. How to manage drug allergy
  - f. How to investigate historical drug allergy (antibiotic allergy de-labelling, referral pathways to clinical immunology/allergy specialists)

This training should also address management of food and latex allergy in the medical setting.

3. Standardised clinical education regarding cross-reactivities with cephalosporins and penicillin antibiotics (e.g. allergy against ampicillin warrants avoidance of cephalexin and ceclor).
4. Standardisation of terminology used on medical identification jewellery to assist hospital staff and paramedics with identifying a patient's drug allergy status.
  - a. Engagement with medical identification jewellery providers is recommended. It would be ideal to have medical practitioners completing the forms for the medical identification jewellery, allowing only specific terms to be used on the jewellery with some uniformity.

5. Site specific education for all staff who enter data into patient records to ensure current and accurate data entry into the hospital's electronic health system. Clinical education regarding drug allergy coding to ensure accurate entry of information is essential.
6. Site specific education for all staff regarding allergy (drug, food and latex) alert systems within the hospital.
7. A consumer awareness raising campaign to encourage and empower consumers to engage in MHR is recommended once the allergy component of MHR has been improved.

## Summary of budget request

	2019/20	2020/21	2021/22	Cost over 3yrs
Standardising drug allergy terminology	165,000			
Health professional education	190,000			
Improvement of electronic health records and My Health Record		115,000		
Developing standardised drug allergy 'de-labelling' guidelines		655,000		
Communication strategy for health professionals and consumers			795,000	
Scoping a national drug allergy registry			190,000	
<b>TOTAL</b>	<b>355,000</b>	<b>770,000</b>	<b>985,000</b>	<b>2,110,000</b>

## Budget request information

### 1. Standardising drug allergy/adverse drug reactions definitions and terminology

The following strategies would be employed:

- Conducting a face to face workshop of key stakeholders (clinical immunology/allergy specialists, Australian Commission of Safety and Quality in Health Care, Therapeutic Goods Administration, Australian Digital Health Agency, infectious disease specialists, pharmacy associations, general practitioner associations, Royal Australasian College of Physicians).
- Ongoing engagement with key stakeholders to standardise terminology and to implement the use of the terminology into health record systems.

Budget (2019/20):

0.5 FTE project officer (\$70K includes on costs) + FTF meetings (\$40K) + resource costs (\$40K)  
teleconferences/general expenses (\$15K)

Total = \$165K

### 2. Health professional education

The following strategies would be employed:

- Engagement with key stakeholders to standardised online training incorporating standardised drug allergy/adverse drug reactions definitions and terminology.
- Develop standardised face to face training for health professional education across Australia.
- Develop resource templates to assist with hospital staff training that can be adapted to site specific hospital record systems.
- Resources will be piloted prior to implementation.

Budget (2019/20):

0.5 FTE project officer (\$70K includes on costs) + resource development (110K)  
teleconferences/general expenses (\$10K)

Total = \$190K

### 3. Improvement of electronic health records and My Health Record

While the National Allergy Strategy is not responsible for developing or improving electronic health record systems including My Health Record, the National Allergy Strategy can provide insight into the issues regarding drug allergy (and general allergy) documentation to support improvement to these systems. The National Allergy Strategy would:

- Engage with all state Chief Information Officers, the Australian Digital Health Agency and the Australian Commission of Safety and Quality in Health Care.
- Engage with health professionals, particularly general practitioners and pharmacists.
- Engage with consumers.

Budget (2020/21):

0.5 FTE project officer (\$75K) + face to face meetings (\$30K) + teleconferences/general expenses (\$10K)

Total = \$115K

### 4. Developing standardised drug allergy 'de-labelling' guidelines

To reduce the number of people who erroneously carry a drug allergy 'label', the development of nationally standardised drug allergy 'de-labelling' guidelines will ensure that people can be safely assessed to confirm their drug allergy status. The National Allergy Strategy would engage with:

- The Australian Commission of Safety and Quality in Health Care who would ideally develop the guideline with support from the National Allergy Strategy.
- The ASCIA drug allergy committee.

- Hospitals who already have drug allergy de-labelling programs.
- Other key stakeholder organisations (e.g. RACGP, RACP, ACRRM).

Budget (2020/21):

0.5 FTE project officer (\$75K) + ACSQHC costs to develop guideline (see appendix X) (\$550K) + face to face meetings (\$20K) teleconferences/general expenses (\$10K)

Total = \$655K

## 5. Communication strategy for health professionals and consumers

Effective communication with health professionals and consumers is important to raise awareness about the importance of accurate drug allergy information. The National Allergy Strategy would engage with a social marketing company to assist with developing a communication strategy suitable for health professionals and consumers. This would include separate health professional and consumer focus groups to ensure effective messages are developed.

Budget (2021/22):

1.0 FTE project officer (\$150K) + focus groups (\$65K) + social marketing strategy (\$180) + social media strategy (\$80K) + Tonic health media strategy for pharmacists and GPs (\$320K)

Total = 795K

## 6. Scoping the development of a national drug allergy registry

To protect patients with confirmed life-threatening allergies, a drug allergy registry should be created, similar to drug allergy registries in New Zealand and Europe. The National Allergy Strategy would consult with key stakeholder organisations to determine:

- The ideal specifications for a drug allergy registry for Australia.
- The process for which drug allergy information is verified.
- The requirements regarding who needs to be able to access the information and the process for achieving this.
- The possibility for interoperability between the registry and other electronic health records (e.g. My Health Record).

Budget (2021/22):

1.0 FTE project officer (140K) + face to face meetings (40K) + teleconference/general expenses (10K)

Total = \$190K

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