australasian society of clinical immunology and allergy

Submission to Parliamentary Inquiry: Allergies and Anaphylaxis in Australia

ASCIA is the peak professional body of clinical immunology and allergy specialists in Australia and New Zealand

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Introduction

The Australasian Society of Clinical Immunology and Allergy (ASCIA) welcomes the opportunity to make this submission in response to the House of Representatives Standing Committee for Health, Aged Care and Sport Parliamentary Inquiry into Allergies and Anaphylaxis in Australia.

ASCIA is the peak professional body for allergy and clinical immunology in Australia and New Zealand, and is committed to improving allergy and anaphylaxis prevention, diagnosis, treatment, management and research.

In developing this submission, ASCIA invited feedback from ASCIA members (677 in total) comprising:

- 260 Full members - including 241 clinical immunology/allergy specialists.
- 417 Associates - including medical practitioners with an interest in allergy (e.g. general practitioners and paediatricians), allergy nurses and dietitians.

ASCIA is a partner with Allergy & Anaphylaxis Australia in the National Allergy Strategy, and some issues raised in this submission will overlap with issues raised in the National Allergy Strategy and Allergy & Anaphylaxis Australia submissions.

There are currently no cures for allergies and anaphylaxis, which affect around one in five Australians. This high prevalence and lack of a cure makes allergies and anaphylaxis major public health issues. Significant health and economic gains can therefore be made by improving prevention, diagnosis, treatment, management and research.

People with allergies have an abnormal response to usually harmless substances (allergens). This immune system response is damaging to the body and can be life threatening. They can have an allergic reaction every time they are exposed to the allergen/s, which are common in our environment.

People with allergies to foods, drugs or insect venom may be at risk of having a severe allergic reaction, known as anaphylaxis, which is potentially life threatening. Anaphylaxis is a medical emergency and treatment should include the steps that are outlined on the ASCIA Action Plan for Anaphylaxis, available on the ASCIA website.

Many people with allergies are burdened with more than one of the allergic diseases listed below, which are chronic conditions that significantly affect quality of life:

- Food allergy
- Drug allergy
- Allergic rhinitis (hayfever)
- Eczema (atopic dermatitis)
- Insect and tick allergy.

Allergic diseases can be challenging for health professionals to diagnose and treat, and often require management by clinical immunology/allergy specialists.

Issues that are barriers to providing optimal care for people with allergies are summarised in this submission, as well as suggested solutions. The table in Appendix B summarises how the issues outlined in the following pages relate to the terms of reference for the Parliamentary Inquiry into Allergies and Anaphylaxis in Australia.

Issue 1: Support is required for quality allergy and anaphylaxis educational and training resources for patients, carers and health professionals

Widespread, accessible, reliable and consistent evidence-based educational and training resources developed by experts are required to improve the quality of care of people with allergies and management of anaphylaxis. ASCIA has developed a range of reliable evidence-based allergy and anaphylaxis educational resources for patients, carers, consumers, school staff, early childhood education/care staff, first aid providers and health professionals. These resources include action plans, e-training courses and documents that are accessible online, that can be downloaded and printed. Providing, updating and promoting these resources requires ongoing funding.

Suggested solution:

- **Federal government funding support of evidence-based ASCIA online allergy and anaphylaxis educational resources is essential to provide sustainability.**

Issue 2: Support is required for quality, evidence-based allergy and anaphylaxis education and training for all health professionals

Medical education in the area of allergies and anaphylaxis, both undergraduate and postgraduate, has been inconsistent and inadequate in Australia. This has resulted in the majority of general practitioners, paediatricians, other medical specialists and other health professionals having inadequate training or experience in the management of allergic disease.

This has a flow on effect to patient care, when advice given to patients may be incorrect, inappropriate, inadequate and at times dangerous. Even in 2019, most general paediatrician trainees will qualify with no exposure or training in allergic diseases and will be ill equipped to manage children with allergies.

Suggested solutions:

- **Federal government funding support of ASCIA to develop minimum standards of allergy training for health professionals.**
- **Federal government endorsement of minimum standards of allergy training in the curriculum for all university medical schools and training of general practitioners, physicians and paediatricians.**
- **Federal government funding support of ASCIA to provide face to face training for upskilling of health professionals.**

Issue 3: Improved access to timely, equitable and quality care for patients with allergic disease is needed

The issue of timely and equitable access to quality care for patients with allergic disease is critical. At present many parts of Australia, particularly regional, rural and remote areas, are underserved in terms of the availability of clinical immunology/allergy specialists. Quality allergy care should include clinical immunology/allergy specialists working closely with general practitioners, other medical specialists and allied health professionals.

The long wait lists for patients to see clinical immunology/allergy specialists working in public and private allergy services can result in patients seeking help from practitioners who are inadequately trained and qualified to provide evidence-based diagnosis, treatment and management of allergic

disease. This may lead to potential harm, additional healthcare encounters, increased costs and burden on the health system.

Timely access to quality care for infants and young children with suspected food allergy is particularly important as it can prevent food allergy and anaphylaxis, reduce unnecessary food restrictions and decrease the risk of nutritional and growth problems.

Suggested solutions:

- **Federal government funding support for regional, rural and remote outreach programs, to provide the right care for the right patient at the right time in the right place.**
- **Federal government funding support for ASCIA to develop minimum standards of care. This could potentially help inform a shared care model which is currently being scoped by the National Allergy Strategy.**

Issue 4: Improved access to skin testing reagents for allergy diagnosis by clinical immunology/allergy specialists is needed

Skin testing is an important diagnostic tool for clinical immunology/allergy specialists. It provides high quality information when performed optimally and interpreted correctly. The current access process for clinical immunology/allergy specialists is time consuming and complicated. This time would be much better spent providing quality patient care.

Suggested solution:

- **Federal government endorsement of ASCIA to be recognised by the Therapeutic Goods Administration (TGA) as a legal entity, to enable ASCIA to provide Authorised Prescriber endorsement letters to ASCIA Full members (clinical immunology/allergy specialists), which will simplify access to skin testing reagents.**

Issue 5: A specific food allergen challenge MBS item number is needed

Food allergen challenges are the gold-standard for diagnosis of food allergy and an essential part of high quality patient care. A food allergen challenge is a medical procedure that takes an average of four hours for each patient and requires close supervision and monitoring of the patient by trained medical and nursing staff in appropriate facilities.

There is currently no specific Medical Benefits Schedule (MBS) item number to cover the costs incurred to provide this service, and this is a barrier to optimal care. This makes it unfeasible for many medical specialists to provide this service and as a result current wait times for food allergen challenges are unacceptably long.

Suggested solution:

- **Federal government endorsement for introduction of a specific MBS item number for food allergen challenges.**

Issue 6: A specific drug allergen challenge MBS item number is needed

The majority of people who believe they have drug allergy, most commonly antibiotic allergy, are actually not truly allergic to these drugs. Drug allergy assessment (“de-labelling”), which requires drug allergen challenges, has shown that 90% of patients with presumed but unverified drug allergy can

tolerate the medication safely. Optimising medication use in our health system will lead to improved, safer and cost-effective care. This especially includes optimised use of antibiotics in our hospitals which contributes directly to the reduction of multi-resistant infections.

Suggested solution:

- **Federal government endorsement for ASCIA to apply for a specific MBS item number for drug allergen challenges.**

Issue 7: Improved access to evidence-based and cost-effective treatments is needed

Many established, evidence-based treatments for allergic disease are registered with the Therapeutic Goods Authority (TGA), but are not listed on the Pharmaceutical Benefits Schedule (PBS). Improving access to these treatments can improve the course of a person's disease and greatly improve quality of life. Many new treatments are emerging in this field and expert representation is needed for their evaluation.

In contrast, unscientific methods that are not evidence-based are at best ineffective and at worst can cause serious side effects, health issues and even fatalities as a result of misdiagnosis. These methods can lead to potential harm, additional healthcare encounters, increased costs and burden on the health system.

Suggested solutions:

- **Federal government recommend a review of existing TGA-registered treatments for allergic disease to consider for inclusion on the PBS (subject to agreement by the supplier/sponsor to make a PBS application).**
- **Federal government recommend (to relevant authorities) that all products or services claiming to diagnose or treat allergies are subject to an independent evidence-based review.**

Issue 8: Support is required for further research into all allergic diseases

There is an urgent need to improve understanding of the underlying pathology of allergic diseases, including further research into prevention, diagnosis and treatment of food allergy, drug allergy, eczema and allergic rhinoconjunctivitis. This will ultimately lead to improved diagnostics and treatments.

Suggested solutions:

- **Federal Government funding support dedicated to allergic diseases via the Medical Research Future Fund (MRFF) and NHMRC Targeted Call for Research.**
- **Federal Government matched funding for annual AIFA (Allergy and Immunology Foundation of Australasia) grants for allergy and immunology research.**

Issue 9: Support is required for further research into food allergy treatments including food oral immunotherapy

There are many potential treatments for food allergy that are currently for research only in Australia, including oral immunotherapy (OIT) for food allergy. The role of OIT as a potential management tool for people with food allergy is currently unclear. In its current form OIT does not provide a cure for most people and there are significant side effects, including potential risk of anaphylaxis. Therefore, further assessment of safety, patient selection and appropriate use in Australia is required.

Suggested solution:

- **Federal government funding support for further quality, peer reviewed, multicentre (across all states), clinical research into optimal food allergy treatments in Australia. This includes various approaches such as OIT.**

Issue 10: National anaphylaxis and drug allergy registers do not exist

The incidence of many allergic diseases in Australia, including anaphylaxis and confirmed severe drug allergy is currently unknown. There are no national mechanisms to alert consumers of potentially lethal allergen contamination in foods in a timely manner. Models for drug allergy registries exist globally.

Suggested solution:

- **Federal government funding support for a national anaphylaxis and confirmed severe drug allergy register.**

Concluding comments

We note that the Committee prefers that submissions are made public, and we approve for all of the ASCIA submission, including the appendices, to be made public by the Committee.

If there are any queries regarding this submission please don't hesitate to contact us by emailing education@allergy.org.au

We trust that the ASCIA submission will be given due consideration in the Parliamentary Inquiry into Allergies and Anaphylaxis in Australia, and we look forward to your response.

Yours sincerely,

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ASCIA President

Clinical Professor Michaela Lucas
ASCIA President Elect

Associate Professor Jane Peake
ASCIA Director

Dr Michael O'Sullivan
ASCIA Director

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ASCIA CEO

Appendix A: About ASCIA

The Australasian Society of Clinical Immunology and Allergy (ASCIA) is the peak professional body of clinical immunology and allergy in Australia and New Zealand. Established in 1990, ASCIA is a world leading, innovative and active professional society with strong leadership and sustainable operations.

ASCIA's mission is to advance the science and practice of allergy and clinical immunology, by promoting the highest standard of medical practice, training, education and research, to improve the health and quality of life of people with allergies and other immune system disorders.

ASCIA is committed to providing high quality training, education and research to improve the health and wellbeing of all Australians with allergies and anaphylaxis. This commitment is demonstrated by:

- Hosting of **ASCIA Annual Conferences** for the past 30 years, which provide an international standard of education for ASCIA members and other health professionals. The announcement of a national Parliamentary Inquiry into Allergies and Anaphylaxis at the ASCIA 2019 Conference was welcomed by ASCIA www.allergy.org.au/conferences/ascia-annual-conference

- Continued development and updating of **ASCIA educational resources** over the past 20 years, which provide quality online educational resources for health professionals and the community. All of these resources are available on the **ASCIA website,** which is a trusted and extremely well utilised source of information, with more than three million pageviews each year www.allergy.org.au

- Development of the **ASCIA Action Plans for Anaphylaxis** since 2003, which are now recognised as world leading resources and used throughout Australia and New Zealand, along with other ASCIA allergy and anaphylaxis resources www.allergy.org.au/anaphylaxis

- Development of world renowned **ASCIA allergy and anaphylaxis e-training courses** since 2010, for schools and early childhood education/care https://etraining.allergy.org.au/, health professionals https://etraininghp.ascia.org.au/ and community https://anaphylaxis.ascia.org.au/

- Establishment of **AIFA** (**Allergy and Immunology Foundation of Australasia**) in 2013, to fund allergy and immunology research project grants www.allergyimmunology.org.au/projects

- Development of the first **National Allergy Strategy** for Australia in 2015, in partnership with Allergy & Anaphylaxis Australia and stakeholders www.allergy.org.au/national-allergy-strategy

- Implementation of the National Allergy Strategy, including the **250K Youth Project** (for the 250,000 young people with severe allergies), **All About Allergens training for food service** and **Nip allergies in the Bub** food allergy prevention project, which implements ASCIA Guidelines for infant feeding and allergy prevention.

The aim of the suggested solutions in this submission is to significantly improve the health and quality of life for all Australians with allergies, by supporting and promoting the continued use of existing resources (as listed above) and developing new strategies and resources.

Appendix B: Terms of Reference

This submission focuses on ten issues that are relevant to the following parliamentary inquiry terms of reference, and key areas of prevention, diagnosis/treatment/management and research, as outlined in the table below.

Terms of Reference:

1. The potential and known causes, prevalence, impacts and costs of anaphylaxis in Australia.
2. The adequacy of food and drug safety process and food and drug allergy management, auditing and compliance (including food allergen labelling by manufacturers and food service providers).
3. The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis.
4. Access to and cost of services, including diagnosis, testing, management, treatment and support.
5. Developments in research into allergy and anaphylaxis including prevention, causes, treatment and emerging treatments (such as oral immunotherapy).
6. Unscientific diagnosis and treatments being recommended and used by some consumers.
7. The impact of unnecessary drug avoidance due to unconfirmed drug allergies and its management, such as drug allergy 'de-labelling'.

ASCIA ISSUES 1-10	PREVENTION	DIAGNOSIS, TREATMENT, MANAGEMENT	RESEARCH	TERMS OF REFERENCE
1. Support for educational resources				**3, 2**
2. Support for education and training of all health professionals				**3, 2**
3.Improved access to quality care				**4, 6, 3**
4. Improved access to skin testing reagents				**4**
5. MBS item number for food allergen challenges				**4, 3, 2**
6. MBS item number for drug allergen challenges				**7, 4, 2, 3**
7. Improved access to evidence-based treatments				**4, 6, 3**
8. Allergy research				**5, 1**
9.Food allergy research				**5, 1**
10.National registers				**1, 7**

Appendix C: Further Information About Issues

Issue 1: Support is required for evidence-based allergy and anaphylaxis educational resources for patients, carers and health professionals

Widespread, accessible, reliable and consistent evidence-based educational resources developed by experts are required to improve the quality of care of people with allergies and management of anaphylaxis. ASCIA has developed a range of reliable evidence-based allergy and anaphylaxis educational resources for patients, carers, consumers, school staff, early childhood education/care staff, first aid providers and health professionals. These resources include action plans, e-training courses and documents that are accessible online, that can be downloaded and printed. Providing and updating these resources requires ongoing funding.

Suggested solution:

- **Federal government funding support of evidence-based ASCIA online allergy and anaphylaxis educational resources is essential to provide sustainability.**

This issue is directly relevant to the following terms of reference:

- The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis.
- The adequacy of food and drug safety process and food and drug allergy management, auditing and compliance (including food allergen labelling by manufacturers and food service providers).

FURTHER INFORMATION

ASCIA anaphylaxis e-training courses provide information about how to:

- Recognise allergic reactions, including anaphylaxis.
- Treat allergic reactions, including anaphylaxis.
- Prevent allergic reactions in people with allergies, including anaphylaxis, by implementing measures to minimise or avoid exposure to known allergens.
- Diagnose, treat and manage allergic diseases (for health professionals).

It is important to note that only ASCIA allergy and anaphylaxis e-training courses have been developed by the peak professional body for allergy (ASCIA), and are regularly reviewed and updated by experts on a voluntary basis, facilitated by medical editors and writers (paid ASCIA staff).

ASCIA has continued to provide these courses free of charge since 2010, and has therefore been subsidising the increasing costs for review and updating of content, website hosting and user help lines for these courses. To ensure sustainability and enable ASCIA to continue providing the highest quality evidence-based education into the future, an annual grant from the federal government would enable ASCIA to maintain and update e-training courses and education, without requiring payment from users to access the training.

ASCIA anaphylaxis resources: www.allergy.org.au/anaphylaxis
ASCIA allergy and anaphylaxis e-training courses:
Schools and early childhood education/care https://etraining.allergy.org.au/
Health professionals https://etraininghp.ascia.org.au/
First Aid/Community https://anaphylaxis.ascia.org.au/

Issue 2: Support is required for quality, evidence-based allergy and anaphylaxis education and training for all health professionals

Medical education in the area of allergies and anaphylaxis, both undergraduate and postgraduate, has been inconsistent and inadequate in Australia. This has resulted in the majority of general practitioners, paediatricians, other medical specialists and other health professionals having inadequate training or experience in the management of allergic disease.

This has a flow on effect to patient care, when advice given to patients may be incorrect, inappropriate, inadequate and at times dangerous. Even in 2019, most general paediatrician trainees will qualify with no exposure or training in allergic diseases and will be ill equipped to manage children with allergies.

Suggested solutions:

- Federal government endorsement of minimum standards of allergy training in the curriculum for all university medical schools and training of general practitioners, physicians and paediatricians.
- Federal government funding support of ASCIA to develop minimum standards of allergy training for health professionals.
- Federal government funding support of ASCIA to provide face-to-face training for upskilling of health professionals.

This issue is directly relevant to the following terms of reference:

- The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis.
- The adequacy of food and drug safety process and food and drug allergy management, auditing and compliance (including food allergen labelling by manufacturers and food service providers).

FURTHER INFORMATION

There is a need to upskill the current workforce, because the current cohort of GPs, paediatricians, physicians and other health professionals generally do not have adequate skills in this area to meet the growing demand for quality allergy care. There is also a need to address the growing number of young adults with food allergies transitioning from paediatric to adult care, and support for food allergen challenges in adult hospitals.

ASCIA Scope of Practice for clinical immunology/allergy specialists in Australia:
www.allergy.org.au/ascia-reports#s2

Issue 3: Improved access to timely, equitable and quality care for patients with allergic disease is needed

The issue of timely and equitable access to quality care for patients with allergic disease is critical. At present many parts of Australia, particularly regional, rural and remote areas, are underserved in terms of the availability of clinical immunology/allergy specialists. Quality allergy care should include clinical immunology/allergy specialists working closely with general practitioners, other medical specialists and allied health professionals.

The long wait lists for patients to see clinical immunology/allergy specialists working in public and private allergy services can result in patients seeking help from practitioners who are inadequately trained and qualified to provide evidence-based diagnosis, treatment and management of allergic disease. This may lead to potential harm, additional healthcare encounters, increased costs and burden on the health system.

Timely access to quality care for young children with suspected food allergy is particularly important as it can prevent food allergy and anaphylaxis, reduce unnecessary food restrictions and decrease the risk of nutritional and growth problems.

Suggested solutions:

- **Federal government funding support for regional, rural, remote outreach programs, to provide the right care for the right patient at the right time in the right place.**
- **Federal government funding support for ASCIA to develop minimum standards of care. This could potentially help inform a shared care model which is currently being scoped by the National Allergy Strategy.**

This issue is directly relevant to the following terms of reference:

- Access to and cost of services, including diagnosis, testing, management, treatment and support.
- Unscientific diagnosis and treatments being recommended and used by some consumers.
- The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis.

FURTHER INFORMATION

The issue of access to care for allergy services is critical. A regional outreach shared care model is a potential solution. For example, periodic regional multidisciplinary clinics could be run with a team from the tertiary hospital with the local health professionals. Patients would be seen together with the local paediatricians, nurses and dietitians which would upskill them, and provide family centred care to the patients. The development of these health networks would allow local delivery of their ongoing care and procedures such as food allergen challenges to be supported. This would reduce the rate at which patients are consulting unqualified or unorthodox practitioners, who often give poor advice leading to complications in managing their condition.

It needs to be recognised that the needs of patients in urban areas may be very different to the needs of patients in regional, rural or remote areas in terms of access to specialist care. It is vital that the education and training of all health professionals is improved to allow for the development of an outreach program (please refer to Issue 2 for details).

Information about the National Allergy Strategy Shared Care Model project:
https://nationalallergystrategy.org.au/projects/shared-care-model-for-allergy

Issue 4: Improved access to skin testing reagents for allergy diagnosis by clinical immunology/allergy specialists is needed

Skin testing is an important diagnostic tool for clinical immunology/allergy specialists. It provides high quality information when performed optimally and interpreted correctly. The current access process for clinical immunology/allergy specialists is time consuming and complicated. This time would be much better spent in quality patient care.

Suggested solution:

- **Federal government endorsement of ASCIA to be recognised by the Therapeutic Goods Administration (TGA) as a legal entity, to enable ASCIA to provide Authorised Prescriber Endorsement letters to ASCIA Full members (clinical immunology/allergy specialists), which will simplify access to skin testing reagents.**

This issue is directly relevant to the following terms of reference:

- Access to and cost of services, including diagnosis, testing, management, treatment and support.

FURTHER INFORMATION

Skin testing reagents that were registered with the Therapeutic Goods Administration (TGA) were discontinued in 2008. It is not financially feasible for suppliers to register their products under current TGA requirements, so medical practitioners need to use unregistered products, using either of the following:

- Endorsement as a TGA Authorised Prescriber.
- TGA Special Access Scheme (SAS) C.

To be an Authorised Prescriber currently requires a letter of endorsement supplied by a medical college or ethics committee. Clinical immunology/allergy specialists who are Full ASCIA members have therefore had to obtain endorsement letters from one of the following:

- Royal Australasian College of Physicians (RACP).
- Royal College of Pathologists of Australasia (RCPA).
- Human research ethics committee (HREC).

Despite ASCIA being a legal entity, the TGA has not previously recognised ASCIA as being qualified to provide a letter to endorse its Full members as Authorised Prescribers.

The RCPA has recently provided ASCIA with a letter of endorsement for authorised prescribers, which is applicable to all Full ASCIA members who are fellows of the RCPA.

Whilst the RACP previously provided ASCIA with a letter in 2010, the RACP has since refused to provide ASCIA with a new endorsement letter for TGA Authorised Prescribers, which has greatly disadvantaged clinical immunology/allergy specialists who are not fellows of the RCPA. Whilst they, and any other medical practitioners can access skin testing reagents using TGA SAS C, this is not a feasible solution for busy allergy clinics with large numbers of patients. Due to the large amount of administration and paperwork, the SAS C process is not designed for use in this setting.

ASCIA information about access to skin testing reagents:
www.allergy.org.au/members/ascia-member-access-to-spt-reagents#s3

Issue 5: A specific food allergen challenge MBS item number is needed

Food allergen challenges are the gold-standard for diagnosis of food allergy and an essential part of high-quality patient care. A food allergen challenge is a medical procedure that takes an average of four hours for each patient and requires close supervision and monitoring of the patient by trained medical and nursing staff in appropriate facilities.

There is currently no specific Medical Benefits Schedule (MBS) item number to cover the costs incurred to provide this service and this is a barrier to optimal care. This makes it unfeasible for many medical specialists to provide this service and as a result current wait times for food allergen challenges are unacceptably long.

Suggested solution:

- **Federal government endorsement for introduction of a specific MBS item number for food allergen challenges.**

This issue is directly relevant to the following terms of reference:

- Access to and cost of services, including diagnosis, testing, management, treatment and support.
- The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis.

FURTHER INFORMATION

In July 2019 ASCIA submitted an application for a food allergen challenge MBS item number which included restrictions to ensure appropriate use and cost containment. This application was rejected on the basis that “cases of severe allergies should be assessed in public hospitals and current food allergen challenges for less severe allergies are currently appropriately renumerated under the MBS”. These explanations for rejection of our application are not valid for the following reasons:

- Whilst it is sometimes possible to stratify food allergen challenges into high or low risk on the basis of clinical history, specific IgE and/or skin testing, it is not possible to determine whether a patient has “severe” allergy or not without performing a food allergen challenge to determine this.
- It is currently unfeasible to perform food allergen challenges in private practice or in a private hospital clinic due to the absence of an MBS item number, without incurring significant costs for patients or treating specialists. Most food allergen challenges are therefore currently performed in public hospitals, resulting in extensive waiting lists and a significant burden on the public hospital system. This burden would be alleviated if clinical immunology/allergy specialists could perform food allergen challenges on appropriately selected patients, in private practice and private hospitals with the necessary facilities and expertise for managing anaphylaxis and allergic reactions.
- Improved access to food allergen challenges would allow for enhanced clinical management of Australians living with food allergy and would have flow on effects in terms of both standards of care and ongoing costs to the health system. For example, an enhanced ability to perform low-risk food challenges on infants who are found to be sensitised to food on skin tests or blood tests would allow for earlier introduction of these foods, which has been shown in large published studies to be an important strategy for preventing the development of food allergy. It is also very important to be able to de-label a patient when it is thought that they have outgrown a food allergy. This process almost always requires a food allergen challenge and allows the patient to improve their quality of life, liberalise their diet and removes the need for ongoing medications such as adrenaline autoinjectors.

ASCIA submission for MBS item number: www.allergy.org.au/about-ascia/ascia-initiatives#collab
ASCIA patient information: www.allergy.org.au/patients/food-allergy/food-allergy-challenges-faqs

Issue 6: A specific drug allergen challenge MBS item number is needed

The majority of people who believe they have drug allergy, most commonly antibiotic allergy, are actually not truly allergic to these drugs. Drug allergy assessment ("de-labelling"), which requires drug allergen challenges, has shown that 90% of patients with presumed and unverified drug allergy can tolerate the medication safely. Optimising medication use in our health system will lead to improved, safer and cost-effective care. This especially includes optimised use of antibiotics in our hospitals which contributes directly to the reduction of multi-resistant infections.

Suggested solution:

- **Federal government endorsement for ASCIA to apply for a specific MBS item number for drug allergen challenges.**

This issue is directly relevant to the following terms of reference:

- The impact of unnecessary drug avoidance due to unconfirmed drug allergies and its management, such as drug allergy 'de-labelling'.
- Access to and cost of services, including diagnosis, testing, management, treatment and support.

FURTHER INFORMATION

An allergic reaction to a drug is called 'immediate' when it occurs within one to six hours after taking a medication, or non-immediate when the reaction occurs after 24 hours of starting a medication.

- Symptoms of a mild or moderate allergic reaction to a drug can include itchy rashes (hives) and swelling (angioedema). Sometimes rashes due to infection are mistaken as a drug allergic reaction.
- Severe non-immediate rashes are associated with fever, flu-like and other systemic symptoms, and can be life-threatening. These severe cutaneous adverse reactions require urgent specialist care.
- Severe and immediate allergic reactions to drugs can affect breathing, the heart and blood pressure, and are called anaphylaxis. These reactions can be life threatening and require urgent medical attention. Anaphylaxis as a result of drug allergy is more likely when the drug is given by an injection, rather than if it is taken orally.

When drug allergy is uncertain, skin testing or a medically supervised test called a drug challenge can be conducted by clinical immunology/allergy specialists, usually in hospital clinics. It is important that these tests are available to allow:

- People with a true drug allergy to be diagnosed after specialist assessment and avoid the drug and carry or wear medical alert identification.
- Documentation of a diagnosed drug allergy in My Health Record, GP and hospital records.
- People who do not have a drug allergy to be 'de-labelled' so that they can take the drug in future. In the case of antibiotics this can lead to more appropriate treatment and considerable cost savings due to the use of less expensive options.

Aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) can cause reactions in some people. Symptoms include flushing, itchy rashes, blocked/runny nose, and sometimes severe asthma, usually within an hour of taking a tablet. Aspirin allergy is more common in people with nasal polyps and asthma. Other people may have an intolerance to all NSAIDs. Allergic reactions to antiseptics, latex and anaesthetic drugs given during operations are rare, but can be serious. Allergic reactions to chlorhexidine antiseptics are increasing in frequency and are possibly related to more common usage of products containing chlorhexidine.

ASCIA patient information: www.allergy.org.au/patients/drug-allergy

Issue 7: Improved access to evidence-based and cost-effective treatments is needed

Many established, evidence-based treatments for allergic disease are TGA-registered but are not listed on the PBS. Improving access to these treatments can improve the course of a person's disease and greatly improve quality of life. Many new treatments are emerging in this field and expert representation is needed for their evaluation.

In contrast, unscientific methods that are not evidence-based are at best ineffective and at worst can cause serious side effects, health issues and even fatalities as a result of misdiagnosis. These methods can lead to potential harm, additional healthcare encounters, increased costs and burden on the health system

Suggested solutions:

- **Federal government recommend a review of existing TGA-registered treatments for allergic disease to consider for inclusion on the PBS (subject to agreement by the supplier/sponsor to make a PBS application).**
- **Federal government recommend (to relevant authorities) that all products or services claiming to diagnose or treat allergies are subject to an independent evidence-based review.**

This issue is directly relevant to the following terms of reference:

- Access to and cost of services, including diagnosis, testing, management, treatment and support.
- Unscientific diagnosis and treatments being recommended and used by some consumers.
- The adequacy and consistency of professional education, training, management/treatment standards and patient record systems for allergy and anaphylaxis.

FURTHER INFORMATION

The following treatments for allergies and anaphylaxis are currently available on the Pharmaceutical Benefits Schedule (PBS) and it is important that these listings are retained:

- **Adrenaline (epinephrine) autoinjectors** for emergency treatment of anaphylaxis (two per patient).
- **Amino acid based or extensively hydrolysed Infant formula** for cow's milk allergy (CMA), which allows infants with confirmed CMA to gain important nutrients, whilst avoiding the milk proteins that cause allergies and anaphylaxis.
- **Venom immunotherapy** (also known as desensitisation) which prevents allergic reactions including anaphylaxis to bee or wasp stings. It involves regular injections of increasing doses of venom extracts, usually over a period of three to five years.

The following treatments for allergies and anaphylaxis are NOT currently available on the PBS:

- **Allergic rhinitis (hay fever) medications** include non-sedating antihistamines (tablets, syrups, nasal sprays, eye drops), intranasal corticosteroid (INCS) sprays, combined INCS and antihistamine sprays, salt water nasal sprays and rinses. Most of these are available over the counter (OTC) and are not on the PBS. Combined INCS and antihistamine sprays (which work in a similar way to asthma preventers) are only available on private prescription at a cost of around $50 each. The inequality of allergic rhinitis versus asthma medications (that are listed on the PBS) is an issue for patients with allergic rhinitis as preventer medications may not be used due to the costs.
- **Aeroallergen immunotherapy** to inhaled allergens (including pollen and dust mites) which reduces the severity of allergy symptoms and the need for medications. It involves regular administration of gradually increasing doses of allergen extracts, usually over a period of three to five years. It can be given as injections or as sublingual (under the tongue) tablets, sprays or drops. It is usually

recommended for severe allergies to stinging insects and allergic rhinitis when symptoms are severe.
- **New immunomodulation therapy (e.g. Dupilumab)** for severe atopic dermatitis (eczema), has also been developed as a result of recent research. This is expected to be available for routine use in the near future.

It is likely that suppliers of the following treatments will apply for PBS listing in the future:
- **Oral immunotherapy for food allergy**, which is currently the subject of research in Australia and is yet to enter routine clinical practice.
- **Other new immunotherapy methods for food allergies** (e.g. epicutaneous immunotherapy), which have been developed as a result of recent research.

Allergy is a science-based speciality, which relies on understanding the biological mechanisms that underly allergies and anaphylaxis. Accurate diagnosis requires a combination of allergy tests and clinical (medical) history, to check if allergy or another immune condition is the cause of symptoms.

Some people with allergies consult alternative practitioners for unproven diagnostic allergy testing or treatments, even though there have been great advances in scientific knowledge about allergic disorders. There are several methods that claim to test for allergy but are unproven. These include cytotoxic food testing, IgG4 food allergy testing, kinesiology, vega testing, electrodermal testing, pulse testing, reflexology and hair analysis. These tests have not been scientifically validated and may lead to unnecessary, costly and (in the case of some changes in diet) dangerous avoidance strategies. Furthermore, it often falls on suitably qualified allergy and immunology specialists to council patients who have received inaccurate diagnoses from these testing methods that in turn leads to an unnecessary waste of resources, increased waiting times to see specialists and increased medical costs to patients and the health care system. Use of these methods is therefore not recommended.

When considering tests and treatments, advice needs to be evidence based. There should be evidence that a test or treatment is reliable, based on published studies of other people with the same condition. Studies are designed to show if any improvement seen is due to the treatment, and not just due to chance or coincidence. Studies can also confirm if a treatment may cause harm as well as benefit.

There are currently limited regulations of unproven tests, treatments and devices, which can be listed by the TGA in Australia without having to prove that they work. Unsubstantiated claims to test, treat or cure allergy and other immune disorders are only regulated by government, medical boards or advertising regulators if the practitioner is a registered medical practitioner.

Many unscientific tests claim to detect “hidden” allergies due to many conditions that include headaches, migraine, irritable bowel, muscle tension, pain, addiction, premenstrual syndrome, fatigue or depression. These tests and “hidden” allergies have no scientific basis and have not been shown to be reliable or reproducible in studies. ASCIA strongly advises against the use of these tests for diagnosis or to guide medical treatment. Unlike skin testing or blood allergen specific IgE testing, no Medicare rebate is available in Australia for unproven tests.

It is also important to note that while complementary and alternative medicines (including herbal medicines) are often considered to be safe, allergic reactions can occur. Allergic reactions to herbal medicines are more common in people with other allergic conditions, such as asthma or allergic rhinitis.

ASCIA patient information:
www.allergy.org.au/patients/allergy-treatment
www.allergy.org.au/patients/allergy-testing/unorthodox-testing-and-treatment

Issue 8: Support is required for further research into all allergic diseases

There is an urgent need to improve understanding of the underlying pathology of allergic diseases, including further research into prevention, diagnosis and treatment of food allergy, drug allergy, eczema and allergic rhinoconjunctivitis. This will ultimately lead to improved diagnostics and treatments.

Suggested solutions:

- **Federal Government funding support dedicated to allergic diseases via the Medical Research Future Fund (MRFF) and NHMRC Targeted Call for Research.**
- **Federal Government matched funding for annual AIFA (Allergy and Immunology Foundation of Australasia) grants for allergy and immunology research.**

This issue is directly relevant to the following terms of reference:

- Developments in research into allergy and anaphylaxis including prevention, causes, treatment and emerging treatments (such as oral immunotherapy).
- The potential and known causes, prevalence, impacts and costs of anaphylaxis in Australia.

FURTHER INFORMATION

Allergic diseases are amongst the fastest growing chronic and complex health conditions affecting children and adults in Australia. As there are currently no cures for allergic diseases, funding of research is needed to:

- Understand why allergic diseases are increasing so rapidly.
- Prevent allergy from developing in children.
- Improve diagnosis of allergic diseases.
- Develop new treatments and cures for allergic diseases.

It is important that clinicians work closely with researchers to translate discoveries into prevention strategies, new diagnostics and better treatments, that can:

- **Save lives** - research has the potential to eliminate preventable deaths and disabilities due to severe allergic reactions (anaphylaxis).
- **Improve patients' wellbeing and quality of life** - research has the potential to improve health outcomes due to allergic diseases that cause significant and chronic impairment in day-to-day functioning.

The Allergy and Immunology Foundation of Australasia (AIFA) was established by ASCIA in 2013, specifically to fund allergy and immunology research.

Projects funded by AIFA grants are listed on the AIFA website:
www.allergyimmunology.org.au/projects

Issue 9: Support is required for further research into food allergy treatments including food oral immunotherapy

There are many potential treatments for food allergy that are currently for research only in Australia, including oral immunotherapy (OIT) for food allergy. The role of OIT as a potential management tool for people with food allergy is currently unclear. In its current form OIT does not provide a cure for most people and there are significant side effects, including risk of recurrent anaphylaxis. Therefore, further assessment of safety, patient selection and appropriate use in Australia is required.

Suggested solution:

- **Federal government funding support for further quality, peer reviewed, multicentre (across all states) clinical research into optimal food allergy treatments in Australia. This includes various approaches such as OIT.**

This issue is directly relevant to the following terms of reference:

- Developments in research into allergy and anaphylaxis including prevention, causes, treatment and emerging treatments (such as oral immunotherapy).
- The potential and known causes, prevalence, impacts and costs of anaphylaxis in Australia.

FURTHER INFORMATION

Oral immunotherapy (OIT) for food allergy involves giving gradually increasing amounts of food allergen under medical supervision and continued daily consumption of the food allergen at home.

If the goal of desensitisation or sustained unresponsiveness is reached, there is an increase in the amount of food allergen that can be consumed before an allergic reaction occurs.

At present OIT is only available in Australia in clinical research settings. However, the field is expanding rapidly and overseas it is offered in some centres as part of clinical care of food allergy patients, with many Australian families choosing to relocate overseas to access OIT.

It is therefore very important that Australian clinical immunology/allergy specialists are able to perform further quality, peer reviewed, multicentre (across all states) clinical research into optimal food allergy treatments in Australia, including OIT.

It is important that OIT is performed safely and responsibly, including patients undergoing a food allergen challenge prior to commencing OIT, as this is integral to patient selection. At present it would not be possible to meet the demand for OIT in Australia due to the absence of an MBS item number for food allergen challenges.

ASCIA patient information:
www.allergy.org.au/patients/allergy-treatment/oral-immunotherapy-for-food-allergy

Issue 10: National anaphylaxis and drug allergy registers do not exist

The incidence of many allergic diseases in Australia, including anaphylaxis and confirmed severe drug allergy is currently not known. There are no national mechanisms to alert consumers of potentially lethal allergen contamination in foods in a timely manner. Models for drug allergy registries exist globally.

Suggested solution:

- **Federal government funding support for a national anaphylaxis and confirmed severe drug allergy register.**

This issue is directly relevant to the following terms of reference:

- The potential and known causes, prevalence, impacts and costs of anaphylaxis in Australia.
- The impact of unnecessary drug avoidance due to unconfirmed drug allergies and its management, such as drug allergy 'de-labelling'.

FURTHER INFORMATION

Registers are opportunities to optimise and enhance service delivery. ASCIA has been involved in the development of two registries and has identified the following areas of concern:

- Funding challenges – A sustainable funding model is required, but many registers in the past have relied on funding from industry, including pharmaceutical companies. Independent funding (e.g. government) would be the preferred option.
- IT issues - Support for establishment and maintenance of registers is important, with systems that are flexible to allow changes in diagnosis and treatment which evolve over time.
- Ethics - Ethical issues related to the establishment and maintenance of registers have in the past been substantial barriers to the development of registers. These include a lengthy process of approval especially when multiple sites are involved. Ethics cover is generally time limited and expiry of cover and the processes associate with regular renewals are considered a disincentive to the development and maintenance of registers.

There is currently no structured reporting system for anaphylaxis and drug allergy in Australia, except for the anaphylaxis notification system recently established in Victoria. This was an outcome of a coronial inquiry, which has also recommended the development of a national anaphylaxis register.

Development of anaphylaxis notification systems and a national anaphylaxis register has been considered as part of the National Allergy Strategy. It is acknowledged that this is a major task and there may be significant challenges to progressing this initiative.

Once established, an anaphylaxis notification system and register would enable:

- Collection of de-identified data.
- Timely removal of unsafe foods from the marketplace.
- A better understanding of gaps in knowledge and learn how to prevent, treat and educate people on the management of allergies and the risk of anaphylaxis.

This submission was developed by ASCIA, the peak professional body of clinical immunology and allergy specialists in Australia and New Zealand.
24 October 2019