

Plain Language Statement

Melbourne Dental School



Project: Dental PEARLS: Dental Penicillin Allergy Referral Study

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What is this research about?

Around 10% of the Australian population have a reported penicillin allergy, but of the 10%, only 1% will be correct; the other 9% is in error. This is either because the person had a side effect (e.g. nausea), or the allergy has worn off; 50% of allergies wear off after 5 years. Most rashes reported in association with a penicillin antibiotic during childhood are also not true allergies.

In dentistry, patients who report a penicillin allergy and need an antibiotic, will be prescribed clindamycin. Clindamycin has a much higher side effect profile and is more toxic than amoxicillin. While dentists are encouraged to appropriately screen and refer patients for penicillin allergy testing, there is no direct pathway for dentists to do so.

The aim of this study is to determine the proportion of patients with a low-risk of penicillin allergy assessed by dentists and the proportion of patients that can have their penicillin allergy label removed by referrals from dentists. The aim is also to assess this method for dentists to appropriately screen and refer patients for penicillin allergy de-labelling as there is no current method for dentist to do this.

What will I be asked to do?

You will be provided a link to a Qualtrics screening tool through an email from the eviDent Foundation. This tool will help you screen which patients are eligible to be referred to the Austin Health for penicillin allergy testing.

While the wait list for penicillin allergy testing is usually around 2 years, for this study, these patients will be fast-tracked to the low-risk clinic that operates on a Friday morning, where they will only need to wait around 4 weeks for an appointment.

Screening eligible patients will only take around 1-2 minutes.

Eligible adult patients (>18 years) are those who:

1. Report a penicillin allergy

AND

2. Have a PEN-FAST score of 0-2 (determining a PEN-FAST score will take around 1 minute)

AND

3. Have a specified condition/requirement listed (including: requires antibiotic prophylaxis, immunosuppressed, diabetes, previous gastrointestinal surgery, age>65 years, splenectomy and prior C. difficile infection)

If your patient is eligible, you will be directed to fill out a form to email directly to the Austin Hospital Centre for Antibiotic Allergy and Research, to refer your patient for penicillin allergy testing. You will be informed of the results by email.

What is involved for your patient with penicillin allergy testing at Austin Hospital?

Your patient will be informed of the penicillin allergy testing process and consent will be obtained. The patient will then be asked to swallow a capsule of a small amount of penicillin and watched closely for 2

hours by a nurse. If they do not have any reaction, they will be deemed not allergic to penicillin. For more information, please click [this link](#).

What are the possible benefits?

It is anticipated that around 90% or more of the patients referred for allergy testing by dentists will show the patient is actually not allergic to penicillin, and their penicillin allergy label removed. This will support future promotion of direct referrals by dentists to penicillin allergy centres to assess if a patient's antibiotic allergy is true. It will also enable safer and more appropriate antibiotic use for these patients.

What are the possible risks?

There are no anticipated risks to participants. Patients will be fully informed of the process of penicillin allergy testing as per standard protocol at the Austin Hospital Centre for Antibiotic Allergy and Research and consent by the patient obtained then. Please click [this link](#) for more information and risks about penicillin allergy testing.

Do I have to take part?

No. Participation is completely voluntary. If you refer a patient and the patient consents, you cannot withdraw your patient from the testing process. However, penicillin allergy testing will not occur if your patient does not consent to the testing process.

What will happen to information about me?

The data collected will be stored on the University of Melbourne One Drive account, accessible to only the named researchers. Data collected by Austin Health following referral will be retained and analysed by Austin Health staff. The retention and destruction of the records will occur 5 years after the study completion in line with the University of Melbourne Records and Disposal Authority Requirements. At Austin Health, you will be named as the referring practitioner for your patient.

Is there any potential conflict of interest?

There is no potential conflict of interest.

Who is funding this project?

This project was supported by the eviDent foundation and funded by the Special Purpose Fund (SPF) Austin Health/UoM Investigator A/Prof Jason Trubiano. Project coordination, data collection and statistical analysis provided in kind by Austin Health Investigators.

Where can I get further information?

If you would like more information about the project, please contact the researchers: Dr Leanne Teoh, Associate Professor Jason Trubiano or Professor Michael McCullough.

Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. Data collected for testing performed at Austin Health already has site specific ethics approval for the PIPA study - HREC/15/AUSTIN/74. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au.

All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project. (24464)