Information Statement, Version 8a; 08/12/2005:

Australian **S**tudy for the **P**revention through **I**mmunisation of **C**ardiovascular **E**vents

Thank you for your interest in AUSPICE!

You're invited to participate in this new study, which aims to reduce the risk of heart attacks and stroke.

Before we start…

The **pneumococcal vaccine is not the same as the influenza vaccine**. Most adults will be given the pneumococcal vaccine only once or twice, whereas the influenza vaccine may be given every year.

Why is the research being done?

Animal and human studies suggest that the pneumococcal vaccine may protect against, or even reverse, a build-up of fatty material inside your arteries. This fatty material can lead to heart attack and stroke. We aim to conduct the first randomised controlled trial in the world to determine whether pneumococcal vaccine reduces the risk of heart attack and stroke.

Who can participate in the research?

AUSPICE aims to recruit 6000 men and women aged 55-60 years from around Australia. We are seeking those who are at risk of, but have not had, a heart attack or stroke.

To be eligible you must not:

1. have previously received the adult pneumococcal vaccination (Pneumovax 23); or
2. be at higher risk of pneumococcal disease, where it is recommended that you are vaccinated earlier than 65 years (standard practice), defined by The Australian Immunisation Handbook, 10th edition, www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/handbook10-4-13

Our research team will ask you some questions to determine if you are eligible to participate, or should seek the pneumococcal vaccination through your GP.

What choice do you have?

Participation in this research is entirely your choice. Only people who give their informed consent will be included in this study. Your decision will not disadvantage you, whether or not you decide to participate. If you do participate, you may withdraw at any time without giving a reason. You will also have the option of withdrawing your data. Please notify a member of the research team before you withdraw, so we can tell you which injection you received and discuss what happens to your data.

What would you be asked to do?

Half of the participants will be given the pneumococcal vaccine (an existing vaccine originally developed for pneumococcal pneumonia) and the other half will be given a placebo vaccine (saline). An Authorised Nurse Immuniser will give the injection. Participants will not be told which group they are in. Data from linked health-related records will be used to track cardiovascular and other health events during the 4-5 years after the immunisation is given. Therefore, this trial will only require participants to attend one clinic visit, with a telephone follow-up after the immunisation. Participants will be told whether they were given the active vaccine or saline at the conclusion of the study. At the clinic visit we will collect:

- Height, weight, waist circumference and blood pressure measurements;
- Basic medical history, including recent vaccinations and medications;

- Education, marital status and other participant characteristics.

Access to health records
With your consent, we will apply for access to your state-based and national health records for linkage with each other and with the data we collect. The datasets that will be accessed include hospital, cancer, death, pneumococcal and influenza notifications, and the Department of Human Services records. If you consent, the Department of Human Services will release information about the services provided to you under Medicare, the Department of Veterans' Affairs, the Pharmaceutical Benefits Scheme, and the Repatriation Pharmaceutical Benefits Scheme, including past information, until the end of the study or for the duration of your involvement. The research team may apply to access to your health records that pre-date the start date of this study by up to 10 years, and continue for 10 years following your clinic visit. We are requesting access to all of your health records so that we can fully evaluate the effectiveness of our trial and, if you agree, may use your data for other ethically approved studies in the future.

How much time will it take?
The clinic visit and follow-up phone call should not take more than one hour in total.

What are the risks of participating?
The pneumococcal vaccine is safe and effective for preventing pneumococcal disease and has been used in Australia for more than 30 years. Common side effects from vaccination include pain, redness, swelling, and a small lump at the site of the injection. A low-grade temperature may also occur. Side effects are usually mild and pass within a few days. A very rare but severe side effect of vaccination is an allergic reaction. The research team will be prepared in the unlikely event that this occurs.

What are the benefits of participating?
The pneumococcal vaccination will be provided at no cost to you. The group given saline will be educated about getting vaccinated when they turn 65, at the conclusion of the trial. It is possible that some participants will get cardiovascular benefits from participating in this study. However, we will not know if this is the case until the conclusion of the trial.

How will your privacy be protected?
Study participants will be assigned a unique identifier and identifying information will be stored separate to the research data, in a password-protected computer file. All information will be stored securely and only accessed by the research team, except as required by law. Data will be retained for a minimum of 20 years at the University of Newcastle.

Use of your data in future research studies
The attached Consent Form includes the additional option of providing "unspecified" consent for the storage and use of your information for future studies about the patterns, causes, and effects of health and disease conditions. These future studies will not be undertaken without approval from a properly constituted Human Research Ethics Committee. In any future studies, your data will be used in such a way that you cannot be identified. However, this means you will not receive any individual results from future studies. Participation in these future studies is entirely voluntary and will not affect your ability to participate in the current study.

How will your information be used?
Reports, scientific publications and presentations from the study will be based on de-identified information and will not personally identify any individual who has taken part.

What do you need to do to participate?
If we have not heard from you within 3 days of receiving this Information Statement a member of our research team will get in touch to find out if you would like:

- more time to consider the study;
- any further information;
- to participate in the study; or,
- to receive no further contact from the research team.

If you agree to participate, please complete the attached Consent Form and a member of the research team will book you in for a clinic visit at a time that is convenient to you. Your signed consent form will be collected or reissued at the clinic visit. Please ensure you have read, understood, and kept a copy of this Information Statement.

Further information
It is possible that some individuals in this trial will develop a medical condition that puts them at higher risk of pneumococcal disease and their GP may recommend Pneumovax 23. If this happens to you, please contact our research team so that we can let you know whether you have already been given Pneumovax 23, and therefore may not need to have it again.

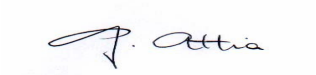
For further information **please contact** Josette Wood Project Manager 1300 725 272 or the Chief Investigator of AUSPICE, Professor John Attia.

AUSPICE
Australian Study for the Prevention through Immunisation of Cardiovascular Events

The Research Team

AUSPICE Chief Investigator and Site Lead, Newcastle

Professor John Attia, Epidemiologist and General Medicine Physician



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University of Newcastle

- Associate Professor Jonathan Sturm, Neurologist (Site Lead, Central Coast)
- Professor Chris Levi, Neurologist
- Professor David Durrheim, Public Health Physician
- Professor Phil Hansbro, Immunologist
- Associate Professor David Newby, Clinical Pharmacist
- Dr Mark McEvoy, Epidemiologist
- Dr Alexis Hure, Dietitian
- Ms Roseanne Peel, Registered Nurse and Authorised Immuniser

Australian National University

- Professor Walter Abhayaratna, Cardiologist (Site Lead, Canberra)
- Professor Cate'D'Este, Biostatistician

Monash University

- Professor Andrew Tonkin, Cardiologist (Co-Site Lead Melbourne)
- Dr Ingrid Hopper, Medical physician
- Professor Mandy Thrift, Epidemiologist

Flinders University

- Professor Derek Chew, Cardiologist (Site Lead Adelaide)

University of Western Australia

- Professor Joseph Hung, Cardiologist (Site Lead Perth)
- Associate Professor Tom Briffa, Epidemiologist

Australian Institute of Health and Welfare

- Dr Phil Anderson, Data linkage experts
- Dr Lynelle Moon, Data linkage experts

Complaints about this research

This study has been approved by the Hunter New England Human Research Ethics Committee reference number 15/08/19/3.01.If you have concerns or complaints about the conduct of this study you should contact:

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The Manager is the person nominated to receive complaints from research participants. You will need to quote reference number 15/08/19/3.01.