

ASAVI | Urban Strep A Surveillance Study

Introduction to ASAVI

The Australian Strep A Vaccine Initiative (ASAVI) is an Australian-led global initiative with the goal of reducing the disease burden caused by Strep A infections through effective vaccination. Funded by the Australian Federal Government's Medical Research Future Fund (MRFF), ASAVI is a partnership between Murdoch Children's Research Institute (MCRI) and Telethon Kids Institute, led by Co-Directors Jonathan Carapetis and Andrew Steer.

ASAVI has taken a leading role in the global effort to develop a Strep A vaccine and is working closely with public health organisations, industry and academic partners, to accelerate the development of a Strep A vaccine. The project is being undertaken in several phases.

The overall **ASAVI objectives** are:

1. To commence a Phase 2b pharyngitis efficacy study of a lead candidate vaccine in Australia by 2024
2. To identify and establish global partnerships that will facilitate licensure of a vaccine
3. To develop an Indigenous consultation plan to enable vaccine studies to be conducted in remote communities
4. To position Australia as an international leader in *Strep A* vaccine clinical development and, if possible, attract benefits to Australia such as early introduction of a vaccine and preferential pricing.

ASAVI Strep A surveillance – current phase

ASAVI's primary objective is to demonstrate safety and efficacy of a lead vaccine candidate against pharyngitis in children living in the urban setting. It is critical that we develop accurate and robust surveillance for pharyngitis, Strep A carriage, and circulating strain serotypes to establish the baseline epidemiology of Strep A pharyngeal infection as a first step toward advancing a vaccine clinical trial.

Aims of the surveillance study

The **primary aim** of the surveillance study is **to determine the incidence rates of sore throat**, Strep A positive sore throat and serologically proven Strep A sore throat in urban children.

The secondary aims are to:

- Determine prevalence of asymptomatic throat carriage of Strep A in urban children.
- Investigate the natural immune response to Strep A pharyngitis in urban children.
- Identify circulating Strep A strains and investigate the characteristics of Strep A DNA (bacterial genetic variation) among these strains.
- Evaluate the use of POC testing for diagnosis of Strep A pharyngitis in primary care.
- Explore the non-clinical/economic impact of paediatric sore throat and respiratory illness on children and families.
- Determine the prevalence of skin sores in urban living children.

Target population

The surveillance study will run concurrently in two urban centres (Perth and Melbourne).

- We aim to recruit 525 children in both Perth and Melbourne (**1050 children** total).
- The target group for this surveillance study are healthy children **aged 3 to 14 years**.
- Exclusion criteria are immune compromise, current serious medical condition and inability to tolerate a throat swab.

Role of the GP practice

GPs who take part in the study will be asked to:

- Identify and invite families who attend their practice with at least one child aged between 3-14 years. Recruitment materials will be provided by the research team.
- Complete a "GP trigger visit" should a participant experience any signs or symptoms of a sore throat. This involves:
 - Collection of some clinical information about the child's episode of sore throat via an electronic data collection form.
 - Use of the Point of Care (POC) testing machines (please see below for more information) to diagnose the child's sore throat.
 - Collection of some biospecimens (throat swabs and blood samples) from the child as required.

Practice nurses are also invited to be actively involved in these activities.

Benefits of taking part

The Sore Throat study is being conducted in partnership with general practices and research-interested GPs will be given:

- The opportunity to join as Associate Investigators.
- Remuneration for Practices and GPs.
- Access to a point of care testing device.
- High levels of support from the research team.

Point of Care Tests

This study will be providing GPs with a POC testing device, which will also play a major role in the Sore Throat Study. The device works by using one of the throat swabs collected from a participant, rubbing the end against a strip, and inserting the strip into a machine to run the test. The participant's result will be available at their GP appointment and will help guide the GP to prescribe the best treatment for the management of the participant's sore throat.

In this study, we will be using the Abbott ID NOW™ STREP A2 POC device. This device detects a gene highly specific for Strep A. Positive results are detected in approximately 2 minutes and negative results in 6 minutes.

More information and sign up

If you have any questions or would like to schedule a visit with the ASAVI study team to become a participating practice, please contact us at ASAVI-project@unimelb.edu.au.