



Government of **Western Australia**  
Department of **Health**

# Department of Health Western Australia Human Research Ethics Committee

**Project Summaries for Approved Proposals**

January to March 2023 Quarter

## Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – January to March 2023 quarter.

The material contained in this document is made available to assist researchers, institutions and the general public in searching for projects that have ethics approval from the Department of Health Human Research Ethics Committee (DoH HREC). It contains lay descriptions/summaries of projects approved in the January to March 2023 quarter.

Under the WA Health mandatory Research Governance Policy, the DoH HREC, must review all research projects that require the use and disclosure of personal health information from the DoH Data Collections, including data linkage. DoH HREC approval cannot occur until access to DoH data collection is approved by the data collections' Data Steward or their delegate.

The lay descriptions/summaries outlined below have been provided by the respective Principal Investigator and are shared with their consent.

<b>Project Title</b>	Risk of myocarditis attributable to SARS-CoV-2 vaccination and SARS-CoV-2 infection in the cohort of vaccinated persons in Western Australia.
<b>Coordinating Principal Investigator</b>	Paul Effler
<b>Institution</b>	Department of Health
<b>Ethics Approval Date</b>	Tuesday, 21 February 2023

### Background

To mitigate the impact of the SARS-CoV-2 pandemic, many countries, including Australia, rapidly implemented large-scale, immunisation programs using novel SARS-CoV-2 vaccines. In Western Australia (WA), administration of SARS-CoV-2 vaccines began in February 2021 and as of 6 October 2022 nearly 7 million doses have been administered statewide. While SARS-CoV-2 vaccines have been shown to prevent severe illness and death, there is growing recognition of the potential for severe vaccine adverse events following vaccination, including potentially life-threatening myocarditis (inflammation of the heart muscles). Studies in other countries have attempted to estimate the risk of myocarditis following SARS-CoV-2 vaccination, compared to that following SARS-CoV-2 infection, to inform risk-benefit considerations. However, there are conflicting results across different study populations, potentially due to differences in locally circulating SARS-CoV-2 variants, the background of pre-existing immunity in the community, and/or the cohorts studied. There was very little autochthonous transmission of SARS-CoV-2 in WA (and therefore background immunity due to natural infection) prior to 1 February 2022, when the state experienced a large pandemic wave exclusively caused by the Omicron variant of concern. The aim of this study is to accurately estimate the risk of acute myocarditis following SARS-CoV-2 vaccination or SARS-CoV-2 infection in WA's unique pandemic landscape.

### Methods

Study subjects: This study will involve all WA residents aged five and over who received at least one dose of any SARS-CoV-2 vaccine and/or tested positive for SARS-CoV-2 between 1 February 2021 and 31 August 2022.

Data source: We will use pre-existing, de-identified data in the WA Department of Health SARS-CoV-2 Vaccination Linked Data Repository (CVLDR). The CVLDR contains statewide data on

SARS-CoV-2 vaccination, SARS-CoV-2 testing, SARS-CoV-2 diagnoses, hospitalisations, emergency department visits and deaths.

Study variables:

Exposure variables: The exposures of interest are: 1) receipt of at least one dose of SARS-CoV-2 vaccine or 2) a positive test for SARS-CoV-2. Covariates included in the analysis will be age, sex, and a history of prior hospitalisation due to specific conditions such as myocarditis or other cardiovascular disease.

Outcome variables: The key outcomes of interest are 1) an emergency department visit or hospital admission to myocarditis, or 2) death from any cause within 28-days following receipt of any dose of SARS-CoV-2 vaccine or a first positive test for SARS-CoV-2 occurring between 1 February 2022 and 31 August 2022. Myocarditis has been defined based on a set of International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) codes.

Study design: We will use two different study designs and compare the results. The first will be a Self-Controlled Case Series (SCCS) in which a vaccinated individual's risk of developing myocarditis within 28 days after each vaccination dose or a SARS-CoV-2 infection (whichever occurs first) will be compared to the same individual's baseline period (a six-month period prior to any vaccinations or SARS-CoV-2 infection). The outcome will be the averaged Incidence Rate Ratio (IRR) between the two time periods for all those diagnosed with myocarditis after vaccination or infection.

The second study design will be a retrospective Cohort. The Cohort study will be used to determine population-based incidence of myocarditis among all persons who received at least one SARS-CoV-2 vaccine dose by 31 August 2022. Study Participants will be digitally followed from 1 February 2021 until an incident diagnosis of myocarditis or the end of the follow-up period, 31 August 2022.

Data analysis: We will apply Poisson regression to determine incidence rate ratios (IRRs) with 95% Confidence intervals (CIs). We will conduct sub-analyses by age group, gender and vaccine dose number.

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