23 November 2023



Mark Shelly fyi-request-24335-d6525d53@requests.fyi.org.nz

Tēnā koe Mark

Your Official Information Act request, ref: HNZ00031226

Thank you for your email which was transferred to Te Whatu Ora on 26 October 2023, asking for the following which has been considered under the Official Information Act 1982 (the Act).

On 1 November 2023, Te Whatu Ora contacted you to clarify your request, to ensure we were able to provide a response that best met your needs. Unfortunately, Te Whatu Ora has not received a response from you, therefore, we are providing information that is readily available and may not cover the entire scope of your request.

For the sake of clarity, I will address each question in turn.

Regarding covid-19 vaccine independent safety monitoring board media release of 20 Dec 2021. https://www.health.govt.nz/news-media/media-releases/statement-covid-19-vaccine-independent-safety-monitoring-board. Please provide evidence supporting the claim that: COVID-19 infection increases the risk of myocarditis substantially more than vaccination with the Pfizer vaccine. The statement refers to an Israeli study. Please advise if it is this study: <a href="https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nejm.org/%2Fdoi%2Ffull%2F10.1056%2FNEJMoa2110737&data=05%7C01%7Coiagr%40health.go/vt.nz%7Cdaffc45fb40c4c85f4d808dbc45c45a1%7C23cec7246d204bd19fe9dc4447edd1fa/%7C0%7C0%7C638319672804401247%7CUnknown%7CTWFpbGZsb3d8eyJWljoiMC4wLjAwMDAiLCJQljoiV2luMzliLCJBTil6lk1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C/&sdata=ZGBaAaJsUklLTAHa4xkQz9eaXbL0fFnPRQEoyhxmRDc%3D&reserved=0. If it is not this study, please advise what study the statement refers to.

Te Whatu Ora cannot find the mention of any study in the media release, nor can we find any mention of an Israeli study in any of the released ISMB minutes, interim report, or final report. The only study mentioned in the media release page is the SAFE study, from Auckland University. The SAFE study helps to provide background rates for Adverse Events of Special Interest (AESIs).

The above study found that for males aged between 16 and 29 the incidence of myocarditis following receipt of a Comirnaty injection exceeded 1 in 10,000. "The highest incidence (10.69 cases per 100,000 persons; 95% CI, 6.93 to 14.46) was observed among male patients between the ages of 16 and 29 years. "The statement claims that the risk of myocarditis from COVID-19 infection is much greater than from COVID-19 vaccination.

Studies have found that the risk of myocarditis following SARS-CoV-2 infection is substantially greater than after COVID-19 mRNA vaccination. The published study, Adverse Events Following the BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech) in Aotearoa New Zealand, https://pubmed.ncbi.nlm.nih.gov/37556109/, see references 8, 12 and 37.

The Ministry of Health and Te Whatu Ora - Health New Zealand have continuously monitored local and international evidence regarding COVID-19 vaccines and their safety and efficacy. The Centre for Adverse Reaction Monitoring (CARM) collects voluntary reports of adverse reactions to medicines, vaccines, and other health products. Medsafe and Te Whatu Ora utilise the reports received by CARM, a variety of statistical tools, international literature, and communications with

other regulators and the respective manufacturers to evaluate potential safety concerns for the COVID-19 vaccines.

All reports of adverse reactions following COVID-19 vaccination are available here: <u>COVID-19</u> Overview of Vaccine Reports (medsafe.govt.nz).

Please advise what rate of myocarditis the ministry attributes as resulting from a COVID-19 infection in this cohort (males 16 to 29) and what source it uses to substantiate this claim.

Unfortunately, this part of your request is refused under section 18(e) of the Act as the information does not exist, and Te Whatu Ora is not required to create new information.

Please provide evidence that vaccination (1) protects individuals from contracting COVID-19 and (2) reduces the rate of the occurrence myocarditis if infected (include the rate of reduction of infection that vaccination results in and how this has been established). It would be particularly helpful if this evidence was stratified by age and sex (eg, in males aged 16 - 29 it has been shown that for every 1,000 vaccine doses administered 999 individuals have been protected against infection).

Manatū Hauora, Medsafe and relevant agencies consider a range of information when deciding on whether to introduce a new vaccine, and do not rely on a single source or assessment to confirm a vaccine's effectiveness (VE). Additionally, please note that vaccine effectiveness varies depending on the type of COVID-19 variant and type of outcome we are monitoring.

This includes considering national and international studies, data, and research about the COVID-19 Pfizer vaccine, as well as detailed information from the manufacturer which must be supplied as part of the application process. The COVID-19 vaccine has been thoroughly assessed for safety by our own Medsafe experts. Medsafe only grants consent for using a vaccine in New Zealand, once they're satisfied it has met strict standards for safety, efficacy and quality.

The COVID-19 Vaccine Technical Advisory Group (CV TAG) has made evidence-based recommendations to Manatū Hauora (The Ministry of Health) surrounding the use of COVID-19 vaccines as a tool to reduce the burden of disease. These recommendations are publicly available on Manatū Hauora website here: www.health.govt.nz/about-ministry/leadership-ministry/expert-groups/covid-19-vaccine-technical-advisory-group-cv-tag.

Information on vaccine effectiveness against specific variants is publicly available at: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-response-planning/covid-19-science-news. This includes information about vaccine effectiveness against infection, transmission, hospitalisation, death, and reinfection.

Information on how vaccines provided substantial protection against death can be found here: www.health.govt.nz/publication/covid-19-mortality-aotearoa-new-zealand-inequities-risk.

Report:

https://www.health.govt.nz/news-media/media-releases/statement-covid-19-vaccine-independent-safety-monitoring-board

Claim

There are many possible causes of myocarditis, the most common being viral infection; an average of 95 people (SAFE study) are discharged from hospital with a principal diagnosis of myocarditis in New Zealand every year.

Please provide a copy of the report referred to above.

Please provide updated statistics (ie number of people discharged from hospital with a principal diagnosis of myocarditis in NZ every year subsequent to dates used in this study. Please stratify by age and sex if possible.

In response to your request, please find **Appendix One** identified as in scope of your request attached.

This document details the acute myocarditis publicly funded hospital discharges from July 2014 – June 2023.

Please note the following when reviewing this data:

- "Myocarditis" is being interpreted as *Acute myocarditis* (ICD-10 code I40). This may not be the same definition used in the report being referenced.
- Data from 2021/22 onwards is provisional and has not undergone full quality assurance.
- People hospitalised multiple times (transfers, readmissions, multiple incidents) are counted each time.

How to get in touch

If you have any questions, you can contact us at hnzOIA@health.govt.nz.

If you are not happy with this response, you have the right to make a complaint to the Ombudsman. Information about how to do this is available at www.ombudsman.parliament.nz or by phoning 0800 802 602.

As this information may be of interest to other members of the public, Te Whatu Ora may proactively release a copy of this response on our website. All requester data, including your name and contact details, will be removed prior to release.

Nāku iti noa, nā

Michael Cleary

Acting OIA Manager Government Services