

“2. Please provide the information that has shown the Pfizer COVID-19 vaccine Comirnaty to be safe in the 12 year to 16 year old age group that has been used in the decision making to allow 12 to 16 year olds to get it.”

Pfizer submitted clinical trial data with the application to change the indication of the Pfizer vaccine to cover 12- to 16-year-olds. This information is withheld under section 9(2)(b)(ii) of the Act, where its release would likely unreasonably prejudice the commercial position of the person who supplied the information. However, the safety, immunogenicity, and efficacy of the BNT162b2 Covid-19 Vaccine in adolescents for Comirnaty is publicly available at: www.nejm.org/doi/full/10.1056/NEJMoa2107456.

“3. Please provide the information that provided evidence to award the decision of the face covering mandate and shows its safety and effectiveness against contraction and transmission of a virus.”

The Ministry does not conduct scientific research or studies. Please refer to online scientific studies for further information: <https://pubmed.ncbi.nlm.nih.gov/>.

The Ministry constantly reviews international studies and evidence on mask wearing in the community setting. Our current advice aligns with that of the World Health Organization (WHO): [https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak).

As part of reviewing international evidence, the Ministry considers other advice from international organisations including Centres for Disease Control and Prevention, Public Health England, the European Centre for Disease Control and Prevention, Australian jurisdictions and a range of scientific and medical journals.

The information is collated through Ministry specialist technical advisory groups whose membership include a variety of expert professions such as infection prevention and control, public health, infectious diseases, microbiology and primary care. When reviewing evidence, we ensure it is applicable to the current New Zealand situation and can be applied in our context.

Please refer to the below previously released responses regarding face coverings:

- www.health.govt.nz/system/files/documents/information-release/h202006250_20_oct_2020.pdf.
- www.health.govt.nz/system/files/documents/information-release/h202008732_15_dec_2020_0.pdf.

Maintaining the requirement for face coverings provides wider benefits that support the overall response to the pandemic. Face coverings are a constant reminder of the ongoing threat posed by COVID-19 and will help prompt people to be more vigilant about other important behaviours, such as physical distancing, scanning using the New Zealand COVID Tracer App, hand hygiene and coughing and sneezing etiquette. Familiarity with using face coverings also supports community preparedness and may help to limit transmission of COVID-19 in the event of any subsequent community outbreak where transmission may have been undetected for a time.

You may wish to request information from the Department of the Prime Minister and Cabinet directly as they may hold information relating to this part of your request.

On 19 September 2021 you requested further information relating to PCR COVID-19 tests. Please find a response to each part of your request below. You asked:

“1. Please provide the evidence that the PCR test for COVID-19 is effective at detecting SARs-COV-2.”

Evidence contributing to the Ministry’s confidence in the efficacy of COVID-19 tests used includes:

- robust validation of the tests used, both internationally and within New Zealand;
- participation of the laboratories in both internal and external quality assurance programmes, with acceptable performance, as required by the laboratory accreditation standard;
- the additional validation of positive results provided by whole genome sequencing.

COVID-19 virus delta variant genetic material has been found in PCR testing of samples, which confirms the presence of the virus in the community.

“2. At what cycle threshold (ct) value do false positives begin to occur? Please provide the percentage of false positives including the mentioned ct value and each ct value thereafter that is used here in New Zealand.”

The Ministry does not hold data for the reporting of false positive results. All COVID-19 testing of people done as part of the public health response in in New Zealand is undertaken in laboratories that are accredited to international laboratory standards (ISO 15189) by International Accreditation New Zealand. The requirements of accreditation mean there are documented quality assurance and result validation processes which must be followed for every test performed.

To ensure that any incidences of false positives are identified and corrected, all positive results are quality assured by the laboratory where the sample is tested by using a different method or a different gene target. Subsequently, all positive results are confirmed once more when Whole Genome Sequencing is completed for every positive sample.

No laboratory test provides 100 percent certainty of the result. The viral test for COVID-19 is not 100 per cent sensitive or able to correctly identify individuals with the disease every time. This is the reason individuals are tested more than once, for example, in managed isolation facilities.

While false positives may have occurred in New Zealand, as in other countries, it is believed to have occurred only a handful of times. If a false positive result has been released and actioned, the patient is informed as soon as possible of the error. The Ministry does not hold data about how many times a false positive has been actioned, for example, through quarantining.

“3. When testing for COVID-19 will it pick up other variants of COVID-19, other coronavirus’s and other bacterial infections?”

The PCR Test used in New Zealand can, for example, differentiate between SARS-CoV-2 and influenza. Presumably this question has been prompted by misinformation about the CDC decision to withdraw the FDA Emergency Use Authorisation for a PCR test it developed early in the pandemic. There is more information about this issue at:

www.factcheck.org/2021/07/scicheck-viral-posts-misrepresent-cdc-announcement-on-covid-19-pcr-test/.

The withdrawal of the PCR test developed by the CDC does not affect the PCR testing undertaken by New Zealand diagnostic laboratories. The CDC's RT-PCR test was only looking for SARS-CoV-2 and ignoring genetic material from other viruses. The changes to testing procedures were to encourage labs to switch to tests that can look for flu viruses at the same time. The CDC's announcement about the changes to RT-PCR testing for COVID-19 can be found at: www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html.

On 21 September 2021 you requested further information relating to COVID-19. Please find a response to each part of your request below. You asked for:

*“Please provide the studies or research that show social distancing reduces the spread of COVID-19?
Please only provide evidence that was used by the government to implement social distancing.”*

As advised above, the Ministry does not conduct scientific research or studies. Therefore, these parts of your request are refused under section 18(g) of the Act as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

However, modelling studies performed by Te Pūnaha Matatini, a centre of research excellence hosted by the University of Auckland, demonstrate the value of lockdowns in reducing the spread of COVID-19:

<https://cpb-ap-se2.wpmucdn.com/blogs.auckland.ac.nz/dist/d/75/files/2017/01/technical-report-7-september.pdf>, and for the original outbreak the evidence can be found following this link: www.tepunahamatatini.ac.nz/2020/04/22/effect-of-alert-level-4-measures-on-covid-19-transmission/.

The Ministry has published information regarding how COVID-19 is spread. This information can be found on the public facing website. Scientific reviews of the method of spread have also been undertaken (link to RFA 213). The current evidence suggests SARS-CoV-2 is spread by both airborne and droplet spread, and that physical distancing is effective against the former but less effective against airborne spread. Computer simulations generally use real world estimates to inform the model wherever possible and are often fitted to the known data to date for a specific scenario such as an outbreak. Modelling studies usually state explicitly which values (including ranges) they have used, the source of these values study would normally specify the data sources on which the model is fitted, and any assumptions used in the model. Real world data that lock-downs decrease the R value have been presented above.

Please provide evidence that the Pfizer COVID-19 vaccine Comirnaty reduces any serious outcomes and hospital admissions of COVID-19.

The Ministry does not treat patients, therefore it cannot provide guidance regarding specific treatment protocols that are the responsibility of district health boards, hospitals and medical and other health professionals. General guidance for health professionals is available at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-information-health-professionals/covid-19-advice-all-health-professionals.

As advised above, the Ministry does not undertake scientific research. A wealth of scientific information about COVID-19 is publicly available on PubMed, a service of the National Library of Medicine in the United States at: <https://pubmed.ncbi.nlm.nih.gov/>. Likewise, the Ministry publishes summaries of a range of scientific information at: www.health.govt.nz/our-

[work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news](https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news).

However, the Ministry has published vaccination data of all cases people infected in the August 2021 outbreak, including their vaccination status. Of the 158 people hospitalised in this outbreak as at 9am on 11 October 2021, just three were fully vaccinated (two doses and more than 14 days since the second dose) Likewise, of the 1622 infected, just 66 were fully vaccinated (two doses and more than 14 days since the second dose). This information is publicly available and regularly updated at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics#vaccinations-details.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā



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