

7 October 2021

██████████
By email: ██████████
Ref: H202111971

Tēnā koe ██████████

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 7 September 2021 for information related to COVID-19 vaccination for minors.

Please find a response to each part of your request below:

Please tell me how a 12 year old can give informed consent and why you think it is ok to bypass parental consent for a child to be injected with an experimental medical mRNA device with no long term safety studies? All information needs to be explained in detail how your statistics were determined with legitimate references

Informed consent for COVID-19 vaccinations is in accordance with the existing law. Consent to healthcare for people under 16 years is provided by the Health and Disability Services Code of Consumer Rights. It presumes that every consumer of health services is competent to make an informed choice or give consent, unless there are reasonable grounds for believing the consumer not competent.

In practice, it is the role of the health provider to make a judgement on whether the person is competent to give informed consent to a procedure, based on that individual's understanding and maturity, and the risk involved in the procedure. Under New Zealand law, it is the level of understanding of the child or young person determining this judgement, not their chronological age.

The test for legal competence is based in common law in the form of the *Gillick*¹ test. A child and/or young person under 16 years will be considered competent and able to choose whether to accept the treatment if they are mature enough to fully understand the treatment that is offered, including the purpose, risks and benefits of that treatment. If the young person has a good understanding, they can say yes or no to getting the vaccine themselves. Where a healthcare provider is not satisfied a young person is capable of giving informed consent then parent or guardian informed consent is sought. A parent or caregiver can also provide consent if the young person prefers. You can find more information about the informed consent policy for

¹ This is from a UK court case: *Gillick v West Norfolk & Wisbeck Area Health Authority* [1986] AC 112 (HL).

12-15 year olds on our website at: www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-informed-consent-young-people-aged-12-15-years-policy-statement-16092021.pdf.

The Ministry is developing further resources specific to 12–15-year-olds, which will encourage young people to discuss vaccination with their whānau prior to making a decision. You can find further information here: www.health.govt.nz/system/files/documents/pages/12-15s-getting-covid-vaccine-07092021.pdf. Training is being provided to vaccinators on the consent process for young people.

Can a child now book at a pop up vaccination site or do they have to do it through a medical clinic? You state that the child's Dr needs to assess whether they are able to give informed consent so not sure how they can book at a pop up clinic. What about children that don't currently have a regular Dr? are they allowed to book without a Dr? How is a child's medical record going to be reviewed before the vaccine is given and what will cause the Dr to decide the vaccine is not appropriate for the child? What if the child and Dr do not know the full medical history of the child? What if there is an immediate adverse reaction or death? Who will inform the parent and how will this be done?

Young people can book their vaccinations at pop-up vaccination sites. The vaccinator, who is a healthcare professional, will assess the young person's ability to give informed consent at the time of the vaccination appointment. It does not have to be carried out by their general practitioner, and it is not necessary for the person's medical record to be reviewed before offering a vaccination. As described above, health care professionals are able to vaccinate 12 to 15-year-olds, provided they are confident that the young person is competent to make an informed decision.

There are protocols in place for managing any adverse event that occurs at any vaccination site. Severe allergic reactions (anaphylaxis) are very rare, but life-threatening and can occur almost immediately after any vaccination. All vaccinators are required to know how to do CPR and administer adrenaline, and to know how to distinguish anaphylaxis from stress-related responses, such as fainting, palpitations or vomiting. Everyone is asked to wait for at least 15 minutes after their COVID-19 vaccination for observation.

Do you provide the pfizer fact sheet to 12-15 year olds who have made an appointment (and in fact all people making an appointment)? Consumer Medicine Information 2020 Template (medsafe.govt.nz) How is this fact sheet going to be explained to a 12 year old? How will a Dr determine if the 12-15 year old understands the implications in the fact sheet? How much time will be allowed to determine if the child understand the fact sheet? What if the child does not understand the fact sheet and it's implications? Will the DR go ahead and allow the jab? Will the parents then be called? How will this be handled?

A young person can decide whether or not they wish to be vaccinated against COVID-19. They are provided with the same information about the vaccine which is provided to all other age groups and a specific information sheet has also been developed for 12 to 15-year-olds. As mentioned above through a conversation with a young person, healthcare professionals are expected to use their professional judgement to assess a young person's competence to provide informed consent. If the young person has a good understanding, they can say yes or no to getting the vaccine themselves. Where a healthcare provider is not satisfied a young person is capable of giving informed consent then parent or guardian informed consent is sought. A parent or caregiver can also provide consent if the young person prefers.

Have the 58 questions from medsafe to Pfizer been answered? please send me the answers to those questions.

Information regarding the status of the conditions of provisional consent for Comirnaty is available here: www.medsafe.govt.nz/COVID-19/status-of-applications.asp. The information provided by Pfizer to address these conditions is commercially sensitive and is therefore withheld under s9(2)(b)(ii) of the Act where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

What dose is given to a child is it based on weight and age?

Information on dosing and administration instructions are available in the New Zealand data sheet here: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf. 12–15-year-old persons receive the same dose as adults.

How has the correct dosage for a child been determined?

What are the effects of the vaccine on puberty hormones? I expect you to reference actual studies done of the pfizer vaccine.

Dosing instructions are based on the results of clinical trials conducted to support the safety and efficacy of the vaccine. All known safety information is described in the data sheet linked above.

What long terms affects on fertility have been studied? show actual data

As mentioned, all known safety information for the Comirnaty vaccine is described in the data sheet above.

How many 12-15 year olds were in the pfizer trial?

How many and what kind of side effects did the children in the trial have?

How are those children doing NOW? You need to quote reputable information.

Please refer to an article published by the New England Journal of Medicine for a study conducted on the effects of the Pfizer vaccine on 12 to 15-year-olds which include information on experienced side effects here: www.nejm.org/doi/full/10.1056/NEJMoa2107456. Conclusions found that the vaccine in 12 to 15-year-olds recipients had a favourable safety profile and was highly effective against COVID-19.

What is the actual statistical risk of myocarditis and pericarditis?

Actual reputable studies need to be referenced? How does this compare to the background rate for the 12-15 age group

Information relating to this part of your request is publicly available here:

www.who.int/news/item/09-07-2021-gacvs-guidance-myocarditis-pericarditis-covid-19-mrna-vaccines.

What is the severity of myocarditis and pericarditis when it occurs and what is the treatment plan and what are the long term prognosis?

Myocarditis and pericarditis symptoms include chest pain, feelings of having a fast-beating, fluttering or pounding heart and shortness of breath, One or more of these symptoms can occur shortly after vaccination due to stress or anxiety. However, if anyone experiences these symptoms after receiving Comirnaty (Pfizer mRNA vaccine) from more than 6 hours to 7 days (typically around 1 to 5 days), they should seek immediate medical attention.

This information regarding treatment plan and the long-term prognosis varies with each case and is determined by health practitioners in consultation with their patients. As such this part of your request is refused under section 18(g)(i) 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.

What is the covid 19 death rate for 12-15 years?

What is the vaccine death rate for 12-15 year olds? world wide - look at vaers, the yellow card system, carm in NZ and all others and remember that that reporting is only 1-10% of actual - you do the math - I expect an answer with actual references.

Up to and including 28 August 2021, a total of 40 deaths were reported to the Centre for Adverse Reactions Monitoring (CARM) after the administration of the Comirnaty vaccine. Following medical assessments by CARM and Medsafe it has been determined that:

- 19 of these deaths are unlikely related to the COVID-19 vaccine
- 5 deaths could not be assessed due to insufficient information
- 15 cases are still under investigation.
- 1 death was likely due to vaccine induced myocarditis (awaiting Coroner's determination).

The mortality by the age group of 10-29 years old up to 28 August 2021 in New Zealand is 0.

What is the actual case rate for 12-15 year olds of the disease and I don't mean a positive PCR test I mean real cases i.e., children with disease symptoms?

As of 9am 17 September 2021, there have been 187 confirmed or probable cases of COVID-19 in the 12- to 15-year-old age group. Of these 187 cases, 42 of these are recorded as being asymptomatic. Note that some of these are from the current outbreak and their case records may not have been finalised.

You can find further information on COVID-19 cases by age group on the Ministry's website here: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics#age-gender.

What is the vaccine adverse event rate for the 12-15 year olds? again look at the world wide systems for recording this information and remember only 1-10% of events are recorded, do the math, I expect this to be broken down by type of adverse reaction.

All known safety information is described in the data sheet linked above. You may also find information about Adverse Events Following Immunisation (AEFI) on Medsafe's website, which includes the age group 10-19 years. You can find it at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

What research has been done to determine if a person who has covid antibodies should get a vaccine? Natural immunity is proven scientifically to be better than vaccine immunity especially since the pfizer vaccine only creates the spike protein from the virus not the whole virus. Do you test that a child or any person for that matter has the antibody or T cell markers indicating has had exposure to covid before you determine a vaccine is appropriate for them?

New Zealand does not routinely check for antibodies prior to vaccination. As such this part of your request is refused under section 18(e) as the information requested does not exist.

What is the data on adverse reactions to the vaccine for people who have already had covid or have antibodies to covid?

Please refer to the original study here: www.nejm.org/doi/full/10.1056/nejmoa2034577. There is no New Zealand data on adverse reactions to the vaccine for people who have already had COVID-19 or have antibodies to COVID-19.

I trust this information fulfils your request. 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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

A handwritten signature in black ink, appearing to read 'Jo Gibbs', with a period at the end.

Jo Gibbs
National Director
COVID-19 Vaccine and Immunisation Programme