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19 January 2022

s 9(2)(a)

[redacted]

Ref: H202115654

Tēnā koe s 9(2)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 8 November 2021 for information relating to the COVID-19 Vaccine Technical Advisory Group (CV-TAG) advice on vaccinating 12 to 15 year olds.

You requested:

> *"all meeting minutes, notes and correspondence made by the COVID-19 Technical Advisory Group from January 2021 to the latest date, in relation to and pertaining to all information and research used which enabled the COVID-19 Technical Advisory Group to conclude why 12-15 year olds should receive 2 doses of the Comirnaty Pfizer-BioNTech covid-19 vaccinations in New Zealand?*
>
> *all meeting minutes, notes and correspondence made by the COVID-19 Technical Advisory Group in relation to and pertaining to where they sent said information, advise and recommendations?*

Information within scope of this request is itemised in Appendix one of this letter with copies of the documents are enclosed.

You also requested:

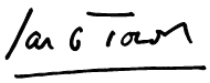
> *the official URL website address of the COVID-19 Technical Advisory Group? Note not the list of members as per the government website. I am requesting the official URL website address of the COVID-19 Technical Advisory Group?"*

There is no official website for CV-TAG. The list of members on the Ministry's website is the only page available. Therefore, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

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 website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā



Dr Ian Town
Chief Science Advisor
Health System Improvement and Innovation

Appendix 1: Documents for release

#	Date	Title	Decision on release
1	11 May 2021 25 May 2021 8 June 2021 22 June 2021 29 June 2021 6 July 2021 20 July 2021 27 July 2021 3 August 2021 17 August 2021 14 September 2021 21 September 2021 19 October 2021	Excerpts from Minutes: COVID-19 Vaccine Technical Advisory Group 11 May 2021 to 19 October 2021	Excerpts released in full. Where information is deemed out of scope, this is noted on the documents themselves
2	14 21 September 2021	Memo: Additional Pfizer mRNA vaccine dose in the immunocompromised: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	Released in full
3	4 August 2021	Memo: Priority groups for vaccination among 12-15 year olds: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine.	
4	25 March 2021	Memo: The use of COVID-19 vaccines in children younger than 16 years old: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	
5	24 June 2021	Memo: Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12-15 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	
6	13 August 2021	Memo: Extending age groups who can receive COVID-19 vaccine	

Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 11 May 2021

2.0	**Science Updates** The Chair summarised key points from the briefing that was held with Janssen the previous evening. Janssen provided an overview of the Phase 1, 2, and 3 studies, followed by a detailed breakdown of adverse events, including thrombotic thrombocytopenic disorders. Janssen noted that their decision to market the vaccine as a single dose was deliberate and strategic given the positive Phase 1 results but studies using a second dose are underway. The vaccine also shows promising results against variants of concern. Future studies in adolescents, children, and pregnant persons were also outlined. The Ministry's policy team will be looking at potential use of the Janssen vaccine in NZ in the following weeks, as the vaccine is under consideration by Medsafe. If approval is granted, a discussion will be held with CV TAG around the use of the Janssen vaccine, similar to the process following approval of the Pfizer vaccine. Updates on the Pfizer vaccine were highlighted: • The emergency use authorisation has been extended by the FDA to include use in ages 12-15 years. • Phase 1 studies on a prototype vaccine targeting variants of concern will be commencing soon. • More data is emerging around the effectiveness of a single dose and generally suggest that two doses are more effective than one. • Data is emerging around the vaccine's effect on transmission, with studies in household settings showing that the vaccine reduced onwards transmission. • Revised manufacturing target to 3 billion doses produced by end of 2021. • Data is emerging for pregnant persons, with no safety signals detected in this population yet but only a small number have been vaccinated. AstraZeneca has begun preclinical studies for a prototype vaccine targeting variants. Due to the blood clotting issues, trials in children have been suspended temporarily until this can be investigated further. Novavax has released results showing that the vaccine has around 50% efficacy against the B.1.351 (South African) variant. They are currently developing a prototype vaccine targeting this variant. Novavax have also extended their Phase 3 trial to include children aged 12-17 years.
3.0	**Research in Children** Canada and US have extended Pfizer's emergency use approval to include ages 12-15. Pfizer are also seeking extension of the EMA approval. Pfizer will be submitting data to Medsafe shortly for extension of the approval to 12-15 years. The Medicines Assessment Advisory Committee (MAAC) meeting in June will consider this information and the CVIP are looking at timing of administration via high school events, which may land in Q3 and Q4. This will have to be managed carefully as the timing may coincide with other events such as the examination period.

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Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 25 May 2021

2.0	**Science Updates** Updates on the Pfizer vaccine were highlighted: • The US FDA has authorised storage of the undiluted vaccine at fridge temperatures for up to a month. • The vaccine received full regulatory approval in Switzerland, Japan, and Brazil. • The vaccine has been approved for use in ages 12-15 in the US, Singapore, and the UAE. • Preliminary data on extended dose intervals showed that a 12-week interval was associated with increased antibody titres but decreased T cell responses, compared to a 3-week interval. However, it is not clear what role each of these responses play in long term protection. • Preliminary evidence on mixed vaccine schedules with Pfizer and AstraZeneca showed that heterologous vaccine schedules were more reactogenic than homologous schedules. • Data from Public Health England indicated that the Pfizer and AstraZeneca vaccines were effective against the B.1.1.7 (UK) and B.1.617.2 (Indian) variants. • The CEO of Pfizer has stated that there may be a need for booster doses, however, no data have been released on antibody waning. It is also not clear whether "booster" refers to a third shot of the original vaccine or a second-generation vaccine targeting variants of concern. • [redacted] Key points of discussion: • CV TAG noted that the Pfizer storage temperature is an important issue as we move into the wider rollout and an expedited approval process for changing the storage conditions may be beneficial. • The WHO Strategic Advisory Group of Experts (SAGE) are evaluating whether there is a differential degree of risk of thrombotic thrombocytopenia syndrome for Janssen versus AstraZeneca, however, no recommendations have been made. Given the increased risk of thrombosis in pregnancy, some counties have specifically recommended against administering adenoviral-vector vaccines to pregnant persons. • The Janssen vaccine is being studied in 400 pregnant women. CV TAG members were asked to send any new research, updates, or changes to the Secretariat.
3.0	**Research in Children** Key points: • Medsafe are considering an extension of the Pfizer provisional approval to include ages 12-15.

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Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 08 June 2021

2.0	**Science Updates** Updates on the COVID-19 vaccines were highlighted: • Pfizer published the Phase 3 trial data from 12-15 year-olds. • Out of Scope [redacted] • The rate of thrombosis with thrombocytopenia Syndrome is approximately 1 case in 100,000 for the AstraZeneca vaccine and 1 case in 300,000 for the Janssen vaccine. • Preliminary data from the UK reported that the Novavax vaccine has an overall efficacy of 89.7% which is higher than the previously reported efficacy of 60% from South African trials where the B.1.351 variant was prevalent. • Preliminary data suggests that an 8-week interval between two doses of the mixed schedule of AstraZeneca and Pfizer vaccines leads to high immunogenicity. It was noted that the AstraZeneca science overview document will be provided to CV TAG shortly. CV TAG members were asked to send any new research, updates, or changes to the Secretariat.
3.0	**Research in Children** Key points: • Pfizer published the Phase 3 trial data from 12-15 year-olds. In general, safety and efficacy results from the 1,131 children enrolled were consistent with the Phase 3 trial in adults.
6.0	**Decision to Use Pfizer for 12 -15 years** The policy team sought advice from CV TAG regarding the Decision to Use the Pfizer COVID-19 vaccine for 12-15 year-olds. Medsafe are expected to make a decision on regulatory approval this week, with advice going to Cabinet thereafter. CV TAG discussed the results from the Phase 3 trials in children aged 12-15 years for the Pfizer vaccine. Key points of discussion: • Out of Scope [redacted] • Children with severe neurodisabilities in institutional care are a vulnerable population in countries with high prevalence of the disease. This group has been listed as a priority population in the UK. • There should be a clear reason to vaccinate children at a population level. The potential role of transmission in schools will have to be evaluated against the potential risks of vaccination in children. The Science and Technical team are setting up a sub-TAG on testing in children to understand whether there is a requirement to test more in children and this information will feed into the discussion on the decision to use.

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	• There is some very early informal discussion in Australia on vaccinating children as they may have played a role in transmission of the virus during the current Victoria outbreak. • Some countries have recommended deferring vaccination of children until there is more equitable coverage globally in the elderly, healthcare workers, and the general adult population that are at higher risk from COVID-19 than children. CV TAG will provide recommendations in the form of a memo to inform the decision to use the Pfizer vaccine for 12-15 year-olds, including an evaluation of the risks and the benefits. CV TAG noted that they would also like to review any conditions recommended by Medsafe, prior to finalising their recommendations.

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Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 22 June 2021

6.0	**Decision to Use Pfizer for 12 -15 years** Medsafe has provisionally approved the Pfizer COVID-19 vaccine for 12-15 year-olds. The Policy team sought advice from CV TAG regarding the decision to use the Pfizer vaccine in this age group. Key points of discussion: • Children in this age group are at low risk for poor outcomes if they contract COVID-19. However, achieving target coverage will require immunisation of younger age groups. We will need geographic as well as demographic, e.g., ethnicity, coverage. • No safety signals have been observed in this specific age group but there are limited data available to date. • Out of Scope [redacted] • No subgroups were identified for prioritisation (with the exception of a small number of children undergoing cancer treatment or under specialist care) or for precautions, at this stage. • New Zealand is in a low prevalence COVID-19 environment and other groups in the Sequencing Framework are a higher priority because of the risk of severe health outcomes. • Consideration should be given to equity and whānau-based approaches and ensuring that other childhood immunisation programmes are not compromised, e.g., measles and HPV vaccination. Overall, CV TAG felt that there are other groups with higher priority than children at this stage. CV TAG discussed the option to delay the recommendations for decision to use until more safety data becomes available.

Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 29 June 2021

2.0	Out of Scope [redacted]
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Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 06 July 2021

6.0	Out of Scope [redacted]

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Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 20 July 2021

5.0	Out of Scope [redacted]

	Out of Scope [redacted]
6.0	**Children Priority Groups** • Draft recommendations for potential priority groups among children were shared with the group, to inform the Decision to Use for 12- to 15-year-olds • Priority groups overseas have included children who are about to under long-term immunosuppression, immunocompromised, in long-term residential care, requiring transplants, or who have neurologic disabilities or gastrointestinal (multi-system medically vulnerable) conditions. Risk factors for COVID-19 such as obesity, respiratory disease, and ethnicity should also be taken into account. • CV TAG noted that the New Zealand's lack of community transmission was an important consideration for now, and vaccinating adults was the priority at this time. • STA will revise draft recommendations and share with CV TAG.

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2.0	Out of Scope [redacted]

	Out of Scope [redacted]
3.0	**Decision to Use Pfizer 12-15 year-olds** CV TAG reviewed the memo on the Decision to Use Pfizer for 12- to 15-year-olds (dated 24 June 2021). • CV TAG noted the potential for children to play a role in transmission in the community and the benefits of vaccination for children's personal protection. • CV TAG agreed that New Zealand's lack of community transmission was still an important consideration for now, and vaccinating adults was the priority at this time. • CV TAG agreed that exception should be made for priority groups of vulnerable 12 to 15 year-olds that are at higher risk from COVID-19 due to prior comorbidities, as outlined in the draft memo. CV TAG recommended vaccination progressing in these at-risk groups. • CV TAG recommended that the decision on vaccinating other 12–15 year-olds be deferred and reviewed at a future date, for example as the borders re-open and the immunisation of adults has progressed. A plan for vaccinating 12 to 15 year-olds should be in place in case of outbreak management. • CV TAG discussed the possibility of conducting trial research in New Zealand and Australia to compare the efficacy of single doses and two doses in 12 to 15 year-olds. Ongoing discussion of this option would be welcomed. • CV TAG noted that ATAGI's recommendations for 12 to 15 year-olds were under development, and that the Ministry would liaise closely with them, while noting the different portfolio of vaccines available in Australia may influence these decisions. • A memo on priority groups in 12-15 year olds will be provided to the Director-General and the COVID-19 Vaccine and Immunisation Programme (CVIP).

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4.0	Out of Scope [redacted]
5.0	**Decision to Use Pfizer 12- to 15-year-olds and Children Priority Groups** • The challenges posed by the Delta variant and emerging data on differences in clinical severity among children were discussed with respect to vaccination in children. • Earlier advice had been that a broader decision on vaccinating 12- to 15-year-olds should be deferred.

	• Aotearoa New Zealand's lack of community transmission was noted as an important consideration in making this decision. • An exception should be made for priority groups of 12- to 15-year-olds that are at higher risk from COVID-19 due to prior comorbidities, as are outlined in the draft memo, which CV TAG supported. • Vaccinations as part of outbreak management, for example in schools, was also considered an exception. • Opportunities provided by mass vaccination events and vaccinating whānau together were noted as important considerations. • The Decision to Use for 12 to 15-year-olds and memo on priority groups will be provided to the Director-General and the COVID-19 Vaccine and Immunisation Programme (CVIP).
8.0	**MMR/Influenza Coadministration** • The Child and Community Health Group in the Ministry sought advice on the recommended intervals between receiving the COVID-19 vaccination and influenza or MMR vaccinations. The RfA on this topic was reviewed. • Currently a two-week gap between the COVID-19 vaccine and the influenza vaccine is recommended, and four-week gap with live vaccines such as MMR. • These intervals are a programmatic burden for the primary care sector and will become more so if vaccination in 12-15 year olds is progressed. • Based on first principles of vaccinology, it is not expected that there would be a problem with reducing timeframes, however it was noted that there are limited data from clinical trials or observational studies. • Preliminary results from trials and a summary of when data is expected should be included in the RfA by the Science and Technical Advisory team for CV TAG's review. STA will continue to monitor evidence as it emerges. • The Science and Technical Advisory team will bring together a working group to progress the discussion and draft recommendations, which will be brought back to CV TAG.

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Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 17 August 2021

6.0	Out of Scope [redacted]

7.0	**Decision to Use Pfizer 12- to 15-year-olds** • CV TAG's recommendation that vaccination of 12- to 15-year-olds proceeds has been relayed to the Director-General and Vaccine Ministers. • Advice on promoting vaccination in whānau groups has been incorporated. • CV TAG requested the benefits of personal and family protection should be emphasised, rather than indirect benefits such as population protection. • The importance of vaccinating vulnerable groups among 12- to 15-year-olds was raised and discussed. It was noted that 12- to 15-year-olds considered Group 3 will be prioritised through another pathway and given codes to book.

Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 14 September 2021

2.0	**Science Updates** The Science and Technical Advisory provided an update on New Zealand's vaccine candidates: • There are no new data on Novavax, including on its use as a potential booster dose or in a heterologous schedule. Medsafe continues to wait for further evidence as part of its application. • Data has emerged for Pfizer that longer intervals between doses produce higher antibody titres but lower T Cell responses. There is also some evidence that immunity may wane markedly in the elderly, and some further evidence on vaccine efficacy against Delta. • Pfizer is now fully approved in Switzerland, the US, Brazil and Japan. • Out of Scope [redacted]

Minutes: COVID-19 Vaccine Technical Advisory Group: Tuesday 21 September 2021

2.0	**Vaccine Rollout** The Chair provided an update on the vaccine rollout: • Increasing access to vaccination in suburbs affected by the current outbreak is a focus currently. • A range of initiatives are underway (e.g., mobile vaccine buses), with discussions about incentives and ways to reduce barriers. • Discussions are occurring with the Ministry of Education about administering vaccines to 12–15-year-olds and their families in education settings • Progress with vaccination is increasing steadily with the number of first doses administered expected to reach 80% in the next few days.
6.0	**Decision to use for 12–15-year-olds** • Considering the UK's decision to not vaccinate this age group, it was queried whether this decision should be revisited, and/or for only single doses to be administered.

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	• Aotearoa New Zealand's population is immunologically naïve and therefore it is still important that this population is vaccinated with two doses. • However, greater emphasis is needed on the benefits provided by longer dosing intervals, with CV TAG expressing concern that intervals of 3 weeks were becoming more common in Auckland's outbreak. • The opportunity for CV TAG position statements to be shared publicly was noted as something that could be explored in order to reinforce the current recommendation of 6 weeks. • The new Pfizer results released showing a robust immune response in 5–11-year-olds given a 2 lower doses of the Pfizer vaccine were discussed. CV TAG will continue to follow the evidence as it emerges and raise any questions when meeting with Pfizer this week. • No change to the current guidance.

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5.0	Out of Scope [redacted]

6.0	**Decision to Use 5–11-Year-Olds** • Medsafe are expecting an application from Pfizer in mid-November. The US FDA are reviewing data for 5-11-year-olds at the end of October. • Little information has been provided on the paediatric formulation which Pfizer are currently trialling, however it may be of importance. • STA will convene a subgroup of CV TAG to discuss priority groups and equity considerations for recommendations and a Decision to Use. • Whether the 5–11-year-olds and 12–15-year-olds who are of lower weight may need a lower dose was discussed. Medsafe are reviewing whether any dose ranging studies were included in Pfizer's initial application.

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Memo

Additional Pfizer mRNA COVID-19 vaccine dose in the immunocompromised: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	21 September 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
From:	Dr Ian Town, Chief Science Advisor
For your:	Consideration

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Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the use of an additional Pfizer mRNA COVID-19 vaccine dose in those who are immunocompromised.

Background and context

2. Some immunocompromised people do not mount an immune response following vaccination that is sufficient to provide protection from COVID-19.[1] Immunocompromised individuals are also at higher risk of severe outcomes from COVID-19 compared to the general population. Several underlying medical conditions, including diabetes, asplenia, and chronic lung and kidney disease, are also associated with increased risk of severe outcomes from COVID-19.[2, 3]

3. Immunocompromised individuals tend to have prolonged infection and viral shedding, are at higher risk of developing a new variant during infection, and are more likely to transmit the virus to household contacts than non-immunocompromised groups.[4] They are also more likely to have a breakthrough infection after being vaccinated, with studies in the US and Israel having estimated that 40-44% of hospitalised breakthrough cases are immunocompromised.[5, 6] Consequently, an additional vaccine dose may deliver better protection in immunocompromised individuals.

4. Emerging evidence suggests that a third dose of the Pfizer COVID-19 vaccine may increase the antibody titres in immunocompromised individuals who developed low antibody titres to the original two-dose regimen and result in the detection of antibodies in some of the non-responders.[4] Among those who had no detectable antibody response to an initial 2-dose mRNA vaccine series, about 33-50% developed an antibody response to a third dose. So far, reactions reported after the third dose in small studies were similar to those after two doses, with fatigue and pain at injection site being the most commonly reported side effects, and overall, most side effects reported were mild to moderate.[7]

5. One study evaluated the humoral response to a third dose of the Pfizer vaccine in 101 solid organ transplant patients.[8] Patients were given two doses of Pfizer one month apart, followed by a third dose of Pfizer two months later. Among the 59 patients who had been seronegative before the third dose, 26 (44%) were seropositive one month after the third dose.

6. Another study found that among 82 hemodialysis patients, only a small proportion (15.9%) failed to seroconvert after two doses.[9] Of these, 12 patients were given a third dose one month later and five (41.6%) developed an immune response following the third dose.

7. The level of individual protection that a third dose confers on an immunocompromised person is unknown. However, based on the emerging data for the COVID vaccines, and principles of vaccinology and immunology, an additional dose in the immunocompromised is unlikely to be associated with any significant risks, and may offer benefits to some individuals.

8. The Pfizer vaccine has been provisionally approved in Aotearoa New Zealand on the basis that two doses, not three, would be administered to a consumer. However, an unapproved indication, such as an additional dose for immunocompromised individuals, can be prescribed with informed consent.

9. On 12 August 2021, the US Food and Drug Administration (FDA) approved the use of an additional dose of the Pfizer COVID-19 vaccine at least 28 days following the original two-dose regimen in those who are immunocompromised.[10] The US Centers for Disease Control (CDC) have recommended that "*...moderately to severely immunocompromised people receive an additional dose. This includes people who have:*

    - *Been receiving active cancer treatment for tumours or cancers of the blood*
    - *Received an organ transplant and are taking medicine to suppress the immune system*
    - *Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system*
    - *Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)*
    - *Advanced or untreated HIV infection*
    - *Active treatment with high-dose corticosteroids or other drugs that may suppress their immune response*

    People should talk to their healthcare provider about their medical condition, and whether getting an additional dose is appropriate for them."[7]

10. On 01 September 2021, the UK's Joint Committee on Vaccination and Immunisation (JCVI) issued guidance for COVID-19 vaccinations for individuals aged 12 years and over with severe immunosuppression.[11-13] JCVI recommended that a third dose should be offered to people aged 12 and over who were severely immunosuppressed at the time of their first or second dose, including those with leukaemia, advanced HIV, and recent organ transplants.

11. JCVI noted that the guidance for third doses for severely immunocompromised groups was separate to any potential booster programme for the general population: "*A third primary dose is an extra 'top-up' dose for those who may not have generated a full immune*

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response to the first 2 doses. In contrast, a booster dose is a later dose to extend the duration of protection from the primary course of vaccinations."[11]

Recommendations

12. CV TAG met on 31 August and 07 September 2021 to discuss recommendations for the use of an additional dose in the immunocompromised.

13. CV TAG noted that:

    a. An additional dose of the Pfizer COVID-19 vaccine is likely to be beneficial and well-tolerated in the severely immunocompromised.

    b. An additional dose would offer extra protection to severely immunocompromised people and may help to reduce transmission from immunocompromised individuals who become infected.

    c. People with functional or anatomical asplenia and those with chronic liver or kidney disease not taking immunosuppressants (including those receiving hemodialysis) may also have immunocompromise. In addition, those with diabetes are at higher risk of severe infection. Thus, emerging information for these groups will be monitored and considered for any potential recommendations as data become available.

    d. 'Ring-fencing' of immunocompromised people through vaccination of household contacts can provide indirect protection to people with immunocompromise.

    e. People with immunocompromise may have a suboptimal immune response to vaccination and should be counselled to continue other protective measures against COVID-19 even after vaccination, such as physical distancing, wearing a face mask, practicing hand hygiene, and isolation or quarantine as advised by public health authorities.

14. CV TAG recommend that:

    a. Those with severe immunocompromise be offered an additional dose of the Pfizer vaccine. The list of eligible individuals is taken from the one developed by JCVI and is provided in Appendix 1.

    b. The additional dose should be administered more than 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible, the third primary dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment.

    c. The administration of an additional dose is covered by s25 of The Medicines Act 1981, and as such, should only be offered by an authorised prescriber with informed consent from the consumer.

    d. The standard two-dose course of vaccine should be offered to any eligible unvaccinated household contacts aged 12 and over, of immunocompromised individuals.

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15. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence becomes available.

Dr Ian Town

Chief Science Advisor and Chair of the COVID-19 Vaccine Technical Advisory Group

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Appendix 1

JCVI list of eligible individuals[12]

1. Individuals with primary or acquired immunodeficiency states at the time of vaccination due to conditions including:
    a. acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who were under treatment or within 12 months of achieving cure.
    b. individuals under follow up for chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (note: this list is not exhaustive).
    c. immunosuppression due to HIV/AIDS with a current CD4 count of <200 cells/µl for adults or children 12 years of age and over.
    d. primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder.
    e. those who had received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months.
    f. those who had received a stem cell transplant more than 24 months ago but had ongoing immunosuppression or graft versus host disease (GVHD).
    g. persistent agammaglobulinaemia (IgG < 3g/L) due to primary immunodeficiency (for example, common variable immunodeficiency) or secondary to disease/therapy.
2. Individuals on immunosuppressive or immunomodulating therapy at the time of vaccination including:
    a. those who were receiving or had received immunosuppressive therapy for a solid organ transplant in the previous 6 months.
    b. those who were receiving or had received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but in this case the recipient would be considered immunosuppressed for a 6-month period), T-cell co-stimulation modulators, monoclonal tumour necrosis factor inhibitors (TNFi), soluble TNF receptors, interleukin (IL)-6 receptor inhibitors, IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (note: this list is not exhaustive).
    c. those who were receiving or had received in the previous 6 months immunosuppressive chemotherapy or immunosuppressive radiotherapy for any indication.
3. Individuals with chronic immune-mediated inflammatory disease who were receiving or had received immunosuppressive therapy prior to vaccination including:
    a. high-dose corticosteroids (equivalent to ≥ 20mg prednisolone per day) for more than 10 days in the previous month.
    b. long-term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months.
    c. non-biological oral immune modulating drugs, such as methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day, 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day in the previous 3 months.

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   d. certain combination therapies at individual doses lower than above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months.

4. Individuals who had received high-dose steroids (equivalent to >40mg prednisolone per day for more than a week) for any reason in the month before vaccination. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / chronic obstructive pulmonary disease / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.

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Memo

Priority groups for vaccination among 12- to 15-year-olds: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine

Date:	4 August 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Cc:	Dr Ashley Bloomfield, Director-General of Health Maree Roberts, DDG, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Information

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Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on priority groups for Pfizer mRNA COVID-19 vaccination among 12- to 15-year-olds.

Context

2. In June, CV TAG advice was sought for the use of the Pfizer mRNA COVID-19 vaccine for children aged 12 to 15 years, following the provisional approval for use in this age group by Medsafe.

3. At that time, CV TAG recommended that the rollout continue to focus on the existing population groups aged 16 years and over, and that any decision to use the COVID-19 vaccine in the 12- to 15-year-old age group should reflect that priority.

4. Generally, children have a lower risk of poor health outcomes from COVID-19 than adults. Internationally, a number of peak bodies, such as the US CDC, recommend that everyone 12 years and over should be vaccinated to help protect against COVID-19, in the context of widespread community transmission in the US.[1]

5. In Australia, the TGA has approved the Pfizer COVID-19 vaccine for ages 12 to 15 years.[2] On 2 August 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) provided recommendations for vaccinating adolescents and children aged 12 to 15 years. ATAGI recommended that 12- to 15-year olds with specified medical conditions that increase their risk of severe COVID-19 be prioritised for vaccination (these conditions included asthma, diabetes, obesity, cardiac and circulatory congenital anomalies, neuro-developmental disorders, epilepsy, immunocompromised individuals, and trisomy). Aboriginal and Torres Strait Islanders aged 12 to 15 years were also prioritised, as well as all adolescents and

children aged 12 to 15 years in remote communities. ATAGI deferred a decision on whether to vaccinate all 12 to 15 year olds, and they expect to make that decision in the coming months.

6. In late 2020, the UK's Joint Committee on Vaccination and Immunisation (JCVI) advised that only children at very high risk of exposure and serious outcomes, such as those with severe neuro-disabilities in residential care, should be offered vaccination.[2] On 19 July 2021, the JCVI issued an update to their advice, stating that "*At the current time, children 12 to 15 years of age with severe neuro-disabilities, Down's syndrome, underlying conditions resulting in immunosuppression, and those with profound and multiple learning disabilities (PMLD)..., severe learning disabilities or who are on the learning disability register are considered at increased risk for serious COVID-19 disease and should be offered COVID-19 vaccination*".[4]

7. Furthermore, JVCI recommended that vaccination be offered to children and young people who have immunocompromised people in their household: "*JCVI advises that children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed should be offered COVID-19 vaccination on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.*"[4] The recommendations from JVCI were made in the context of widespread community transmission.

8. Additionally, a North American study has found that 83% (40/48) of children in intensive care with COVID-19 had co-morbidities.[5] These were mostly "medically complex" (including long-term dependence on technological support, such as tracheostomy), immunosuppression/ malignancy, or obesity.

9. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the use of the Pfizer COVID-19 vaccine for priority groups who are 12 to 15 years of age. This advice will be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Immunisation Programme.

Recommendations

10. CV TAG met on 20 July, 27 July, and 3 August 2021 to discuss the use of the Pfizer COVID-19 vaccine in priority groups among 12- to 15-year-olds, within the COVID-19 Immunisation Programme.

11. **CV TAG noted that:**

    a. Aotearoa New Zealand's focus in the sequencing approach is on coverage of those most at risk of COVID-19 i.e., personal protection of individuals that may be more likely to be exposed to COVID-19 or experience severe health outcomes.

    b. The current recommendations are made in the context of the very low prevalence of COVID-19 in Aotearoa New Zealand. The recommendations may need to be reviewed in the event of new community transmission or outbreaks in Aotearoa New Zealand.

12. **CV TAG recommends that:**

    a. Children and young people aged 12 to 15 years should be vaccinated if they are at high risk of severe outcomes from COVID-19. Those at high risk include 12- to 15-year-olds with severe neuro-disabilities that require residential care, and those who

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are about to undergo long-term immunosuppression, such as solid organ transplant candidates prior to transplant.

b. Children and young people aged 12 to 15 years who are household contacts of persons (adults or children) who are immunosuppressed should be offered vaccination noting that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.

c. As part of outbreak management, vaccination should be offered to 12- to 15-year-olds in the affected area.

d. The COVID-19 vaccine should not be routinely administered to children and young people aged 12 to 15 years of age, at this time. Children and young people have a low risk of severe disease or death due to COVID-19 compared to adults, and, given the low prevalence of SARS-CoV-2 infection in Aotearoa New Zealand, there is currently a low risk of exposure.

e. CV TAG will make recommendations for use in all children in the 12 to 15 years age group at a later date, following a review of emerging information on several issues including:

   i. the safety and effectiveness of COVID-19 vaccines in adolescents as observed in overseas vaccination programmes;

   ii. Out of Scope [redacted]

   iii. the updated advice from peak bodies internationally, including the updated advice from ATAGI on vaccinating children expected in the coming months.

f. Consideration should be given to equity and whānau-based approaches and ensuring that other childhood immunisation programmes are not compromised, e.g., measles and HPV vaccination.

13. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence and peak body recommendations become available.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

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Document Four

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

The use of COVID-19 vaccines in children younger than 16 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	25 March 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Cc:	Dr Ian Town, Chief Science Advisor
From:	Sue Gordon, Deputy Chief Executive COVID-19 Health Systems Response
For your:	Information

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Purpose of report

1. To outline the COVID-19 Vaccine Technical Advisory Group's recommendations for the use of COVID-19 vaccines in children younger than 16 years.

Context

2. The only COVID-19 vaccine currently available in NZ is the Pfizer vaccine, which is approved by Medsafe for use only in people aged 16 years and above.
3. There has been and continues to be a very low incidence of COVID-19 disease in NZ and the likelihood of moderate to severe disease following infection with SARS-CoV-2 in children between 12-15 years, although very low, is comparable to 16-18 years.
4. In a community setting, children under 5 years of age are less likely to acquire and transmit infection than older children and adults.
5. As at March 2021, data on the safety and effectiveness of Pfizer and other COVID-19 vaccines in children under 16 years of age are limited.
6. CV TAG noted that based on specific studies and extensive clinical experience with other non-live vaccines in children 12-15 years of age, such as Human Papilloma Virus Vaccine (HPV – Gardasil9) and Hepatitis B, the most likely scenario is that immune responses in this age group will be more robust than in those aged 16-18, however, data from specific studies suitable for Medsafe review are expected by the end of 2021.

Recommendations

7. The CV TAG recommends that:
   a) Given the current epidemiology and risk profile of COVID-19 in NZ, routine vaccination of children under 16 years of age in the absence of specific data is not justified.
   b) In an outbreak setting, if a community-wide vaccination strategy was implemented, extending the age criteria for vaccination to include children of high-school age (year 9

and above) could be justified at the discretion of the local public health authority. This recommendation is based on experience in NZ and elsewhere showing that older children may play a role in community transmission.

c) Given the current epidemiology and risk profile of COVID-19 in NZ, routine vaccination is not recommended for children who may be viewed as high-risk for COVID-19 complications based on the presence of co-morbidities. This is because there is no data to suggest this is necessary, particularly in a low-incidence population like NZ.

d) Recommendations should be reviewed when safety and efficacy data on COVID-19 vaccines in children becomes available in the context of the population strategy for COVID-19 immunisation programmes in NZ.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

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Memo

Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12 -15 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	24 June 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Cc:	Dr Ashley Bloomfield, Director-General of Health Allison Bennett, Manager, System Enablers, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Information

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Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12-15 years.

Context

2. In February 2021, CV TAG advice was sought for use of the Pfizer COVID-19 vaccine for people who were 16 years and over following Medsafe provisional approval.
3. Cabinet agreed that the COVID-19 Immunisation Programme proceed with the roll out of the Pfizer COVID-19 vaccine. It was noted that there were no specific exclusions for the use of the vaccine that would materially impact on the Sequencing Framework or the Immunisation Programme delivery.
4. It was also noted at the time that clinical trials had not yet concluded for those under 16 years and that once further paediatric trials are reported that Medsafe would be able to consider broadening the approval conditions for the Pfizer vaccine.
5. Medsafe has recently granted provisional approval conditions for the Pfizer vaccine to include people who are 12 years of age and over.
6. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the use of the Pfizer COVID-19 vaccine for people who are 12-15 years of age. This advice will be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Immunisation Programme.

Recommendations

7. CV TAG met on 22 June 2021 and discussed the use of the Pfizer COVID-19 vaccine in children aged 12-15 years.

8. CV TAG noted:

    - our focus in the sequencing approach is on coverage of those most at risk of COVID-19 ie, personal protection of individuals that may be more likely to be exposed to COVID-19 and/or experience severe health outcomes
    - our current context relating to the very low prevalence of COVID-19 in New Zealand
    - generally, children have a lower risk of poor health outcomes from COVID-19 infection
    - there is a relatively limited amount of data from the trials as well as limited experience internationally, which makes it difficult to provide certainty about the risks and benefits of vaccinating this age group
    - Out of Scope [redacted]
    - overall, there is not an urgent need to progress with vaccination of this group, but consideration should be given to equity and whānau-based approaches and ensuring that other childhood immunisation programmes are not compromised, e.g., measles and HPV vaccination.

9. CV TAG recommended that the rollout continue to focus on the existing population groups aged 16 years and over that are at risk of COVID-19 and that any decision to use the COVID-19 vaccine in the 12-15 age group should reflect this current priority.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

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Memo

Extending age groups who can receive COVID-19 vaccine

Date:	13 August 2021
To:	Dr Ashley Bloomfield, Director General of Health
Copy to:	
From:	Dr Ian Town, Chief Science Advisor, Ministry of Health
For your:	Action

Purpose of the memo

1. This is a noting memo confirming support from the COVID-19 Vaccine Technical Advisory Group (CV TAG) to extend the age of people who can receive the Pfizer-BioNTech comirnaty COVID-19 vaccine to 12 to 15 year-olds.

Background and context

2. CV TAG convened by email on 12 August to discuss extending eligibility for the vaccine.
3. There was agreement that children aged 12 to 15 years should be vaccinated.
4. Potential benefits include helping to provide equitable vaccination coverage in Māori and Pacific Peoples, as young people represent a greater proportion in these communities compared to the overall population, and given that Māori and Pacific Peoples are higher risk from COVID-19.
5. It was also noted that this would likely lead to a reduction on school closures and disruption in the education system.

Recommendations

It is recommended that you:

1.	Note	CV TAG supports extending the eligibility for the Pfizer-BioNTech comirnaty COVID-19 vaccine 12-15 year-olds	

Signature _____ Date: 13/08/2021

Dr Ashley Bloomfield
Director General of Health

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