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28 January 2022

Athina Andonatou

By email: fyi-request-17871-6d982bd1@requests.fyi.org.nz

Ref: H202117274

Tēnā koe Athina

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 7 December 2021 for information regarding the COVID-19 vaccine.

On 13 January 2022, the Ministry contacted you to refine your request. On the same day, you refined the third part of your request. On 14 January 2022, the Ministry contacted you to refine part two of your request, because the way it was worded was for a large amount of information which could be refused under section 18(f) of the Act. We have not received a response from you to date. A response to each part of your request is responded to below.

 Please provide me with all documentation, scientific studies and minute meetings being used to determine the value of vaccinating children aged 5-11, especially all documents, scientific studies and minute meetings showing that the benefits outweigh the risks.

The Ministry has identified 11 documents within scope of this part of your request. The documents are attached to this letter as Documents 1-11 and are itemised in Appendix 1 to this letter. Excerpts of the COVID-19 Vaccine Technical Advisory Group (CV TAG) meeting minutes have been provided under section 16(e) of the Act. Please note, where information is withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

Please note in Document 11, the sections in red indicate text that is 'new in this update'.

2) Please provide me with the research and documents from Pfizer being used to determine whether to vaccinate children 5-11

This part of your request is refused under section 18(f) of the Act, as the information requested cannot be made available without substantial collation or research. I have considered whether charging or extending the time to compile the information that would enable the Ministry to respond, however, as each piece of correspondence would have to be individually reviewed, I do not believe it is in the public interest to do so. The Ministry remains willing to engage with you on a revised scope for your request.

3) Communication between Chris Hipkins and Medsafe and the approving of Comirnaty for 5-11 year olds:

all communications about when the topic of giving Comirnaty to 5-11 year olds was first discussed

communication and research shared between Chris Hipkins and Medsafe outlining the rationale of giving Comirnaty to 5-11 year olds

The Ministry has searched its records and has not found any written communication between Medsafe and Hon Chris Hipkins. The Ministry is only aware of verbal updates on progress of the application discussed at the weekly vaccine ministers meeting. Therefore, this part of your request is refused under section 18(e) of the Act, as the information requested does not exist.

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

lan 6 10ws

Dr Ian Town

Chief Science Advisor COVID-19 Technical Advisory Group

Appendix 1: List of documents

#	Date	Title	Decision on release
1	21 September 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	Excerpt provided under section 16(1)(e) of the Act. Released with some information withheld under section 9(2)(k) of the Act, to prevent the disclosure or use of official information for improper gain or improper advantage.
2	5 October 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	
3	19 October 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	
4	2 November 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	
5	9 November 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	
6	23 November 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	
7	29 November 2021	Joint report on expected impacts to Maaori children and their whanau from the planned shift to the COVID-19 Protection Framework	Information released in full.
8	30 November 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	Excerpt provided under section 16(1)(e) of the Act. Released with some information withheld under section 9(2)(k) of the Act.
9	7 December 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	
	15 December 2021	Memo: Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 5- 11 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	Information released in full.
11	22 December 2021	Request for Advice (RfA) – COVID-19 and Vaccination in 5–11-year-olds	



Date:	Tuesday 21 September 2021
Time:	11:00am to 12:00pm
Location:	9(2)(k)
Chair:	lan Town
Members:	David Murdoch, Elizabeth Wilson, Helen Petousis-Harris, Ian Frazer, James Ussher, Nikki Moreland, Nikki Turner, Peter McIntyre, Sue Crengle, Tony Walls
Ministry of Health Attendees:	Brooke Hollingshead, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Fiona Callaghan, Juliet Rumball-Smith, Niki Stefanogiannis, Pippa Scott, Shayma Faircloth
Guests:	Kris Golding, Maria Cotter
Apologies:	Andi Shirtcliffe, Caroline McElnay, John Tait, Sean Hanna

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.
- 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.



Date:	Tuesday 05 October 2021
Time:	11:00am to 12:00pm
Location:	s 9(2)(k)
Chair:	lan Town
Members:	David Murdoch, Elizabeth Wilson, Ian Frazer, James Ussher, Nikki Moreland, Peter McIntyre, Sean Hanna, Sue Crengle, Tony Walls
Ministry of Health Attendees:	Andi Shirtcliffe, Brooke Hollingshead, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Erin Smith, Fiona Callaghan, Juliet Rumball-Smith, Pippa Scott
Guests:	Kris Golding, Mariana Traslosheros Reyes
Apologies:	Caroline McElnay, Helen Petousis-Harris, John Tait, Niki Stefanogiannis, Nikki Turner

10.0 Agenda items for next meeting

Items that will be brought to CV TAG in the near future include:

Decision to Use for 5–11-year-olds and priority groups



Date:	Tuesday 19 October 2021
Time:	11:00am to 12:00pm
Location:	s 9(2)(k)
Chair:	lan Town
Members:	David Murdoch, Elizabeth Wilson, Helen Petousis-Harris, James Ussher, Nikki Moreland, Peter McIntyre, Sean Hanna,
Ministry of Health Attendees:	Andi Shirtcliffe, Brooke Hollingshead, Chriselle Braganza, Edwin Reynolds, Erin Smith, Fiona Callaghan, Juliet Rumball-Smith, Pippa Scott
Guests:	Chris James, John Tait, Kris Golding, Susan Kenyon, Ralph Stewart
Apologies:	Caroline McElnay, Daniel Bernal, Ian Frazer, Niki Stefanogiannis, Nikki Turner, Sue Crengle, Tony Walls,

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.

10.0 New Action Items Raised During Meeting

68	Decision to Use 5–11-Year- Olds	Convene subgroup to compile evidence and discuss equity considerations	Science and Technical Advisory
69	Decision to Use 5–11-Year- Olds	Review Pfizer's application for 12-to- 15-year-olds for evidence on dosages.	Medsafe

Open Actions:

	Agenda item	Actions	Action Owner	Updates
7	Decision to Use 5– 11-Year-Olds	Convene subgroup to compile evidence and discuss equity considerations	Science and Technical Advisory	19/10 – Action raised
88	Decision to Use 5– 11-Year-Olds	Review Pfizer's application for 12-to-15-year olds for evidence on dosages.	Medsafe	19/10 – Action raised
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Date:	Tuesday 02 November 2021
Time:	11:00am to 12:00pm
Location:	s 9(2)(k)
Chair:	Ian Town
Members:	Elizabeth Wilson, Helen Petousis-Harris, Ian Frazer, James Ussher, Nikki Moreland, Nikki Turner, Peter McIntyre, Sue Crengle, Tony Walls
Ministry of Health Attendees:	Brooke Hollingshead, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Erin Smith, Fiona Callaghan, Juliet Rumball-Smith, Pippa Scott
Guests:	John Tait, Kris Golding, Thomas Teunissen, Liam McConnell
Apologies:	David Murdoch, Sean Hanna, Andi Shirtcliffe, Caroline McElnay, Niki Stefanogiannis

12.0 Any Other Business

Decision to Use for 5-11-year-olds

- An initial discussion occurred on the Pfizer vaccine for 5–11-year-olds.
- The recent clinical trial occurred among a relatively small sample of ~2000 children. Rare adverse events cannot be evaluated in a clinical trial of that size. New Zealand would be able to wait for the real-world data of the vaccine rollout internationally to evaluated safety and effectiveness.
- The benefit:risk ratio was not as obvious for this group as for older populations, as COVID-19
 presents as a mild disease in this age group and there appears to be an increased risk of
 myocarditis after vaccination in younger age groups.
- Concern was also expressed on including 5–11-year-olds under vaccine certificates and mandates, with potential effects on education and wellbeing.
- However, different risks for Māori and 5-11-year-olds vulnerable to severe COVID-19 or immunocompromise should be considered
- A subgroup of CV TAG will be meeting to draft recommendations in the coming days.

13.0 Agenda items for next meeting

Booster doses

Decision to use for 5-11-year-olds

Document 4

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
67	Decision to Use 5–11- Year-Olds	Convene subgroup to compile evidence and discuss equity considerations	Science and Technical Advisory	19/10 – Action raised
68	Decision to Use 5–11- Year-Olds	Review Pfizer's application for 12-to-15-year olds for evidence on dosages.	Medsafe	19/10 – Action raised
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Date:	Tuesday 09 November 2021
Time:	11:00am to 12:00pm
Location:	s 9(2)(k)
Chair:	lan Town
Members:	David Murdoch, Elizabeth Wilson, Helen Petousis-Harris, Nikki Moreland, Nikki Turner, Peter McIntyre, Sean Hanna, Sue Crengle,
Ministry of Health Attendees:	Brooke Hollingshead, Caroline McElnay, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Fiona Callaghan, Juliet Rumball-Smith, Niki Stefanogiannis, Pippa Scott, Imogen Roth
Guests:	Kris Golding
Apologies:	lan Frazer, James Ussher, Tony Wall, Andi Shirtcliffe, Erin Smith, John Tait

3.0 Research in Children

The Science and Technical Advisory team provided an update on vaccine candidates for children:

There is new clinical trial data on the safety and efficacy of the Pfizer vaccine in 5-11-year-olds. A
favourable safety profile is evident with most reactions being mild, self-limiting, and similar to
adults. The US CDC has stated that clinical trial vaccine efficacy against symptomatic labconfirmed COVID-19 was 90.9%.

6.0 Vaccination in 5-11-year-olds

- In general, a cautious approach to wait for more data was agreed, and this has been communicated to the Director-General and Prime Minister. ATAGI is also taking this approach.
- Some vulnerable 5-11-year-old groups may need protection. Individual risk factors such as
 comorbidities and pre-existing conditions were discussed, as well as the importance of broader
 social determinants of health, crowded or intergenerational households, and protection for Māori
 and Pacific Peoples.
- The indirect impacts of exclusions from school or recreation were also noted as being significant, and children's role in transmission.
- The STA team will collate information on the risks and benefits, and this will be brought back to CV TAG for discussion.

13.0 New Action Items Raised During Meeting

#	Agenda item	Actions	Action Owner
75	Vaccination in 5-11-year-olds	Compile evidence on risk and benefits of vaccination in this age group	Science and Technical Advisory

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
68	Decision to Use 5–11- Year-Olds	Review Pfizer's application for 12-to-15-year-olds for evidence on dosages.	Medsafe	19/10 – Action raised
75	Vaccination in 5-11- year-olds	Compile evidence on risk and benefits of vaccination in this age group	Science and Technical Advisory	09/11 – Action raised
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Date:	Tuesday 23 November 2021
Time:	11:00am to 12:00pm
Location:	s 9(2)(k)
Chair:	David Murdoch
Members:	Elizabeth Wilson, Ian Frazer, James Ussher, Nikki Moreland, Nikki Turner, Peter McIntyre, Sue Crengle, Tony Walls
Ministry of Health Attendees:	Andi Shirtcliffe, Caroline McElnay, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Fiona Callaghan, Juliet Rumball-Smith, Niki Stefanogiannis, Pippa Scott, Imogen Roth, Mariana Traslosheros Reyes
Guests:	Hilary Longhurst
Apologies:	lan Town, Brooke Hollingshead, Helen Petousis-Harris, Sean Hanna, John Tait, Kris Golding

5.0 Vaccination in 5–11-year-olds

The Science and Technical Advisory team provided an update on COVID-19 and vaccination in 5-11 year old and discussion followed.

- · Children are at a low risk of severe disease, although the risk is higher in some groups
- There is limited vaccine safety and efficacy data in this age group. With a reported 2 million plus
 doses administered in this age group in the US, real world data is expected to help inform the
 advice
- Equity is an important factor in this group, and consideration will be given to prioritisation for certain vulnerable groups
- Any future advice regarding vaccine certificates or mandates in this younger group, would need to be considered separately to the advice on the decision to use.

9.0 Any Other Business

With regards to modelling studies, CV TAG requested modelling regarding:

 The effect of boosters vs. effect of vaccinating 5-11s i.e. no boosters (waning immunity) and vaccinating 5-11, vs boosters (less waning) and no vaccination in 5-11

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
68	Decision to Use 5–11- Year-Olds	Review Pfizer's application for 12-to-15-year-olds for evidence on dosages.	Medsafe	19/10 – Action raised
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Closed Actions Since Last Meeting:

75 Vaccination in 5-11- and benefits of Science and 23/11 - Draft RfA sha	nical Advisory discussed with CV TAG.		Actions Action Owner	Updates
DUNDER THE OFFICIAL.		Vaccination in 5-11- and benefits of vaccination in this age	nd benefits of Science and accination in this age Technical Advisor	23/11 - Draft RfA shared and discussed with CV TAG.
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A

Joint report on expected impacts to Maaori children and their whaanau from the planned shift to the COVID-19 Protection Framework

Monday 29nd November 2021

Introduction

- 1. This is a Statement of Evidence co-authored by
 - 1.1. Dr Danny de Lore,
 - 1.2. Dr Erik Andersen,
 - 1.3. Dr Teuila Percival,
 - 1.4. Dr Jin Russell,
 - 1.5. Dr Owen Sinclair, and

This is the exhibit marked "A" referred to in the affidavit of Danny Boyd Raniera de Lore sworn at

before me:

- 1.6. Associate Professor Siouxsie Wiles.
- We have been provided with a copy of the Amended Statement of Claim filed by the New Zealand Maaori Council before the Waitangi Tribunal on 1 November 2021. We have been asked by the New Zealand Maaori Council to complete this report in relation to the issues raised in that claim. Specifically, we have been asked to provide expert evidence on the expected impacts to Maaori children and their whaanau from the Government's planned decision to shift to the COVID-19 Protection Framework on the 3rd of December 2021, and our expert opinions on the need for an equitable paediatric COVID-19 vaccine rollout.
- 3. This evidence constitutes the personal expert opinions of its authors and is not the evidence of their employers who are not involved in this matter.

Code of conduct for expert witnesses

- 4. It is intended that this report will be annexed to an affidavit for filing in the Waitangi Tribunal and for possible use in other fora.
- 5. The authors have been provided with Schedule 4 to the High Court Rules Code of conduct for expert witnesses. We have read that code. While it is

intended that this affidavit is to be relied on initially in the Waitangi Tribunal and not the High Court, we nevertheless agree to comply with that code in the completion of this report and with respect to any related evidence we are later asked to give. The matters addressed in this report are within the authors' area of expertise.

Qualifications

6. Relevant to the matters to be addressed in this Statement of Evidence, our qualifications are as follows:

Dr Danny de Lore

6.1. Ko Ngaati Tuwharetoa te iwi. Dr de Lore has a Bachelor of Medicine and Bachelor of Surgery and a Diploma in Child Health. He is a Fellow of the Royal Australasian College of Physicians, qualifying in 2013. Dr de Lore is a Consultant General Paediatrician at Lakes DHB. He is a member of the Royal Australasian College of Physicians Maaori Health Committee and Chair of the RACP Indigenous Child Working Group. He is an Honorary Lecturer at the University of Auckland Medical School.

Dr Erik Andersen

6.2. He uri ahau noo Ngaati Raukawa ki te Tonga. Dr Andersen is a Consultant Paediatric Neurologist at Capital and Coast DHB, providing care for the lower North Island. He completed a Bachelor of Medicine and Bachelor of Surgery in 2005, a Diploma of Child Health in 2010 from the University of Otago. He is a Fellow of the Royal Australasian College of Physicians, having qualified in 2015 as a Specialist Paediatric Neurologist. He also works as a Senior Clinical Lecture in Paediatrics at the University of Otago and as part of Te Roopuu Whakakaupapa Urutaa in the Hospital Care team.

Dr Teuila Percival

6.3. Dr Percival is a Consultant Paediatrician at KidzFirst Childrens Hospital, Counties Manukau Health. She has a Bachelor of Medicine and Bachelor of Surgery from the University of Auckland 1983. She is a Fellow of the Royal Australasian College of Physicians, qualifying in 1993. She is an Honorary Senior Lecturer in the Department of Paediatrics at the University of Auckland.

Dr Jin Russell

6.4. Dr Russell is a Consultant Developmental Paediatrician at Starship Children's Health. She has a Bachelor of Medicine and Bachelor of Surgery in 2007 and a Diploma of Paediatrics in 2009 from the University of Auckland. She is a Fellow of the Royal Australasian College of Physicians, having qualified in 2020 as a Specialist Paediatrician in Community Child Health. She is currently completing her Doctorate of Philosophy (Paediatrics) in the field of paediatric and life-course epidemiology at the Centre for Longitudinal Research at the University of Auckland.

Dr Owen Sinclair

6.5. Ko Te Rarawa Te Iwi. Dr Sinclair has been a General Paediatrician with the Whanganui District Health Board since 2012. He has been working in acute lead paediatrics since 2018. He is an honorary lecturer at The University of Auckland Medical school. He gained a Bachelor of Medicine and Bachelor of Surgery in 1999. He became a Fellow of the Royal Australasian College of Physicians in 2012 in both General Paediatrics and Paediatric emergency medicine. He gained a Masters of Public Health in 2017. He is currently a member of the COVID Vaccine Independent monitoring board, The NRA working group into immunisation in Tamariki and Mokopuna Pae ora: Oranga Peepi & Oranga Tamariki (Early Years) for the Transition Unit assisting in the establishing of Health New Zealand, Transition Unit - Maaori Health Authority.

Associate Professor Siouxsie Wiles

6.6. Dr Wiles is an Associate Professor at the Faculty of Medical and Health Sciences at the University of Auckland. She graduated with a First Class Bachelor of Science Honours degree in medical microbiology from the

University of Edinburgh, Scotland in 1997 and with a PhD in microbiology from Edinburgh Napier University, Scotland in 2002. She worked as a postdoctoral researcher in the field of infectious diseases at Imperial College London, England from 2000-2007. In 2007, she was appointed as a lecturer in the Department of Infectious Diseases at Imperial College London. In 2009, she was awarded a Sir Charles Hercus fellowship from the Health Research Council of New Zealand and relocated to the University of Auckland. She was appointed as a Senior Lecturer at the University of Auckland in 2014. In 2019, she was appointed a Member of the New Zealand Order of Merit for services to microbiology and science communication. She is currently a member of the Chief Science Advisor to the Prime Minister, Dame Prof Juliet Gerrard's infectious diseases expert panel.

Materials relied on

7. Where we have relied on any source material for any of the data or opinions set out below, we have included these sources in numbered footnotes.

Background

8. The Crown has failed to achieve equitable health outcomes for Maaori. Maaori continue to experience higher infant mortality rates,¹ higher rates of paediatric diseases,² higher rates of suicide,³ and lower life expectancy.⁴ The authors are

¹ Rutter, C., Walker, S. Infant mortality inequities for Maaori in New Zealand: a tale of three policies. Int J Equity Health 20, 10 (2021). https://doi.org/10.1186/s12939-020-01340-y.

² The Royal Australasian College of Physicians. Indigenous child health in Australia and Aotearoa New Zealand [Internet]. 2020. Cited 24 November 2021. Sydney. Available from https://www.racp.edu.au/docs/default-source/advocacy-library/indigenous-ch-statement-on-ich.pdf.

³ Ministry of Health. Suicide and intentional self-harm dad [Internet]. Cited 24 November 2021. Available from https://www.health.govt.nz/our-work/populations/maori-health/tatau-kahukura-maori-health-statistics/nga-mana-hauora-tutohu-health-status-indicators/suicide-and-intentional-self-harm.

⁴ Stats NZ. National and subnational period life tables: 2017-2019. [Internet]. 2021. Cited 24 November 2021. Available from https://www.stats.govt.nz/information-releases/national-and-subnational-period-life-tables-2017-2019.

- concerned that the Crown's response to the COVID-19 pandemic does not further exacerbate these already stark inequities.
- 9. COVID-19 is an illness caused by the highly infectious SARS-CoV-2 virus.⁵ COVID-19 poses a significant danger to life and can cause chronic debilitating illness.^{6, 7, 8, 9, 10}
- 10. The elderly and people with a variety of other pre-existing health conditions are more at risk of more serious outcomes from a COVID-19 infection. 11, 12
- 11. The Pfizer vaccine, which is available in New Zealand, has been proven to be safe and highly effective at reducing both the likelihood of infection and the severity of illness.

⁵ Coronaviridae Study Group of the International Committee on Taxonomy of Viruses. The species severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2. Nat. Microbiol. 5, 536–544 (2020).

⁶ Wu, Z. & McGoogan, J. M. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in china: summary of a report of 72314 cases from the Chinese Center for Disease Control and Prevention. JAMA 323, 1239–1242 (2020).

⁷ Chen, T. et al. Clinical characteristics of 113 deceased patients with coronavirus disease 2019: retrospective study. BMJ 368, m1091 (2020).

⁸ Yang, X. et al. Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study. Lancet Respir. Med. 8, 475–481 (2020).

⁹ Twohig, K. A., et al. Hospital admission and emergency care attendance risk for SARS-CoV-2 delta (B.1.617.2) compared with alpha (B.1.1.7) variants of concern: a cohort study. Lancet Infect Dis. Aug 27:S1473-3099(21)00475-8 (2021). doi: 10.1016/S1473-3099(21)00475-8.

¹⁰ Higgins, V., et al. COVID-19: from an acute to chronic disease? Potential long-term health consequences. Crit Rev Clin Lab Sci. 58(5):297-310 (2021). doi: 10.1080/10408363.2020.1860895.

¹¹ Tian, J. et al. Clinical characteristics and risk factors associated with COVID-19 disease severity in patients with cancer in Wuhan, China: a multicentre, retrospective, cohort study. Lancet Oncol. 21, 893–903 (2020).

¹² Liu, Y. et al. Association between age and clinical characteristics and outcomes of COVID-19. Eur. Respir. J. 55, 2001112 (2020).

- 12. By reducing the likelihood of infection amongst those who are vaccinated, the Pfizer vaccine can also reduce the overall level of community transmission.¹³
- 13. Receiving one dose of the Pfizer vaccine provides measurable benefits. 14, 15 However, far greater benefits come from being "fully vaccinated". This requires two doses of the Pfizer vaccine given at least 3 weeks apart and an additional two-week period after the second dose for the recipient to develop full protective immunity. 16,17
- 14. The Pfizer vaccine has so far been approved by Medsafe for use only by people aged 12 and above. 18 Pfizer says that it has concluded stage 2/3 trials establishing a safe and effective protocol for the use of its vaccine with 5- to 11-year-olds. 19 The FDA and Health Canada have examined that data and

¹³ Polcak, P.F., et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N. Engl. J. Med. 383:2603-2615 (2020). doi: 10.1056/NEJMoa2034577.

¹⁴ Barda, N., et al. Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study. Lancet (2021). doi: 10.1016/S0140-6736(21)02249-2.

¹⁵ Steyn, N., Plank, M., Hendy, S. Modelling to support a future COVID-19 strategy for Aotearoa New Zealand. (2021). Available online: https://www.tepunahamatatini.ac.nz/2021/09/23/modelling-to-support-a-future-covid-19-strategy/.

¹⁶ Nasreen, s., et al. Effectiveness of mRNA and ChAdOx1 COVID-19 vaccines against symptomatic SARS-CoV-2 infection and severe outcomes with variants of concern in Ontario. medRxiv (2021). doi: https://doi.org/10.1101/2021.06.28.21259420.

¹⁷ Lopez Bernal, J., et al. Effectiveness of COVID-19 vaccines against the B.1.617.2 variant. medRxiv (2021). doi: https://doi.org/10.1101/2021.05.22.21257658.

¹⁸ Medsafe COMIRNATYTM COVID-19 vaccine New Zealand Data Sheet. Available at: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.

¹⁹ Walter, E.B., et al. Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age. (2021). N. Engl. J. Med. doi: 10.1056/NEJMoa2116298.

approved the Pfizer vaccine for use in the United States and Canada, respectively.^{20, 21} Medsafe is presently examining that data in New Zealand.²²

Expected impacts to Maaori children and their whaanau from the planned shift to the COVID-19 Protection Framework

- 15. A shift to the COVID-19 Protection Framework, the movement of individuals outside of Taamaki, and any loosening of international borders before Maaori achieve equivalent proportions of vaccination coverage to the broader population will negatively and disproportionately affect the health of Maaori children and their whaanau. Maaori currently have the lowest proportions of vaccination coverage of all major ethnic groups in Aotearoa. According to the Ministry of Health at the time of writing (as of Tuesday 23rd November 2021), 64.3% of eligible Maaori have been administered two vaccine doses, compared to 78.9% of Pacific Peoples, >95% of Asian, and 84.1% of European/Other ethnicity.²³ Comparing the second doses administered figures given by the Ministry of Health with the 2018 census data gives a proportion of the total population double vaccinated as 74.9%, and the proportion of the Maaori population double vaccinated as 47.6%.
- 16. In addition to national vaccination rates, the proportion of eligible Maaori vaccinated at a local community level must also be considered. If SARS-CoV-2 were to be present in a particular local area, it is the vaccination rates within

²⁰ FDA approval announcement. Available at: https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.

²¹ Health Canada. [Internet] Cited 29 November 2021.Available at: https://www.canada.ca/en/public-health/services/vaccination-children/covid-19.html.

²² Radio New Zealand. Medsafe intends analysing paediatric vaccine data over Christmas break.

[Internet] Cited 29 November 2021. Available at:

https://www.rnz.co.nz/news/national/456595/medsafe-intends-analysing-paediatric-vaccine-data-over-christmas-break.

²³ Ministry of Health. Covid-19 vaccine data. [Internet]. 2021. Cited 22 November 2021. Available from https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data#ethnicity.

- that community and not the regional or national vaccination rate that is important for protecting the community from COVID-19.
- 17. While differences remain between the proportion of eligible Maaori who are vaccinated compared with the wider population, Maaori children will be disproportionately at risk of exposure to the SARS-CoV-2 virus and subsequent COVID-19 infection.
- 18. The SARS-CoV-2 delta variant of concern is highly transmissible and is the dominant strain worldwide. Transmission risk varies widely by setting, ^{24, 25, 26} and is reduced by vaccination. ^{27, 28} Transmission of SARS-CoV-2 within households is the dominant form of transmission in the current outbreak. ²⁹ The secondary attack rate is 45.6% which means nearly half of household members

²⁴ Singanayagam, A., Hakki, S., Dunning, J., et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. Lancet Infect Dis. 2021; Oct 29;S1473-3099(21)00648-4. doi: 10.1016/S1473-3099(21)00648-4. Available from https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext.

²⁵ Ng, O.T., Koh, V., Chiew, C.J., et al. Impact of Delta Variant and Vaccination on SARS-CoV-2 Secondary Attack Rate Among Household Close Contacts. Lancet Reg Health West Pac. 2021 Dec;17:100299. doi: 10.1016/j.lanwpc.2021.100299. Available from https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(21)00208-X/fulltext.

²⁶ Lee, B., U. A high attack rate of 90% of SARS-CoV-2 Delta variant infections in crew personnel on a single navy ship. J Travel Med. 2021 Oct 20;taab168. doi: 10.1093/jtm/taab168. Available from https://academic.oup.com/jtm/advance-article/doi/10.1093/jtm/taab168/6404468.

²⁷ Ng, O.T., Koh, V., Chiew, C.J., et al. Impact of Delta Variant and Vaccination on SARS-CoV-2 Secondary Attack Rate Among Household Close Contacts. Lancet Reg Health West Pac. 2021 Dec;17:100299. doi: 10.1016/j.lanwpc.2021.100299. Available from https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(21)00208-X/fulltext.

²⁸ Lee, B., U. A high attack rate of 90% of SARS-CoV-2 Delta variant infections in crew personnel on a single navy ship. J Travel Med. 2021 Oct 20;taab168. doi: 10.1093/jtm/taab168. Available from https://academic.oup.com/jtm/advance-article/doi/10.1093/jtm/taab168/6404468.

²⁹ New Zealand Ministry of Health. COVID-19 Variants Update. 22/11/2021. Available from https://www.health.govt.nz/system/files/documents/pages/22-november-2021-variants-update-summary.pdf.

are becoming infected.³⁰ While there is evidence that infected children are less likely to transmit the virus than adults in educational settings,³¹ infected children can and do transmit to other household members.³² 20% of Maaori households are classified as crowded, versus 4% of European households.³³ Furthermore, for children and young people aged 0 - 19 years there is a higher percentage of crowding across all ethnicities.³⁴

19. The SARS-CoV-2 delta variant evolved to become 97% more infectious. The virus will continue to evolve while transmission continues globally. In the future, new variants of concern may emerge that are more transmissible or cause more severe illness. For example, on 25 November 2021 South African Minister of Health Dr Joe Phaahia and the director of the Centre for Epidemic Response & Innovation (CERI) Professor Tulio de Oliveira announced that they had recently identified a new variant of SARS-CoV-2 in the lineage B.1.1.529 with a large

³⁰ Ibid.

³¹ National Centre for Immunisation Research and Surveillance (NCIRS). COVID-19 in schools and early childhood education and care services – the experience in NSW: 16 June to 31 July 2021. National Centre for Immunisation Research and Surveillance, NSW Health. [Internet]. 2021. Cited 22 November 2021. Available from https://www.ncirs.org.au/sites/default/files/2021-09/NCIRS%20NSW%20Schools%20COVID_Summary_8%20September%2021_Final.pdf.

³² Paul, L.A., Daneman, N., Schwartz, K.L., et al. Association of age and pediatric household transmission of SARS-CoV-2 infection. *JAMA Pediatr.* 2021;175(11):1151-1158. doi:10.1001/jamapediatrics.2021.2770. Available from https://jamanetwork.com/journals/jamapediatrics/fullarticle/2783022.

Ministry of Health. Analysis of Household Crowding based on Census 2013 data. Wellington: Ministry of Health. 2014. ISBN 978-0-478-42850-6 (online). Available from https://www.health.govt.nz/system/files/documents/publications/analysis-of-household-crowding-based-on-census-13-data-dec14-v2.docx.

³⁴ Ibid.

³⁵ New Zealand Ministry of Health. COVID-19 Variants Update. 22/11/2021. Available from https://www.health.govt.nz/system/files/documents/pages/22-november-2021-variants-update-summary.pdf.

number of both known and unknown mutations.³⁶ This variant was named Omicron and classified as a Variant of Concern (VOC) by the World Health Organisation on 26 November.³⁷ The emergence of new variants constitutes an ongoing risk to the health of Maaori communities if Maaori have inequitable vaccination coverage.

20. The younger age structure of the Maaori population means that a relatively larger proportion of Maaori compared to the wider population are children who are unable to be vaccinated at present and remain susceptible to infection, with risk of onward spread to their households and communities. According to the 2018 Census, 32% of Maaori are under 15-years of age, versus 19.6% of the total population being under 15-years of age.³⁸ At the time of writing (as of Tuesday 23rd November 2021), in the current August delta outbreak, Maaori represent 43% of COVID-19 cases, 32% of hospitalised cases, and 43% of

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³⁶ South Africa News 24. Urgent briefing on latest developments around the Covid-19 vaccination programme. [Internet] Cited 29 November 2021. Available from https://www.youtube.com/watch?v=Vh4XMueP1zQ..

³⁷ World Health Organization. Classification of Omicron (B.1.1.529): SARS-CoV-2 Variant of Concern. [Internet] Cited 29 November 2021. Available from https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern.

³⁸ 2018 Census, NZ Stat Table Viewer. Statistics New Zealand. [Internet]. 2021. Cited 23 November 2021. Available from

http://nzdotstat.stats.govt.nz/wbos/Index.aspx? ga=2.145049588.1928536397.1637656731-896706472.1637656731#.

- deaths,^{39, 40} despite Maaori comprising approximately 16.5% of the total population.⁴¹
- 21. Maaori children experience worse health outcomes compared to non-Maaori for many other health conditions.⁴² Compared to children of European ethnicity, Maaori children experience a higher burden of risk factors for severe illness and/or negative outcomes from COVID-19 infection,⁴³ including but not limited

³⁹ Covid-19: Case demographics. Ministry of Health. [Internet]. 2021. Cited 23 November 2021. Available from https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics#aug-2021.

⁴⁰ Taonui, R. Another Maaori death and highest cases since Covid-19 began. Waatea News. [Internet]. 23 November 2021. Cited 28 November 2021. Available from https://waateanews.com/2021/11/23/dr-rawiri-taonui-another-maori-death-and-highest-cases-since-covid-19-began/

⁴¹ 2018 Census, NZ Stat Table Viewer. Statistics New Zealand. [Internet]. 2021. Cited 23 November 2021. Available from http://nzdotstat.stats.govt.nz/wbos/Index.aspx?ga=2.145049588.1928536397.1637656731-896706472.1637656731#.

⁴² The Royal Australasian College of Physicians. Indigenous child health in Australia and Aotearoa New Zealand [Internet]. 2020. Cited 23 November 2021. Sydney. Available from https://www.racp.edu.au/docs/default-source/advocacy-library/indigenous-ch-statement-on-ich.pdf; and Duncanson, M; Oben, G; Adams, J; Richardson, G; Wicken, A; Pierson M. Health and wellbeing of under-15 year olds in Aotearoa 2018 [Internet]. Dunedin; 2019. Available from: https://www.otago.ac.nz/nzcyes

⁴³ Graff, K., Smith, C., Silveira, L., et al. Risk factors for severe Covid-19 in Children. The Pediatric Infectious Disease Journal: April 2021 - Volume 40 - Issue 4 - p e137-e145. doi: 10.1097/INF.000000000000304. Available from https://journals.lww.com/pidj/Fulltext/2021/04000/Risk Factors for Severe COVID 19 in Children.2 _aspx?context=FeaturedArticles&collectionId=3.

to asthma and chronic respiratory conditions, ⁴⁴ obesity, ⁴⁵ and diabetes. ⁴⁶ In a large systematic meta-analysis of laboratory-confirmed COVID-19 cases in children, 1 in 20 children with comorbidities experienced severe illness due to COVID-19 infection, compared to 1 in 500 children with no pre-existing conditions. ⁴⁷ In the same study, the risk of mortality from COVID-19 infection was almost three times more likely in children with comorbidities compared to children with no comorbidities. ⁴⁸ Because Maaori children have a higher burden of pre-existing conditions, it is expected that Maaori children will experience a greater burden of hospitalisation and severe illness as COVID-19 spreads. ⁴⁹

22. Maaori children are at significantly more risk of immunisation preventable disease including pertussis⁵⁰ and measles⁵¹. Despite or because of this the health system has long failed to achieve equitable outcomes in childhood immunisations in Maaori. Although there was some improvement between

⁴⁴ The Royal Australasian College of Physicians. Indigenous child health in Australia and Aotearoa New Zealand [Internet]. 2020. Cited 23 November 2021. Sydney. Available from https://www.racp.edu.au/docs/default-source/advocacy-library/indigenous-ch-statement-on-ich.pdf.

⁴⁵ Ibid.

⁴⁶ Sjardin, N., Reed, P., Albert, A., et al. Increasing incidence of type 2 diabetes in New Zealand children <15 years of age in a regional-based diabetes service, Auckland, New Zealand. Journal of Paediatrics and Child Health. 2018;54(9):1005-1010. https://doi.org/10.1111/jpc.13924.

⁴⁷ Tsankov, B.K., Allaire, J.M., Irvine, M.A, et al. Severe Covid-19 infection and paediatric comorbidities: A systematic review and meta-analysis. International Journal of Infectious Diseases. 2021;103:246-256. https://doi.org/10.1016/j.ijid.2020.11.163.

⁴⁸ Ibid.

⁴⁹ Steyn, N., Binny, R.N., Hannah, K., et al. Maaori and Pacific people in New Zealand have a higher risk of hospitalisation for COVID-19. New Zealand Medical Journal. 2021;134(1538):28-43. Available from https://journal.nzma.org.nz/journal-articles/maori-and-pacific-people-in-new-zealand-have-a-higher-risk-of-hospitalisation-for-covid-19-open-access.

⁵⁰ Sinclair O. Ethnic inequalities in health: have we made progress? Pertussis mortality and morbidity in New Zealand for Maaori and non-Maaori over the past century: University of Auckland; 2015.

⁵¹ Turner N. A measles epidemic in New Zealand: Why did this occur and how can we prevent it occurring again? N Z Med J. 2019;132(1504):8-12.

2009 and 2017, all of those gains have been lost and the current levels of completed immunisations are dire. The 2-year immunisation levels are 70.2% for Maaori compared to 86% for New Zealand European.⁵² This leaves Maaori children vulnerable to a predictable resurgence of these diseases when restrictions are lifted.

- 23. Overseas evidence shows disproportionate COVID-19 infection rates in indigenous and ethnic minority children (Black, Hispanic and American Indian and Native Alaskan).^{53, 54} Children of Racial minority groups are also more likely to be hospitalized with more severe COVID-19 illness.⁵⁵
- 24. There is emerging evidence regarding persisting symptoms such as headache, fatigue, concentration difficulties, abdominal pain, cough, and chest pain, following COVID-19 infection in a proportion of children, sometimes referred to as 'Long Covid'.⁵⁶ A recent systematic review concluded that the small number of published studies of persisting symptoms in children after COVID-19 infection all contained major limitations, such as the lack of a clear case definition, inclusion of children without confirmation of infection, selection bias

⁵² Ministry of Health. National and DHB immunisation data. [Internet]. Updated 12 November 2021. Cited 26 November 2021. Available from https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-coverage/national-and-dhb-immunisation-data.

Kim, L., Whitaker, M., O'Halloran, A., et al. Hospitalisation rates and characteristics of children aged <18 years hospitalised with laboratory confirmed COVID-19 - COVID-NET,14 States, March 1-July 25, 2020. MMWR Morb Mortal Wkly Rep 2020 Aug 14;69(32):1081-1088. doi: 10.15585/mmwr.mm6932e3. Available from https://pubmed.ncbi.nlm.nih.gov/32790664/.</p>

⁵⁴ Goyal M, Simpson J, Boyle M, Badolato G, Delaney M, McCarter R, Cra-Bramble D. (2020) Racial and/or ethnic and Socioeconomic Disparities of SARS-CoV-2 Infection Among Children. Pediatrics. 2020 Oct;146(4):e2020009951. Available from https://doi.org/10.1542/peds.2020-009951.

⁵⁵ US Centers for Disease Control and Prevention. Covid-19 disparities in hospitalizations: Racial and ethnic health disparities. US Centers for Disease Control and Prevention. [Internet]. Updated 22 November 2021. Cited 25 November 2021. Available from https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/disparities-hospitalization.html.

⁵⁶ Zimmermann, P., Pittet, L.F., Curtis, N. How common is Long Covid in children and adolescents? The Pediatric Infectious Disease Journal. 2021;40(12):e482-e487. doi: 10.1097/INF.000000000003328.

with low response rates, the absence of control groups, and recommended that further research is needed.⁵⁷ In the majority of studies reviewed, symptoms did not persist longer than 12 weeks.⁵⁸

- 25. It is not clear what proportion of infected children experience persisting symptoms after COVID-19 infection. However even if only a small proportion of infected children experience persistent symptoms after COVID-19 infection this would be concerning since large numbers of children are being/will be infected. A recent preprint study with robust methodology which included healthcare data from almost 12,000 children and adolescents in Germany has found that fatigue, cough, and throat/chest pain were more common in children and adolescents at least 3 months post COVID-19 infection compared to the control group who had not tested positive for COVID-19 infection. In the same study, the incidence of persisting symptoms was lower among children and adolescents compared to among adults.
- 26. Multisystem Inflammatory Syndrome (MIS-C), a rare, severe complication of COVID-19 infection in children, causes fever and inflammation in multiple organ systems.⁶³ MIS-C occurs more frequently among marginalised Black, non-Black Hispanic, Pacific and indigenous children compared with white children

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ Ibid.

⁶¹ Roessler, M., Tesch, F., Batram, M. Post COVID-19 in children, adolescents, and adults: results of a matched cohort study including more than 150,000 individuals with COVID-19. Medrxiv. Preprint. 2021 October 22. Cited 2021 November 24. https://doi.org/10.1101/2021.10.21.21265133.

⁶² Ibid.

⁶³ CDC Case Definition for Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019. Cited 24 November 2021. Available from: https://emergency.cdc.gov/han/2020/han00432.asp.

- according to overseas studies, ^{64, 65} raising concerns that similar inequities may occur for Maaori children.
- 27. Certain socio-politico-environmental factors also place Maaori children at greater risk of negative health outcomes, such as inequities in access to healthcare, ⁶⁶ access to well-resourced schooling, ⁶⁷ poor quality housing and/or housing security, ⁶⁸ and overcrowding and multi-generational homes. ⁶⁹ According to the 2013 New Zealand Census, 50% of all Maaori children live in the lowest three deciles on the New Zealand Deprivation Index. ⁷⁰

⁶⁴ Godfred-Cato S, Bryant B, Leung J, et al. COVID-19–Associated Multisystem Inflammatory Syndrome in Children — United States, March–July 2020. MMWR Morb Mortal Wkly Rep 2020;69:1074–1080. http://dx.doi.org/10.15585/mmwr.mm6932e2.

⁶⁵ Payne AB, Gilani Z, Godfred-Cato S, et al. Incidence of Multisystem Inflammatory Syndrome in Children Among US Persons Infected With SARS-CoV-2. JAMA Netw Open. 2021;4(6):e2116420. Published 2021 June 1. https://doi.org/10.1001/jamanetworkopen.2021.16420.

⁶⁶ Talamaivao, N., Harris, R., Cormack, D., et al. Racism and health in Aotearoa New Zealand: A systematic review of quantitative studies. NZMJ. 2020;133(1521):55-68. Available from https://journal.nzma.org.nz/journal-articles/racism-and-health-in-aotearoa-new-zealand-a-systematic-review-of-quantitative-studies.

⁶⁷ New Zealand Government. Child poverty indicators report. May 2021: New Zealand Government. Available from https://childyouthwellbeing.govt.nz/sites/default/files/2021-05/cpri-report-20210512.pdf.

⁶⁸ Ibid.

⁶⁹ Ministry of Health. Analysis of Household Crowding based on Census 2013 data. Wellington: Ministry of Health. 2014. ISBN 978-0-478-42850-6 (online). Available from <u>Analysis of Household Crowding based on Census 2013 data https://www.health.govt.nz > files > publications</u>.

⁷⁰ Atkinson, J., Salmond, C., Crampton, P. 2014. NZDep2013 Index of Deprivation. Dunedin: University of Otago. Available from: https://www.otago.ac.nz/wellington/otago069936.pdf.

- 28. However, socio-economic factors are not the only contributors to inequitable health outcomes. Maaori receive lower quality care from the health system compared to non-Maaori.^{71, 72}
- 29. Maaori children are also at greater risk of indirect harm if COVID-19 spreads through Magori communities, including illness, disability, hospitalisation, and/or loss of a parent, caregiver, or other member of the child's whaanau. These outcomes would result in psychological and socioemotional harms, as well as socioeconomic harms to Maaori children and their whaanau. More than 1.1 million children worldwide are estimated to have experienced the death of a primary parent or caregiver grandparent during the period from March 1, 2020 to April 30, 2021.⁷³ Indigenous and ethnic minority children are up to 4.5 times more likely to lose a parent or caregiver due to COVID-19 compared to white children.⁷⁴ A study published in Pediatrics found that 140,000 children in the United States are estimated to have lost a parent or grandparent caregiver between April 1, 2020 and June 30, 2021. The same study, an estimated 1 of every 753 white children lost a parent or grandparent caregiver, compared to 1 in 412 Hispanic children, 1 in 310 Black children, and 1 in 168 indigenous children (American Indian/Alaskan native).⁷⁶

⁷¹ Rumball-Smith J. Not in my hospital? Ethnic disparities in quality of hospital care in New Zealand: a narrative review of the evidence. NZ Med J 2009. 122:1297; 68-83.

⁷² Talamaivao, N., Harris, R., Cormack, D., et al. Racism and health in Aotearoa New Zealand: A systematic review of quantitative studies. NZMJ. 2020;133(1521):55-68. Available from https://journal.nzma.org.nz/journal-articles/racism-and-health-in-aotearoa-new-zealand-a-systematic-review-of-quantitative-studies.

⁷³ Hillis, S.D., Unwin, H.J.T., Chen, Y., et al. Global minimum estimates of children affected by Covid-19-associated orphanhood and deaths of caregivers: a modelling study. Lancet. 2021;398(10298):391-402. https://doi.org/10.1016/S0140-6736(21)01253-8.

⁷⁴ Hillis, S.D., Blenkinsop, A., Villaveces, A., et al. Covid-19-associated orphanhood and caregiver death in the United States. Pediatrics. 2021;e2021053760. https://doi-org.ezproxy.auckland.ac.nz/10.1542/peds.2021-053760.

⁷⁵ Ibid.

⁷⁶ Ibid.

The urgent need for an equitable paediatric COVID-19 vaccine rollout

- 30. Maaori children have a right to protect themselves and participate in the protection of their whaanau, hapuu and iwi. The principle of tino rangatiratanga derived from Te Tiriti o Waitangi supports the right of Maaori to express their mana motuhake and make autonomous decisions regarding health systems for Maaori. Decisions based on the needs of the general population exacerbate risk for Maaori and do not comply with the principles of equity and active protection afforded to Maaori by Te Tiriti.
- 31. It is crucial that a COVID-19 vaccination for 5 11-year-old children is made widely available as soon as possible after Medsafe approval.
- 32. Equity for Maaori and upholding Te Tiriti o Waitangi should be central to decisions regarding vaccine approval for children under the age of 12-years. Decisions regarding vaccine approval should go beyond an individual risk/benefit approach, to include wider benefits of vaccination for children, whaanau and their communities. The benefits of vaccination of all children include protection from COVID-19 infection, severe illness, hospitalisation, death, and complications of COVID-19, as well as increasing protection for household members, reducing overall community transmission, and avoiding isolation, quarantine, school closures, and other indirect harms of the pandemic.⁷⁷
- 33. Planning for an equitable paediatric vaccine rollout for all New Zealand children is a priority. Children with pre-existing conditions, Maaori children, and children with medically vulnerable household members should be prioritised in a vaccine rollout given their increased risk of hospitalisation and severe illness.
- 34. To reduce barriers to access, a paediatric vaccine rollout should include a school-based vaccination programme and primary health care vaccine sites in

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⁷⁷ Zimmermann, P., Pittet, L.F., Finn, A., et al. Should children be vaccinated against Covid-19? Archives of Disease in Childhood. 2021;**0**:1–8. doi:10.1136/archdischild-2021-323040. Available from https://adc.bmj.com/content/archdischild/early/2021/11/01/archdischild-2021-323040.full.pdf.

partnership with Maaori leaders and health providers.⁷⁸ A substantial further increase/redistribution in funding and resources should be urgently allocated to Maaori health providers and providers in low decile communities to enable planning for the paediatric vaccine rollout.

Protecting Maaori children in educational settings

35. There is strong evidence that the risk of transmission of COVID-19 within educational settings can be substantially reduced using a multi-layered strategy which includes, but is not limited to, the following mitigations: high levels of vaccination among teachers and eligible students; universal wearing of masks for teachers and students above the age of five (depending on the level of community transmission and other factors); improving ventilation to meet indoor air quality standards; provision of devices to measure CO₂ levels within school rooms as part of ventilation audits; provision of air purifiers with HEPA filters for high-risk rooms or rooms which cannot be adequately ventilated; the use of rapid antigen testing for policies to maximise in-person school days and reduce the risk of infected students attending; improving hygiene and cleaning of surfaces; cohorting of students and limiting mixing between cohorts; and, physical distancing where possible.^{79, 80}

⁷⁸ Whitehead, J., Scott, N., Atatoa-Carr, P., Lawrenson, R. Will access to COVID-19 vaccine in Aotearoa be equitable for priority populations? New Zealand Medical Journal. 2021;134(1535):25-34. Available from https://journal.nzma.org.nz/journal-articles/will-access-to-covid-19-vaccine-in-aotearoa-be-equitable-for-priority-populations-open-access.

⁷⁹ European Centre for Disease Prevention and Control. COVID-19 in children and the role of school settings in transmission - Second update. [Internet]. 8 July 2021. Stockholm: ECDC;2021. Available from https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-in-children-and-the-role-of-school-settings-in-transmission-second-update.pdf.

⁸⁰ US Centres for Disease Control and Prevention. Covid-19: Guidance for Covid-19 prevention in K-12 schools. [Internet]. Updated 5 November 2021. Cited 29 November 2021. Available from https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html.

Additional recommendations

- 36. In addition to our recommendations regarding the rollout of a paediatric vaccine for 5-11-year olds, we make the following recommendations that can be implemented immediately and which may mitigate the harm detailed above.
- 37. Given the disproportionate risks posed to Maaori children and their whaanau from any transmission of COVID-19 within educational settings, we recommend that schools and early childhood education centres (ECEs) in low-decile areas, in areas with lower vaccination coverage, and those schools and ECEs with a high proportion of Maaori students, receive a greater level of funding and resourcing to implement the above mitigations, and that these mitigations are implemented as a matter of urgency.
- 38. While we note that ventilation can be improved through the opening of doors and windows, this is not a practical solution in winter. Given that the rollout of a paediatric vaccine for 5-11-year olds will not apply to students of ECEs and will not completely mitigate the risk of spread of COVID-19 within schools,⁸¹ we recommend that the Ministry of Education continue to work closely with air quality experts. The provision of devices for CO₂ monitoring and portable air purifiers with HEPA filters to schools and ECEs, with operational guidance provided for schools to support their use, is a matter of urgency before winter arrives.⁸²
- 39. Including ECEs in the provision of devices to monitor CO₂ levels and portable air purifiers with HEPA filters is strongly recommended since children aged 0 3 years of age more readily transmit SARS-CoV-2 to household members than

⁸¹ Steyn, N., Plank, M., Hendy, S. Modelling to support a future Covid-19 strategy for Aotearoa New Zealand. Auckland: Te Puunaha Matatini, The University of Auckland. 2021. Available from https://www.tepunahamatatini.ac.nz/2021/09/23/modelling-to-support-a-future-covid-19-strategy/.

⁸² US Centres for Disease Control and Prevention. Covid-19: Ventilation in Buildings. [Internet].
Updated 2 June 2021. Cited 29 November 2021. Available from
https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html#refphf.

school-aged children,⁸³ and Pfizer vaccine trial data for children <5 years are still awaited.

- 40. We support the ongoing mandatory use of masks in schools for students in Year 4 and older at the Red and Orange tiers of the COVID-19 Protection Framework, which balances the developmental needs of young children with the need to mitigate risk of COVID-19 transmission. Schools should be resourced to provide masks for students and their whaanau who arrive at school unmasked, to reduce any inequities in ability to access masks.
- 41. We recommend that urgent preparatory work is undertaken to enable the use of rapid antigen testing to maximise in-person school days while at the same time reducing the risk of infected students attending. Modelling by the Doherty Institute has found that allowing ongoing school attendance for class contacts of a case through a 'test to stay' rapid antigen testing strategy achieves equivalent outbreak containment to home quarantine and maximises face-to-face learning.⁸⁴

⁸³ Paul, L.A., Daneman, N., Schwartz, K.L., et al. Association of age and pediatric household transmission of SARS-CoV-2 infection. *JAMA Pediatr*. 2021;175(11):1151-1158. doi:10.1001/jamapediatrics.2021.2770. Available from https://jamanetwork.com/journals/jamapediatrics/fullarticle/2783022.

⁸⁴ Doherty Institute. Doherty Modelling – Final Report To National Cabinet. [Internet]. Melbourne: Doherty Institute. 5 November 2021. Cited 29 November 2021. Available from https://www.doherty.edu.au/uploads/content_doc/Synthesis_DohertyModelling_FinalReport_NatCab_05Nov.pdf.



Date:	Tuesday 30 November 2021
Time:	11:00am to 12:00pm
Location:	s 9(2)(k)
Chair:	lan Town
Members:	Elizabeth Wilson, Helen Petousis-Harris, Ian Frazer, James Ussher, Nikki Moreland, Nikki Turner, Peter McIntyre, Sean Hanna, Tony Walls
Ministry of Health Attendees:	Brooke Hollingshead, Caroline McElnay, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Fiona Callaghan, Imogen Roth, Juliet Rumball-Smith, Mariana Traslosheros Reyes, Niki Stefanogiannis, Pippa Scott
Guests:	Hilary Longhurst
Apologies:	David Murdoch, John Tait, Kris Golding, Andi Shirtcliffe, Sue Crengle

2.0 Pfizer Vaccination in 5-11 year-olds

The Science and Technical Advisory team provided an update on COVID-19 and vaccination in 5-11 year olds and discussion followed:

- There is concern that if implemented this will need to be very carefully considered in the context of our current national immunisation schedule, particularly with respect to equity of delivery of all childhood vaccines.
- Noted that including numbers needed to treat to prevent disease and death in children and in 5-11
 year olds would be valuable, noting this is a commonly used statistic
- Noted that children at high risk of severe illness should be prioritised for COVID-19 vaccines
- Identified that a longer than three week interval between doses would be preferable
- STA will continue to assess the evidence and bring it back to CV TAG for discussion

13.0 Agenda items for next meeting

Pfizer Vaccination in 5-11 year-olds

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
68	Decision to Use 5–11- Year-Olds	Review Pfizer's application for 12-to-15-year-olds for evidence on dosages.	Medsafe	19/10 – Action raised

Action Action Act 1989.

RELEASED UNDER THE OFFICIAL MEDICAL PROPERTY OF ACTION ACT 1989.

RELEASED UNDER THE OFFICIAL MEDICAL PROPERTY OF ACTION ACT 1989.



Date:	Tuesday 07 December 2021		
Time:	11:00am to 12:30pm		
Location:	s 9(2)(k)		
Chair:	lan Town		
Members:	Elizabeth Wilson, Helen Petousis-Harris, Ian Frazer, James Ussher, Nikki Moreland, Nikki Turner, Peter McIntyre, Sean Hanna, Sue Crengle, Tony Walls		
Ministry of Health Attendees:	Andi Shirtcliffe, Brooke Hollingshead, Caroline McElnay, Daniel Bernal, Edwin Reynolds, Fiona Callaghan, Imogen Roth, Juliet Rumball-Smith, Mariana Traslosheros Reyes, Pippa Scott		
Guests:	John Tait, Kris Golding, Jin Russell, Danny de Lore, Erik Andersen, Owen Sinclair, Teuila Percival, Marise Stuart, Andrew Simpson, Liam McConnell		
Apologies:	David Murdoch, Chriselle Braganza, Niki Stefanogiannis		

5.0 Pfizer Vaccination in 5-11 year-olds

Guests were welcomed by the Chair and provided an overview of their affidavit to the Waitangi Tribunal about the expected impacts to tamariki Māori and their whānau with the planned shift to the COVID-19 protection framework.

An update was provided on vaccination in 5-11 year olds and discussion followed:

- STA outlined the timeline for decision to use for 5-11 year olds and advised Cabinet will make their decision on 23 December, pending Medsafe approval
- The contribution to the Waitangi Tribunal claim was outlined, noting that tamariki Maori do not always have their views represented due to the small numbers of experts and advocates involved in decision making
- It was noted that if decisions were made for the majority or the average but tamariki Māori were not considered then the health inequities that already exist will be exacerbated
- It was noted that tamariki Māori do not have the same standard of health as other children, as they bear the burden more heavily with co-morbidities, which are linked with poorer outcomes as a result of SARS-CoV-2 infection
- The Māori population is younger and has on average more tamariki in an average household
- Tamariki Māori have a right to an intervention that protects them against a direct harm from a preventable disease, and the right to participate in protecting the people around them
- It was felt that if we do not make the vaccine available we will having rolling outbreaks in tamariki Māori, resulting in isolation, sick caregivers, and whānau in hospital
- The te ao Māori understanding of tamariki as being a part of a whānau and community was highlighted, rather than solely as an individual with only individual benefit
- Additional points were raised from the literature indicating that non-white children are likely to disproportionately be affected by COVID-19 with respect to MIS-C, as well as the loss of a parent/caregiver
- It was outlined that including 5-11 year olds in the vaccination program can strengthen efforts to immunise older Māori people noting whānau will get vaccinated together
- Operational suggestions for the rollout were discussed, and this will be taken to the implementation group with regards to the national immunisation programme
- Delivery of successful vaccinations for 5-11 year olds need to be with Māori health providers and networks and iwi and hapu
- The suggestion of a Māori paediatrician(s) joining CV TAG as a continuing member was made, and supported by the group
- STA will develop a draft memo with recommendations for CV TAG to consider next week

Guests were thanked by the Chair and left the meeting

ACTION: CV TAG chair to consider co-opting additional members to CV TAG for 2022

6.0 Next Steps/Decisions Pending

None noted

8.0	Agend	da Items for Next Meeting Pfizer Vaccination in 5-11 ye	ar-olds					
9.0	New Action Items Raised During Meeting							
	#	Agenda item	Actions	Action Owner				
	79	Pfizer Vaccination in 5-11 year-olds	Consider a Māori paediatrician/s to become a standing member of CV TAG	Chair				
		year-olds	become a standing member of CV TAG	Crian				

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
68	Decision to Use 5–11- Year-Olds	Review Pfizer's application for 12-to-15-year-olds for evidence on dosages.	Medsafe	19/10 – Action raised
79	Pfizer Vaccination in 5- 11 year-olds	Consider a Māori paediatrician/s to become a standing member of CV TAG	Chair	07/12 – Action raised



Memo

Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 5-11 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	15 December 2021				
	13 December 2021				
To:	Dr Ashley Bloomfield, Director-General of Health				
Copy to:	Astrid Koornneef, Director of National Operations, COVID Vaccine Immunisation Programme				
	Allison Bennett, Manager, System Enablers, System Strategy and Policy				
	Dr Caroline McElnay, Director of Public Health				
From:	Dr Ian Town, Chief Science Advisor and Chair of CV TAG				
For your:	Information				

Purpose of report

1. To summarise the CV TAG recommendations on the decision to use the paediatric formulation of the Pfizer mRNA COVID-19 vaccine ('the Pfizer vaccine') for children who are 5 to 11 years of age.

Background and context

- In February 2021, CV TAG advice was sought for use of the Pfizer COVID-19 vaccine in people who were 16 years and over, following Medsafe approval. Cabinet agreed that the COVID-19 Immunisation Programme proceed with the roll out of the Pfizer vaccine, and this has been underway since February.
- 3. In August 2021, CV TAG confirmed support to extend the age of people who can receive the Pfizer vaccine to 12- to 15-year-olds, noting that this would likely lead to a reduction in school closures and disruption to education, and contribute to equitable vaccination coverage in Māori and Pacific peoples.
- 4. Medsafe is assessing an application submitted by Pfizer for the use of a paediatric formulation of the vaccine in 5- to 11-year-olds within New Zealand. The CV TAG recommendations presented here are subject to Medsafe approval and any listed clinical conditions.
- 5. The Ministry's Policy team has sought clinical and scientific advice from CV TAG on the use of the Pfizer vaccine for children who are 5- to 11-years of age. This advice will be considered as



part of the Decision to Use Framework, and alongside policy considerations for the sequencing of the COVID-19 Immunisation Programme.

The COVID-19 vaccine in 5- to 11-year-olds

Phase 2/3 trial findings

- 6. One phase 2/3 randomised control trial was conducted to assess the safety, immunogenicity, and efficacy of two doses of the Pfizer vaccine administered 21 days apart in children aged 6 months to 11 years, with findings published for 5- to 11-year-olds to date [1].
- 7. In the phase 2/3 trial, participants were randomly assigned in a 2:1 ratio to receive two doses of either the Pfizer vaccine at 10 µg (a lower dose than the 30 µg used in older age groups), or a placebo. A total of 2268 children were assigned to receive the Pfizer vaccine (1517 children) or placebo (751 children) [1].
- 8. The trial was run across 81 sites in the US, Spain, Finland and Poland. Overall, 52% were male, 79% were White, 6% were Black, 6% were Asian, and 21% were Hispanic or Latinx. The mean age was 8.2 years; 20% of children had coexisting conditions (including 12% with obesity and approximately 8% with asthma), and 9% were SARS-CoV-2—positive at baseline. Demographic characteristics were similar between the 5- to 11-year-old and 16-to 25-year-old Pfizer recipients who were included in the immuno-bridging subset, apart from younger age and the percentage of Black and Hispanic or Latinx in the 5- to 11-year-old group (6% and 18%, respectively) being lower than in the 16- to 25-year-old group (12% and 36%, respectively) [1].

Safety and reactogenicity

- 9. In the 5- to 11-year-olds, as in other age groups, the Pfizer vaccine had a favourable safety profile, with side effects generally comparable to those observed in 16- to 25-year-olds who received the standard 30 µg doses [1].
- 10. Safety evaluations included assessment of reactogenicity events reported by a parent or guardian using an electronic diary for 7 days after each dose. Data on unsolicited adverse events, including confirmed diagnoses of myocarditis or pericarditis, were collected from the first dose through 1 month after the second dose. Data on serious adverse events will be collected from the first dose through 6 months after the second dose [1]. At data cutoff, the median follow-up was 2.3 months [1].
- 11. Most local reactions were mild to moderate, lasting 1-2 days. Injection-site pain was the most common local reaction, occurring in 71-74% of Pfizer recipients. Fatigue and headache were the most frequently reported systemic events. In general, systemic events were reported more frequently after the second dose than first dose. As compared with adults and adolescents in the pivotal trial, 5- to 11-year-olds reported a higher incidence of injection-site redness (15 to 19%, vs. 5 to 7%) and swelling (10 to 15%, vs. 5 to 8%), but a generally lower incidence of systemic events, including fever (3 to 7%, vs. 1 to 20%) and chills (5 to 10%, vs. 6 to 42%) [1-3].
- 12. From the first dose through to one month after the second dose, adverse events were reported by 10.9% of Pfizer recipients and 9.2% of placebo recipients. Slightly more Pfizer recipients (3.0%) than placebo recipients (2.1%) reported adverse events that were considered by the investigators to be related to the vaccine or placebo [1].



- 13. No vaccine-related serious adverse events were noted in the clinical trial; however, the trial was too small to detect rare side effects such as myocarditis. Three serious adverse events were reported from two participants (postinjury abdominal pain and pancreatitis in a placebo recipient and arm fracture in a Pfizer recipient). None of these were considered to be related to the vaccine or placebo. No deaths or adverse events leading to withdrawal were reported [1]. No cases of severe COVID-19 or Multisystem Inflammatory Syndrome in Children (MIS-C) were reported—a condition associated with COVID-19 where body parts can become inflamed [1, 4]. Lymphadenopathy was reported in 10 Pfizer recipients (0.9%) and 1 placebo recipient (0.1%). No myocarditis, pericarditis, hypersensitivity, or anaphylaxis in Pfizer recipients was reported. Four rashes in Pfizer recipients (observed on the arm, torso, face, or body, with no consistent pattern) were considered to be related to vaccination; the rashes were mild and self-limiting, and onset was typically 7 days or more after vaccination [1].
- 14. No safety data are yet available from the large-scale roll out of the Pfizer vaccine to 5- to 11-year-olds in the USA, though will likely be available by late December 2021 or early January 2022.

Immunogenicity and efficacy

- 15. Immune responses in the single clinical trial conducted were assessed one month after the second dose of the Pfizer vaccine were equivalent to those in 16- to 25-year-olds. Children aged 5-11 receiving two 10 µg doses had a similar, statistically non-inferior, neutralising antibody responses with a geometric mean titre (GMT) of 1,197.6 (95% CI: 1,106.1, 1,296.6) vs 1,146.5 (95% CI: 1,045.5, 1,257.2) for ages 16-25 [1].
- 16. Vaccine efficacy against symptomatic NAAT-confirmed COVID-19 at 7 days or more after the second dose (to a median follow up of 2.3 months at data cut-off) was assessed. Among participants without evidence of previous SARS-CoV-2 infection, symptomatic COVID-19 was reported in three recipients of the Pfizer vaccine and in 16 placebo recipients, producing a vaccine efficacy of 90.7% (95% CI, 67.7 to 98.3) [1].

CV TAG Recommendations

- 17. CV TAG discussed the use of the Pfizer COVID-19 vaccine in children aged 5-11 years at meetings between October and December 2021 and consulted with Māori paediatricians and Māori general practitioners at two meetings in December 2021.¹
- 18. CV TAG noted:
 - a. The direct and indirect impacts on children. Children who have COVID-19 will commonly have few or only mild respiratory symptoms. COVID-19 in this age group is rarely severe or fatal [5, 6], and the rate of severe COVID-19 disease in this age group is the lowest of any age group. However, there is a very small but real risk of MIS-C (described above) at this age which has occurred more frequently among ethnic minorities in the US [4, 7]. A very small proportion of children also experience

¹ CV TAG discussed use of the Pfizer vaccine in the 5-11 age group on: 19 October, 2 November, 9 November, 23 November, 30 November, 7 December, and 14 December.



- persistent illness and ongoing symptoms, though evidence about its incidence is limited.
- b. In the current Delta outbreak in New Zealand (data to 19 November 2021), children aged 5-11 made up 14.9% of cases (1,003/6,714). Eight of these children were hospitalised but none were admitted to ICU. Of those who were hospitalised, all but one had a pre-existing condition and three were in hospital for less than six hours. As a comparison, between 16 June and 13 November 2021 in Sydney, 14,154 cases (19.4%) were aged 0-11 years and not eligible for vaccination. Of these cases, 632 were hospitalised, 9 were in ICU, and 0 patients died. It was not mentioned whether any of these cases had pre-existing conditions or comorbidities. The Sydney data further demonstrates that COVID-19 is relatively mild in most young children as despite accounting for 19.4% of cases in Sydney since 16 June, they account for only 5.9% of hospitalisations, 0.6% of ICU admissions, and no deaths [8].
- c. Children living with pre-existing conditions or comorbidities, from disadvantaged backgrounds, or those living within a lower socioeconomic status have a greater risk of severe disease from COVID-19 [7, 9-11].
- d. Even though the direct effects of infection are generally less severe in children, this should not diminish the significance for those who have experienced worse outcomes [6]. Alongside the direct risks and impacts to health and individuals, COVID-19 also has indirect impacts for children on mental health, wellbeing, education and social development, and these are worsened by lockdowns and school closures [7, 12-14].
- e. Children do play a role in transmission however it is significantly smaller than for adults. Transmission within education settings has occurred but is limited and is more likely to occur between adults [15-17]. Transmission in households is much more common [18, 19]. The benefit of vaccination on onward transmission in households could be lower than in other settings due to the ongoing and close nature of exposure [20, 21], but this is not confirmed. The effect of vaccination of children on household transmission is unknown.
- f. There are a number of equity considerations which are important to consider:
 - i. Māori and Pacific children have been disproportionately affected in the current outbreak. To 19 November 2021, Māori made up 52% of cases in 5- to 11-year-olds, and Pacific children have made up 30% of cases among 5- to 11-year-olds.
 - ii. Māori and Pacific adults are at greater risk of COVID-19 hospitalisation and severe disease. Māori and Pacific adults have respectively 2.5-fold and 3-fold higher odds of being hospitalised compared to non-Māori, and Māori are likely to spend 4.9 days longer in hospital [22, 23].
 - iii. Māori and Pacific children are more likely to live in multigenerational families housed in overcrowded conditions, increasing the risk of transmission. The younger age structure of the Māori population also means that a larger proportion are currently unable to be vaccinated and remain susceptible to infection and transmission, with a risk of onwards transmission to whānau and communities [24, 25], though the risk of transmission from children is lower than from adults.



- iv. The vaccine rollout in adults resulted in inequities for Māori and Pacific adults, and the rollout for Māori and Pacific children aged 5-11 will need close consideration and more tailored implementation. This emphasises the need for culturally appropriate messaging and Māori-led initiatives. Whānau-based approaches to the 5-11 rollout may also improve uptake among Māori adults.
- v. According to a Horizon Research survey, 72% of those who care for 5- to 11-year-olds would allow their child to receive the COVID-19 vaccine, however this was lower among Māori caregivers at 51% [26]. However, we note that the Māori adult rate of uptake and the Māori childhood immunisation rates are much higher than 51%. Given this we believe with a correctly tailored programme, high rates of immunisation in tamariki Māori are achievable.
- g. The paediatric formulation of the vaccine has been approved for emergency use and rolled out in the USA, Canada, and Israel. The Advisory Committee on Immunization Practices (ACIP) made an interim recommendation for the emergency use of the Pfizer vaccine in children aged 5-11 years in the United States for prevention of COVID-19 [6, 27]. This was unanimously supported by the Committee. In making this recommendation, ACIP considered the importance of COVID-19 as a public health problem, as well as benefits and harms, parents' values and preferences, acceptability, feasibility, resource use, and equity for use of the vaccine among children [6, 27]. ACIP additionally stated: "children from racial and ethnic minority groups have experienced a disproportionately high incidence of COVID-19 as well as secondary impacts of the COVID-19 pandemic such as reduced in-person learning"[6]. These comments have high relevance for New Zealand given the similar effects of the pandemic on Māori and Pacific peoples as described above.
- h. In Australia, the Therapeutic Goods Administration (TGA) provisionally approved the Pfizer vaccine as safe and effective for use among this age group on 5 December [28]. ATAGI recommends all 5–11-year-olds be vaccinated with an 8-week interval between doses, and that those at risk of severe disease, Aboriginal and Torres Strait Islanders, and children in crowded conditions or outbreak areas be prioritised [29].
- i. Data are still accumulating from the real-world rollout of vaccines in 5- to 11-year-olds, and there is currently limited safety data available post-second dose. Some adverse events in other age groups (e.g. myocarditis) have only become apparent following widespread rollout, and as noted above the trials in young children are too small to be able to detect rare side effects. Further data on potential side effects from the vaccine rollout in this age group in other countries will become progressively available.
- j. **On coadministration and other vaccines,** there is limited evidence on the safety and immunogenicity of coadministration of the Pfizer vaccine with other vaccines in all populations, however based on first principles of vaccinology it is likely to be safe and effective, particularly in younger age groups.
- k. The wider National Immunisation Schedule has been facing challenges for some time with declining vaccination rates since before COVID-19, and are particularly marked for Māori and Pacific infants and children. Catch-up campaigns for the MMR, HPV and Tdap vaccines were further delayed by COVID-19 and lockdowns. There is a risk that rolling out the Pfizer vaccine in this age group could further adversely impact the wider immunisation programme through diverting public health resources. This



could increase the risk of outbreaks of other infectious diseases. The risk of a significant measles outbreak is of particular concern once the international borders re-open. Vaccination rates are lowest among Māori, and therefore there are equity concerns that there will be greater risk in this population. However, there is also the opportunity to increase coverage with other vaccines with a thoughtfully implemented COVID-19 vaccination programme in this age group.

- between doses of the paediatric formulation of the Pfizer vaccine, however, emerging data in adults suggests that the immune response is likely improved by extending the dosing interval [30, 31]. This is consistent with basic principles of vaccinology and immunology which suggests that immune responses are generally better with longer intervals. There may also be a connection between shorter intervals and increased reactogenicity or adverse events, and one pre-print paper on individuals aged 12 and over has shown a statistically significant increase in myocarditis if the second dose was given at a shorter interval of less than 30 days [32]. Australia and Canada have recommended an 8-week interval between doses for 5-11-year-olds, noting this may improve immunogenicity and reduce side effects. Having a longer interval would also allow greater time to monitor international safety data.
- m. On vaccine requirements, there is a significant risk that use of vaccination mandates or certificates in this age group will result in exclusion and an inability to fully participate in schooling and extracurricular activities. This is likely to inequitably impact communities who are already experiencing disadvantage and where current vaccine coverage is poor. Concerns regarding possible stigmatisation and exclusions could be addressed in ways that do not necessarily influence the decision to use. For example, there could be a policy decision that children cannot be denied access to locations/events on the basis of vaccination status, which could be operationalised by not issuing vaccine certificates for this age group.

19. CV TAG recommended:

- a. Two doses of the paediatric Pfizer vaccine be offered to all 5-11-year-olds in Aotearoa New Zealand, with an 8-week interval between doses.
- Māori and Pacific children, children with high-risk pre-existing conditions, and children living with vulnerable people should be prioritised for vaccination and tailored programmes developed.
- c. On the schedule between doses:
 - i. The interval between doses can be shortened in limited circumstances to a minimum of 3 weeks, such as prior to the initiation of significant immunosuppression or international travel.
 - ii. Children who turn 12 after their first dose should follow the authorised schedule which uses the paediatric primary formulation (10 μ g). They should not be offered the adolescent/adult formulation (30 μ g) of the Pfizer COVID-19 vaccine.
 - iii. Children in this age group who experience a clinically significant adverse event after their first dose should be carefully reviewed by a specialist clinician. An individual risk:benefit assessment should be made on whether to administer the



second dose. Children in this age group are not obliged to receive a second dose if not clinically appropriate.

- d. The paediatric Pfizer vaccine can be administered before, after, or at the same time as other vaccines in this age group.
- e. The adolescent/adult Pfizer vaccine formulation (30 μ g) should not be used in children aged 5-11 years.
- f. Mandates, vaccine certificates or vaccine targets **must not** be used or required for this age group, and children in this age group should not be denied access to locations or events based on their vaccination status. There should be no unintended consequences in terms of participation if children in this age group are not vaccinated, and any use of mandates, certificates or targets that may formally or informally encourage inappropriate exclusion from activities. Exemptions from vaccination should therefore also not be required for this age group. We recommend specific public education campaigns about why children should not be excluded from activities, in order to reduce the risk of informal exclusions.
- g. Specific consideration must be given to promoting and improving vaccine access to groups that have experienced disproportionate COVID-19 morbidity and mortality, as well as those with barriers to routine health care, especially for Māori and Pacific peoples. This could be achieved through using the broad geographic accessibility of pharmacies and expanding school-focused strategies. Whānau centred approaches should be considered within these environments to improve primary vaccination and booster rates in the adult population.
- h. Emphasis must be given to using the rollout of the COVID-19 vaccine as an opportunity to improve delivery and uptake of the wider National Immunisation Schedule, and large-scale events with whānau-based approaches should be organised to aid catch-up campaigns for other vaccines. The coverage of the childhood National Immunisation Schedule should be closely monitored to ensure that the COVID-19 vaccination rollout for this age group does not adversely impact on the uptake of other important childhood vaccines.
- i. In making vaccination available, it should not be solely relied upon and other public health measures in schools and other educational settings should be strengthened, including ensuring good ventilation and filtration of air indoors, use of masks, physical distancing, and promotion of children staying at home if sick.
- 20. CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.
 - a. New Zealand and international safety data will be carefully monitored, and the recommendations here will be reassessed by CV TAG in February 2022 prior to second doses being given to any 5–11-year-olds in Aotearoa New Zealand.
 - b. Advice for severely immunocompromised children who may need a third primary dose will be reconsidered once further evidence emerges on the need, safety, and efficacy.



Recommendations

It is recommended that you:

2. Note this advice has been received.

lan G Town

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Waccine Technical Advisory Group

Signature ____

Dr Ashley Bløomfield

Director-General of Health



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Request for Advice (RfA)



This form contains the details relevant to the questions posed to the Science and Technical Advisory (STA). STA will respond to the request using this form which will also be stored in STA content management system for future reference.

This form, or parts of it, may also be forwarded to other relevant parties as appropriate.

Title	COVID-19 and Vaccination in 5-11-year-olds						
Subject	Supporting evidence to inform dis 11-year-olds	cussions of the risks ar	nd benefits of vaccination in 5-				
Reference No.	330	Date Received	12/11/2021				
Requestor	lan Town	Date Due	22/12/2021				
Advisor	Brooke Hollingshead and Sarah Mitchell	Date Completed	Click or tap to enter a date.				
Peer reviewed by	Pippa Scott and Imogen Roth	TEO,					
Advice issued to	CV TAG						
Approved by	lan Town						
Deliverables	Completed summary of evidence of COVID-19, transmission risk, and vaccination in 5-11-year-olds						
Request Outline	Background/Context Pfizer will be applying for the use of vaccines in 5-11-year-olds to Medsafe, and advice is required from the COVID-19 Vaccine Technical Advisory Group on the risks and benefits of vaccinating this age group, alongside if and where there may be a need for prioritisation.						
	Questions						
	COVID-19 and children						
	How does COVID-19 present in children?						
	What do we know about Delta's impact on children? What is the risk of infantion (severe disease) hearitalization?						
	 What is the risk of infection/severe disease/ hospitalisation? What is the risk of long COVID? 						
	 Who is more at risk of severe outcomes among 5-11-year-olds? What are the individual level risk factors? What are broader social risk factors? 						
	Vulnerable populations in the context of Aotearoa New Zealand						
	Within the Aotearoa New and who would be most a		risk factors are more commo				

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 What impact has the current Delta outbreak had on 5-11-year olds? How many cases have there been? What severity and how many hospitalisations? Who is more at risk?

Transmission

- What is known about the role of children in transmission?
- What is known about transmission in education and household settings?

Non-pharmaceutical interventions for the prevention of COVID-19 in children

- What non-pharmaceutical interventions are available for children to prevent COVID-19?
- What evidence is there on the effectiveness of masks, distancing, cohorting, school closures?

Vaccine

- What is the safety and reactogenicity profile of the Pfizer vaccine for 5-11-yearolds?
- What is known about the risk of myocarditis in 5-11-year-olds? Is there a risk profile/factors other than being male and young? What is there info on and what is there not?
- What is the efficacy of the vaccine in 5-11-year-olds against infection, severe disease and hospitalisation?
- Which countries have approved the vaccine for 5-11-year-olds, who has rolled it out, and what data is available from the real-world rollout?
- Do these countries have any specific guidance in relation to the dosing interval and co-administration?

Risks and Benefits of vaccinating 5 – 11-year-olds in Aotearoa New Zealand

What are the relative risks and benefits of vaccinating 5–11-year-old in New Zealand?

Intended application of advice

To inform discussions at CV TAG and the Decision to Use.

Timeline

CV TAG to review this RfA on 30 November, 7 December, 14 December. Memo to be drafted by 7 December and finalised by 21 December.

What are the implications and considerations of this advice on Te Tiriti o Waitangi and equity?

Equity and Te Tiriti are relevant to assessing who is at risk of infection and severe disease, and who is at greater risk and more vulnerable. It is important to examine the increased burden for Māori and Pacific People within New Zealand, particularly in the Delta outbreak.

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Equity issues are relevant in relation to uptake of public health measures and vaccines, and support options available to people with COVID-19. There may be disparities in who can access services.

Individual risk factors such as prevalence of pre-existing conditions or comorbidities increase the risk of severe COVID-19 disease and hospitalisation, and therefore it will be important to examine which conditions this is true for and where there may be increased vulnerability.

Equity is important to consider in relation to different physical and social environments, with Māori and Pacific People more likely to live in overcrowded housing, multigenerational housing, and more likely to face socioeconomic barriers with access to poor housing.[1] People living in rural communities (especially Māori) are more isolated and inaccessible to healthcare interventions including vaccination clinics. These broader social determinants of health will need to be explored to examine where they may be increased vulnerability to infection.

These risks also need to be balanced against the risks of prolonged school closure on wellbeing and education for young people, the need for access to education, and how this could impact on equity by further increasing current social and economic inequities.

The principles of Te Tiriti o Waitangi provide the framework to guide the health and disability system towards health equity for Māori, and principles of tino rangatiratanga, equity, active protection, options and partnership will be forefront in the research. Tino rangatiratanga and self-determination are important in applying public health measures, and therefore it is essential that autonomy and options are given to communities to protect themselves, and in communicating public health measures. Partnership with diverse Māori communities in developing and communicating risk and public health measures are essential to ensure clear understandings of risk and develop appropriate public health measures tailored to the communities' needs.

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Key Points

- COVID-19 disease is rarely severe or fatal in previously well children between 5 and 11 years of age. However, COVID-19 is still a significant public health issue in this age group. The risk is not negligible, and incidence of the severe post-infection Multisystem Inflammatory Syndrome in Children (MIS-C) is highest in this age group. Current evidence is that children in this age group sometimes experience prolonged symptoms post recovery from SARS-CoV-2 infection (long COVID), but the frequency of this is not well established.
- Children living with pre-existing health conditions or comorbidities, disadvantage, low socioeconomic or minority ethnic status have a greater risk of severe disease from COVID-19.
- Māori and Pacific adults are at greater risk of COVID-19 hospitalisation and severe disease and more likely to live in multigenerational families housed in overcrowded conditions. Access to vaccines has been inequitable for Māori and Pacific adults and access issues for children aged 5-11 in these groups need close consideration.
- Children can transmit the virus, though they appear to play less of a role in transmission than teenagers and adults. Evidence to date has shown that transmission of SARS-CoV-2 in the school environment is more likely to occur between adults, followed by adult-to-child transmission, with lower risks of child-to-child or child-to-adult transmission.
- The phase 3 trial of the lower-dose formulation of the Pfizer vaccine in 5–11-year-olds showed local and systemic side effects generally in the same range as those observed with the full dose in 12-to-15-year-olds. Importantly, fever (7 vs 20%) and antipyretic use (20 vs 51%) after the second dose was less common. No cases of myocarditis were observed, but there was an excess of lymphadenopathy cases (10 (0.9%) vs 1 (0.1%) with the placebo).
- In the same phase 3 trial, vaccine efficacy against symptomatic COVID-19 7 days post-second dose was 90.7%, based on 3 cases in the vaccine group and 16 in the placebo group between 21 and 126 days. No cases were severe, but the number of participants was relatively small, with a total of 1,518 vaccine and 750 placebo participants.
- While there is some urgency for vaccination in order to protect New Zealand's population, the only
 available safety and efficacy data are from the phase 3 trial with 2268 participants. This trial had a
 very limited ability to study rare, but serious, side effects. More data on potential side effects from
 the vaccine roll-out in this age group in other countries would be beneficial in determining the riskbenefit ratio in New Zealand.
- The decision to vaccinate children requires careful weighing of the known and potential risks and benefits. The balance of risks and benefits of COVID-19 vaccination in children is more complex than in adults. In addition to direct potential effects (both positive and negative) from vaccination for this group, there are also potential indirect effects. Indirect benefits include, but are not limited to, the avoidance of school closures and other indirect harms of lockdowns for these children and for other population groups. Indirect potential harms include, but are not limited to, the risk that a COVID-19 vaccination roll out in this group may negatively impact the national immunisation schedule for children.
- If vaccination is offered to this age group, to mitigate against unintended consequences such as stigmatisation and exclusion, children aged 5-11 should not be subject to vaccine mandates and should not have to be vaccinated in order to participate in any of their usual activities, including education, childcare, and recreational activities.

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Introduction

Vaccination of 5 to 11 year olds has begun internationally. Planning is underway for a New Zealand roll-out in this age group if it is approved by Medsafe and Cabinet decides to use it. The COVID-19 Vaccine Technical Advisory Group (CV TAG) also has an important role in the Decision to Use. Their advice is required on the risks and benefits of vaccinating this age group, alongside if and where there may be a need for prioritisation. This RfA collates a wide range of information related to children, COVID-19 and the Pfizer vaccine to inform discussions at CV TAG and the Decision to Use.

COVID-19 and Children

COVID-19 presentation and severity

Children and adolescents who have COVID-19 will commonly have no or only mild symptoms, similar to a cold. Those who are symptomatic generally have a short duration of illness and a low symptom burden. A systematic review of COVID-19 in children conducted early in the pandemic found typical symptoms included fever, cough, a sore throat, blocked or runny nose, sneezing, muscle aches, and fatigue. Changes in smell or taste, diarrhoea and vomiting were less common.[2]

COVID-19 disease in children is rarely severe and significantly less likely to cause death than in adults. However, it is important to bear in mind that COVID-19 in children is still a major public health problem,[3] and that the impact of COVID-19 on children should not be minimised by comparison to the impact experienced in adult populations. Even though the direct effects of infection are generally less severe in children, this does not diminish the significance for those who do experience worse outcomes. On 24 November 2021, the WHO published an interim statement on COVID-19 vaccination for children and adolescents,[4] where they note that overall, there are proportionally fewer symptomatic infections and cases with severe disease and deaths from COVID-19 in children and adolescents, compared with older age groups. Age-disaggregated cases reported to WHO from 30 December 2019 to 25 October 2021 show that older children and younger adolescents (5 to 14 years) account for 7% (7,058,748) of reported global cases and 0.1% (1,328) of reported global deaths. Milder symptoms and asymptomatic presentations may mean less testing in these groups, and cases may go unreported.[4] A systematic review and meta-analysis including over 350 studies from between January 2020 and April 2021 estimated that the percentage of cases that never developed clinical symptoms (i.e. truly asymptomatic, rather than pre-symptomatic), was 35.1% (95%CI: 30.7 to 39.9%). Asymptomatic infection was higher among children, at 46.7% (95%CI: 32.0 to 62.0%).[5] A study of 2,143 clinically diagnosed or laboratory confirmed cases among children found that more than 90% were asymptomatic or had mild or moderate disease. [6] The prevalence of severe and critical disease was 10.6% in children aged <1 at diagnosis, 7.3% in those aged 1-5 years, 4.2% in those aged 6-10 years, 4.1% in those aged 11-15 years, and 3% in those aged 16-17 years.[6] When severe COVID-19 occurs in children, it is usually characterised by pneumonia and respiratory distress, and may lead to admission to hospital or intensive care.[7]

Two longer term risks or consequences of SARS-CoV-2 infection might be more of a concern in this age: Multisystem inflammatory syndrome in children (MIS-C, also known as Paediatric Inflammatory Multisystem Syndrome temporally associated with SARS-CoV-2, or PIMS-TS) and long COVID (discussed below).

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The Delta variant does not appear to cause more severe disease than previous variants, but because it spreads faster, the number of children who will develop severe disease and go to hospital will be greater.[7] In addition, in areas where an increasing percentage of adults are fully vaccinated but where children are not vaccinated, there are likely to be relatively more infections among children.[7, 8]

Initial reports through the media from South Africa indicate that the Omicron variant is resulting in a disproportionately large number of children being admitted to hospital with COVID-19, particularly in the under 5 age group, however evidence on this is still emerging. [9]

Multisystem Inflammatory Syndrome in children (MIS-C)

MIS-C is a very rare but serious condition that can occur approximately one month after COVID-19, causing inflammation in different parts of the body.[10] Children and adolescents with MIS-C usually have a fever, rash and abdominal pain. Severe MIS-C may cause inflammation of the heart muscle, and this may result in low blood pressure. Some MIS-C patients do not require treatment, but patients with more severe disease often need admission to an intensive care unit.

MIS-C has caused deaths among a small proportion of children overseas, mainly early in the pandemic. However, increased awareness of MIS-C has allowed for earlier diagnosis, more appropriate treatments and improved outcomes. MIS-C can occur even in those with no symptoms from initial COVID-19 infection. In 2021, almost all children with MIS-C have recovered fully, and the long-term outcomes appear good, with resolution of the inflammation of the heart.[7, 10] In the US, evidence has shown that MIS-C occurs more frequently among marginalised Black, non-Black Hispanic, Pacific and indigenous children compared to white children, and similar inequities may occur for Māori and Pacific children [11, 12]. As of 4 October 2021, the CDC had received reports of 5,217 cases of MIS-C; 44% of MIS-C cases were in children aged 5–11 years.[3]

Long COVID in children

For some people COVID-19 can lead to persistent illness, with ongoing and often debilitating symptoms.[13-15] Long COVID is a generic term used to describe signs and symptoms that continue or develop after acute COVID-19. Symptoms of long COVID are wide ranging, and the World Health Organization has recently developed a clinical case definition of post COVID-19 conditions by a Delphi consensus:[16]

Post COVID-19 condition occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms and that last for at least 2 months and cannot be explained by an alternative diagnosis. Common symptoms include fatigue, shortness of breath, cognitive dysfunction but also others and generally have an impact on everyday functioning. Symptoms may be new onset following initial recovery from an acute COVID-19 episode or persist from the initial illness. Symptoms may also fluctuate or relapse over time.

The WHO notes that a separate definition may be applicable for children.

Long COVID in children is not well described, and the studies to date have generally been of poor quality, with some major limitations (such as a lack of a clear case definition, arbitrary follow up time points, subjective assessment, lack of control groups, and low response rates).[7, 17] Evidence is predominantly limited to select populations without control groups.[18] Relatively few studies have focused on SARS-CoV-2 infection sequelae in children and adolescents, and large, harmonised longitudinal studies are

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needed.[19] Persistent illness in children has been noted in some studies and in patient support groups, but its prevalence, characteristics and duration are unclear.[20, 21]

Estimates of the prevalence of long COVID in children vary widely.[17] The variability in prevalence estimates could be due to a range of factors, such as initial SARS-CoV-2 infection severity, different methodological approaches (clinical assessment vs self-report), definition of cases (diagnosed vs suspected), variable follow-up times, and prevalence of pre-existing clinical conditions.[18] In the U.S, a large long-term study of the impacts of COVID-19 on children has recently begun. It will track up to 1,000 children and young adults and evaluate the impacts on their physical and mental health over three years.[14] Some studies suggest that long COVID in children is less common and tends to be less protracted than in adults. [22]

Some of the studies of long COVID in children include:

- A review of studies of long COVID in children and adolescents identified 14 heterogeneous studies
 (4 cross-sectional, 9 prospective cohort, 1 prospective cohort) investigating long COVID symptoms
 in a total of 19,426 children and adolescents. The prevalence of long COVID symptoms varied from
 4% to 66%, and there was also large variation in the reported frequency of different symptoms.
 Zimmerman et al (2021) note that all the studies in their review were likely to have been conducted
 before the delta variant became dominant, which may have a different risk of long COVID.[17]
- A recent pre-print describes a German study of 157,134 individuals (11,950 children/adolescents and 145,184 adults) with confirmed COVID-19.[23] The COVID-19 and control cohorts were well-balanced regarding covariates. For all adverse health outcomes combined, incidence rates (IRs) in the COVID-19 cohort were significantly higher than those in the control cohort in both children/adolescents. Incidence rate ratio (IRR) estimates were similar for the age groups 0-11 and 12-17. Incidence rates in children/adolescents were consistently lower than those in adults. Among the specific outcomes with the highest IRR and an incidence rate of at least 1/100 person-years in the COVID-19 cohort in children and adolescents were malaise/fatigue/exhaustion, cough, and throat/chest pain.
- The UK Office of National Statistics found that 9.8% of children aged 2–11 years and 13% aged 12–16 years reported at least one ongoing symptom five weeks after a positive diagnosis, whereas 25% of adults aged 35–69-year had symptoms five weeks after a positive diagnosis. [24, 25]
- A paper describing data from the UK COVID Symptom Study (a citizen science project with data collected via an app, which has some associated limitations) found that of 1,734 children aged 5-17 years who were symptomatic at the time of their positive test and reported symptoms regularly for at least 28 days, 4.4% had an illness duration of at least 28 days.[20] Ongoing symptoms for at least 28 days was less common in younger children aged 5-11 years (3.1%, p=0.046). Over 98% of 1,379 children had recovered by 56 days.[20] Using apps is likely to select participants from higher socioeconomic background, who have a lower risk of poor outcomes.[17]
- One of the earliest studies on long COVID in children (a cross-sectional study of 129 children in Italy who were diagnosed with COVID-19 between March and November 2020) reported that 42.6% of children surveyed had 1 or more symptoms >60 days post infection. [26] This included children with mild or asymptomatic initial infection.
- A cohort study of 136 children (most of whom had mild or asymptomatic COVID-19) in Melbourne in 2020 observed that 8% of children had post-acute symptoms. They found that full recovery

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occurred within weeks of acute symptom onset and reported symptoms were mild in severity, but noted this was a young cohort (median age three years).[22]

Long-term SARS-CoV-2 infection—associated symptoms can be difficult to distinguish from pandemic-associated symptoms. [7, 17] Some studies have found that children who tested negative for COVID-19 have had similar symptoms, which are common after other viral infections, and could also be due to the experience of lockdown and other social restrictions. [27, 28] Given that acute COVID-19 generally poses a low risk to children, an accurate determination of the risk of long COVID is important in the debate about the risks and benefits of vaccination in this age group. [17] Similar to adults, it is likely that long COVID in children may have a greater impact on those from socioeconomically disadvantaged areas and ethnic minortity groups. [19]

In summary, "the relative scarcity of studies of long COVID and the limitations of those reported to date mean the true incidence of this syndrome in children and adolescents remains uncertain. The impact of age, disease severity and duration, virus strain, and other factors on the risk of long COVID in this age group also remains to be determined." [17] However, even if the proportion of children experiencing post acute impacts is relatively low, if transmission is widespread then the impact of persisting symptoms will be considerable.

At-risk and vulnerable children

Children living with pre-existing health conditions or comorbidities, disadvantage, low socioeconomic or minority ethnic status have a greater risk of severe disease from COVID-19.[7] Paediatric studies have found comorbidities that increase the risk of severe COVID-19 include, but are not limited to: cancer, obesity, chronic respiratory disease, chronic kidney disease, cardiovascular disease, neurological disorders, immune disorders, metabolic disease and hematologic disorders.[29-31] A systematic review of children and adolescents analysing 42 studies that included 275,661 without comorbidities and 9,353 with comorbidities found that severe COVID-19 occurred in 5.1% of those with comorbidities, and in 0.2% without. There was also a higher risk of COVID-19 associated mortality in those with comorbidities (relative risk ratio 2.81, 95% CI 1.31 - 6.02; I² = 82%).[29]

One meta-analysis found comorbidities in children with the highest risk (in terms of relative risk) include obesity, asthma or chronic respiratory disease, cardiovascular disease, neurologic or neuromuscular disorders, immune disorders, or metabolic disease.[4, 32] Another systematic review identifying predictors of unfavourable prognosis of COVID-19 in children and adolescents found an association with congenital heart disease, chronic pulmonary disease, neurological diseases, obesity, MIS-C, shortness of breath, acute respiratory distress syndrome, acute kidney injury, gastrointestinal symptoms, elevated C-reactive protein and D-dimer.[32] Children with obesity had a relative risk ratio of 2.87 (95% CI 1.16 - 7.07; I2 = 36%).[29] A Scottish study of over 750,000 school-aged children found that 5–17 year olds with poorly controlled asthma (who have been hospitalised with asthma or prescribed two or more courses of oral steroids for asthma within the past two years) are between three to six times more likely to be hospitalised with COVID-19 compared to those without asthma.[33] A recent multinational cohort study (pre-print) of 403 COVID admissions found that in age-stratified adjusted analyses, neurological disorder was associated with disease severity in children under 12 years of age.[34] There is also a strong argument for vaccinating children and adolescents who live with immunosuppressed or other high-risk household members, not only for the protection of the latter but also to benefit the mental health of the former.[35]

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The ECDC notes that the presence of an underlying condition among children aged 5-11 years is associated with about 12 times higher odds of hospitalisation and 19 times higher odds or of ICU admission.[36] However, the majority (78%) of hospitalised children of this age had no reported underlying medical condition.

Indirect impacts of COVID-19 on children

Given the knowledge of the often-mild nature of COVID-19 in children, the Murdoch Children's Research Institute has argued that the main risks to children and adolescents' health in this pandemic continues to be due to indirect effects on mental health, wellbeing and education, which are worsened by continued lockdowns and school closures.[7, 37] Negative impacts of the pandemic, including effects of school closures, have impacts on communities, families and children.

Studies are continuing to emerge that highlight the negative effects of the pandemic on the mental health of children and adolescents. The pandemic limits opportunities for social connection and physical activity while increasing loneliness, uncertainty, fear, and boredom.[19] The WHO has also identified that children have been disproportionately affected by COVID-19 control measures, particularly due to school closures.[4]

Closure of daycares and schools may not only have affected educational outcomes, but also had an effect on social and emotional wellbeing of children through physically being disconnected to schools, with these impacts even more severe for children living with disadvantage.[38, 39] A New Zealand study found that hospital avoidance and reduced access to primary and secondary care were associated with significant potential harm for children in New Zealand during the first lockdown.[40]

Adverse childhood experiences, including family violence, nonaccidental trauma and mental illness, are expected to increase during lockdowns and worsen during the anticipated economic recession. Employment and financial instability as a result of service closures or economic recession also has flow-on effects to children.[41, 42]

Aside from an educational setting, children are also impacted by COVID-19 if a parent or caregiver is hospitalised or dies due to COVID-19. These outcomes result in psychological and socioeconomic harms. It is estimated that more than 1.1 million children worldwide would have experienced the death of a primary parent or caregiver grandparent after the first year of the COVID-19 pandemic.[43] Importantly, indigenous and ethnic minority children are up to 4.5 times more likely to lose a parent or caregiver due to COVID-19 compared to white children.[44] In the United States, 140,000 children are estimated to have lost a parent or grandparent caregiver, with an estimated 1/753 white children, 1/412 Hispanic children, 1/310 Black children, and 1/168 indigenous children experiencing this loss.[44] These losses are likely to be similarly inequitable in Aotearoa New Zealand.

Aotearoa New Zealand context

COVID-19 infections, hospitalisations and deaths in children aged 5-11 years in New Zealand Delta outbreak

To 19 November 2021, children under 12 made up 22.9% of cases in the current Delta outbreak (1,538/6,714), and there had been 1,003 5–11-year-old children who tested positive for SARS-CoV-2 (14.9% of cases, 1,003/6,714). Data about these cases are shown in Table 1.



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Currently, the Ministry of Health's Public Intelligence team cannot specify why the COVID-19 positive cases among 5-11-year-olds were hospitalised, and it is possible that some were in hospital for a reason other than COVID-19. As an estimate of the severity of the hospitalisation event, it is possible to look at length of stay, if they were ever admitted to ICU, and to look at the list of symptoms and comorbidities for each case. All but one case had pre-existing conditions, which included a respiratory disorder (asthma). However, this and the other cases were never admitted to ICU. Four cases had unknown lengths of stay, while three stayed in hospital between 4 and 6 hours. Of note, one case is recorded staying in hospital for 14 days -- but once again this cannot be attributed to COVID-19. No cases showed symptoms at the time of diagnosis apart from one, and none showed serious respiratory symptoms such as dyspnoea (shortness of breath). If needed, any further medical and hospitalisation details should be obtained from local DHB and PHU authorities

Table 1: SARS-CoV-2 infection in children aged 5-11 years in New Zealand (Delta outbreak, data from August 17th - November 19th 2021)

Characteristic		Number of cases (N =1,003)	% of total
Number of Syn	nptoms ¹		
	0 symptoms	832	83
	1 symptoms	62	6
	2 symptoms	59	6
	3 symptoms	31	3
	4 symptoms	14	1.4
	5 symptoms	5	0.5
Hospitalised ²		OK.	
	yes	8	1
	no	995	99
Number of co-morbidities ³			
	0 comorbidities	982	98
	1 comorbidities	18	2
	2 comorbidities	2	0.2
	3 comorbidities	1	0.1
Ethnicity ⁴			
0	Maori	521	52
	Pacific Peoples	304	30
	European or Other	130	13
	Asian	33	3
	Unknown	15	1
Socioeconomic	deprivation		
	1 (least deprived)	26	3
	2	22	2

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3	26	3
4	35	3
5	39	4
6	54	5
7	81	8
8	102	10
9	238	24
10 (most deprived)	367	37
Unknown	13	10

Includes cardiovascular disease, chronic lung disease, diabetes, immunodeficiency, malignancy, liver disease and renal failure

As a comparison, between 16 June and 13 November 2021 in Sydney, 14,154 cases (19.4%) were aged 0-11 years and not eligible for vaccination. Of these cases, 632 were hospitalised, 9 were in ICU, and 0 patients died. It was not mentioned whether any of these cases had prexisting conditions or comorbidities. The Sydney data further demonstrates that COVID-19 is relatively mild in most young children as despite children aged 0-11 years accounting for 19.4% of cases in Sydney since 16 June, they account for only 5.9% of hospitalisations, 0.6% of ICU admissions, and no deaths.[45]

This data shows that the burden of COVID-19 has disproportionately affected Māori and Pacific Peoples aged 5-11, which intersects with socioeconomic deprivation reported for these cases. This mirrors the wider shift in the ethnic groups affected by COVID-19 in Aotearoa, with the outbreak now dominated by those of Māori descent, with 43% of cases identifying as Māori, and 32% of hospitalised cases identifying as Māori.

At-risk groups and vulnerable children in Aotearoa New Zealand

There is limited data on the prevalence of serious health conditions in children in Aotearoa New Zealand. In the 2020 New Zealand Health Survey, 2.1% of under 14-year-olds (estimated 20,000 children) were rated as having poor or fair health by their parents. The percentage rating varied considerably between regions and socioeconomic area. Northland (3%), Tairāwhiti (3.1%), Lakes (3.4%), Hawkes Bay (4.9%) Hutt Valley (4.2%), and the West Coast (5.2%) had the highest rates of children and young people experiencing poor health. [46] There is considerable overlap between areas with poor child health and areas with low vaccination rates. Nationally, as of 19th November 2021, 82% of eligible people are fully vaccinated while 73% are fully vaccinated in Northland, 72% in Tairāwhiti, 75% in Lakes, and 75% in the West Coast.

In adults, risk factors for poor outcomes associated with COVID-19 include respiratory disease and obesity. According to data from the 2020/2021 New Zealand Health Survey, New Zealand has a high prevalence of childhood asthma, with 11.9% (101,000) of children aged 2–14 years reporting taking current asthma medication (though this number is lower than previous years which ranged from 13-15%, and recruitment for the study was impacted by COVID-19 lockdowns).[47] OECD statistics indicate New Zealand has one of the highest hospital admission rates for asthma of OECD countries, and these rates are higher among

² Symptoms at time of diagnosis

³ Includes hospitalisation of any duration (hours to days)

⁴ This is prioritised ethnicity (prioritised order Māori, Pacific, Asian and European/Other)

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Māori, Pacific, and in more deprived areas.[48] New Zealand also has a high prevalence of obesity, with 12.7% (107,000) children aged 2–14 years classified as obese in the 2020/2021 New Zealand Health Survey (with a BMI equivalent to an adult BMI of 30 or greater).[47] Prevalence of obesity also increases in the most deprived living areas with quintile five prevalence at 18.7%. Pacific children are nearly three times as likely to be obese (28.8%).[46]

The other high-risk factor for poor outcomes in the adult population is being disabled, particularly for learning or intellectual disabilities. Ministry of Education enrolment data indicates that at 1 July 2020, there were 10,160 students receiving Ongoing Resourcing Support (ORS) for high or very high educational support needs, with the regions of Auckland (3,359), Waikato (1,019) Wellington (1,050), and Canterbury (1,091) providing education for the bulk of these students.[49] Māori and Pacific students were significantly over represented in these enrolments.[49] Higher Māori enrolment rates are possibly due to a notable increase in tamariki Māori starting school with serious disability in the last 10 years.[50] Child poverty statistics show that 1 in 5 disabled children live in material hardship, two and a half times more often than children who are not disabled.[51]

Māori and Pacific adults are also at greater risk of hospitalisation due to COVID-19 and severe COVID-19, with an 80-year-old patient with COVID-19 who is NZ European/Other without reported comorbidities having the same predicted risk of hospitalisation as a 59.3-year-old (95%CI, 46.9–73.7) patient who is Māori without reported comorbidities. [52] Similar differences are seen across all ages and for cases with at least one reported comorbidity, and therefore it is likely to also be represented in children. Steyn et al. found that Māori have 2.5 times higher odds of being hospitalised (95%CI, 1.39-4.51) than non-Māori and are likely to spend around 4.9 days longer in hospital than other ethnicities, even after controlling for age and pre-existing conditions, while Pacific People have three times greater odds (95%CI, 1.75-5.33).[52] There are an estimated 115,562 tamariki Māori aged 5 to 11 years in Aotearoa, and an estimated 49,398 Pacific children.[53] This amounts to over 160,000 children that are likely at higher risk by virtue of their ethnicity.

In New Zealand, factors which increase the risk of transmission include social deprivation, quality of housing, fuel and heating, poverty and household crowding, and each of these are also more likely to affect Māori and Pacific People.[1] One in five Māori live in overcrowded housing compared to one in 25 New Zealand European.[54]

If and when vaccination does roll out, risk will be higher among areas with low uptake among 5-11-year-olds and examining the uptake of other childhood vaccinations may indicate where there is greater risk of this occurring. Over the last decade there has been increasing concern about falling rates of immunisation for many infectious diseases, and the widening inequities and gaps in immunisation coverage rates in Aotearoa New Zealand.[55] In a 10 year immunisation coverage analysis, Marek et al. showed that although the least deprived regions have the highest immunisation coverage, there was a declining trend in coverage rates over 2006-2017 in high decile regions. Immunisation coverage was lowest in the most deprived areas with the northern part of the South Island, the central-southern part of the North Island, around Auckland, and Northland most negatively impacted by this. Additionally Māori tamariki were more likely to not be fully immunised.[55] The younger age demographic of the Māori population also means that a relatively larger proportion of Māori compared to the wider population are children who are unable to be vaccinated at present and remain susceptible to infection, with a risk of onwards spread to their whānau and communities. Not only does the Māori population have a younger age structure, but Māori whānau often have more tamariki and live in intergenerational households, alongside experiencing disproportionate levels of socioeconomic inequality.[1, 54] According to a Horizon Research survey, 72% of those who care



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for 5- to 11-year olds would allow their child to receive the COVID-19 vaccine, however this was lower among Māori caregivers at 51% [56].

Transmission

During the early pandemic, children were rarely identified as index cases of household transmission clusters, [57] though this was likely influenced by the closure of schools and lockdowns. Meta-analyses from 2020 gave some support to the hypothesis that children are less susceptible to SARS-CoV-2 infection, though their infectivity and overall role in transmission was less clear. [57, 58] However, with schools reopening and extracurricular activities resuming, outbreaks have demonstrated that children do play a role in transmission, though likely less of a role than adults. ATAGI notes that available evidence suggests that the transmissibility of infection in younger children is lower than in older age groups. [56]

Children and young people have become more prevalent in positive case numbers in many countries as the pandemic has progressed,[59] and this population group is also being recognised as a growing community 'reservoir' for the virus.[60] Since the Delta variant emerged, the USA has recorded cumulative increases of childhood cases in most states each week - a trend that is just abating in October after three months.[61] In July 2021 the ECDC updated its assessment of the susceptibility of children to SARS-CoV-2 infection, now noting that children appear to be equally susceptible to SARS-CoV-2 infection compared to other age groups (low confidence), although severe disease is much less common in children than in adults [8]. They note that while multiple studies have suggested that children may be less susceptible to SARS-CoV-2 infection than adults, potential reporting biases due to lower-case ascertainment in children may contribute to this interpretation, particularly for studies published during 2020. Recent prevalence and seroprevalence studies have tended to conclude that there are no significant differences across age groups. However, they note that cases of SARS-CoV-2 in younger children appear to lead to onward transmission less frequently than cases in older children and adults.

Transmission in education settings

Within education settings, transmission of SARS-CoV-2 occurs but appears to belimited. Transmission of SARS-CoV-2 in schools appears to be affected by how widespread the virus is in the broader community.[62-64] The CDC notes that although outbreaks in schools can occur, multiple studies have shown that transmission in school settings is typically lower than – or at least similar to – levels of community transmission, when prevention strategies are in place in schools. [65]

Overall, in the school environment, transmission is more likely to occur between adults, followed by adult-to-child transmission, with the risks of child-to-child or child-to-adult transmission being considerably less.

- An investigation of SARS-CoV-2 transmission in a Georgia school district during December 1, 2020— January 22, 2021, identified nine clusters of COVID-19 cases involving 13 educators and 32 students at six elementary schools. Two clusters involved probable educator-to-educator transmission that was followed by educator-to-student transmission in classrooms and resulted in approximately one half (15 of 31) of school-associated cases. The paper concluded that educators might play a central role in in-school transmission networks.[63]
- Data from a prospective, cross-sectional analysis from the UK's national surveillance also found the majority of cases were in staff. Following the reopening of educational settings during the summer mini-term from 01 June-21 July 2020, staff were found to have an increased risk of infection. Staff



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had higher incidence than students (27 cases [95%CI, 23–32] per 100,000 per day among staff compared with 18 cases [14–24] in early years students, 6.0 cases [4.3–8.2] in primary school students, and 6.8 cases [2.7–14] in secondary school students]), and most cases linked to outbreaks were in staff members (154 [73%] staff vs 56 [27%] children of 210 total cases). The probable transmission direction for the 55 confirmed outbreaks was: staff-to-staff (n=26), staff-to-student (n=8), student-to-staff (n=16) and student-to-student (n=5).[64, 66]

• Data from New South Wales shows that the largest risk to children in schools is from adults. There were 59 individuals (34 students [57.6%] and 25 staff members [42.3%]) from 51 educational settings (19 schools and 32 ECEC services) confirmed as primary COVID-19 cases who had an opportunity to transmit SARS-CoV-2 to others in their school or early childhood centres. 2,347 individuals (1,830 students [77.9%] and 517 staff members [22.0%]) were identified as close contacts of these 59 primary cases. 106 secondary cases (69 students and 37 staff members) occurred in 19 of the 51 educational settings resulting in a secondary attack rate (SAR) of 4.7%. The highest transmission rate occurred between staff members (16.9%). The rate was low in primary schools (1.7%), however this would have been affected by many primary schools being closed. Early childhood education centres remained fully open during the report period, and there was an overall SAR of 6.4%. When transmission did occur to children, the household tertiary attack rates following exposure to a secondary case from a school was 70.7%.[67] Figure 1 provides a breakdown of transmission routes and the associated risks.

Primary case type	Close contact type	n positive NAT/N tested	Attack rate (%)
		Overall	
Any	All	106/2253	4.7%
Adult	All	88/1027	8.6%
Adult	Adult	33/294	11.2%
Adult	Child	51/733	7.0%
Child	All	21/1316	1.6%
Child	Adult	4/274	1.5%
Child	Child	17/1042	1.6%
	Hig	h schools	
Any	All	0/202	0.0%
	Prima	ary schools	
Any	All	9/526	1.7%
Adult	All	3/162	1.9%
Adult	Adult	0/60	0.0%
Adult	Child	3/102	2.9%
Child	All	9/454	2.0%
Child	Adult	2/86	2.3%
Child	Child	7/368	1.9%
	ECE	C services	
Any	All	97/1515	6.4%
Adult	All	85/823	10.3%
Adult	Adult	33/195	16.9%
Adult	Child	51/628	8.1%
Child	All	12/692	1.7%
Child	Adult	2/151	1.3%
Child	Child	10/541	1.8%

Note: For one primary school where both a staff member and student were co-primary cases, the close contacts have been counted in attack rate calculations for both categories of primary cases.

Figure 1: Secondary attack rates in NSW educational settings, by primary and secondary case type and educational setting type, between 16 June and 31 July 2021 [67]

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Transmission in household settings

Transmission within households is common. This is where the greatest risk of transmission is due to the ongoing and close nature of exposure. Pre-Delta, the risk of transmission to a household contact was approximately 30%, however the risk ranged in studies between 10% and 60%.[68-71] This will be higher with the Delta variant, with transmission to households occurring with most cases in the current Delta outbreak. Pre-Delta, children under the age of 10 appeared to be about half as susceptible to infection,[72-75] though in a household cohort study, Li et al. found the secondary attack rate was even lower for children, at 4% compared with 17.1% for adults.[76]

Children were also at a lower risk of transmission or being the index case in households. [74, 77] However, one study suggests that children and adolescents are more likely to infect others. [78] Another study reported that household transmission was more common from children aged 0–3 years than from children aged 14–17 years. [79]

New data from the Imperial-led REACT coronavirus monitoring programme found the highest prevalence was found in children aged 5-12 years at 5.85% (1 in 17), followed by secondary school-aged children aged 13-17 years at 5.75%. Prevalence was also more than four times higher in households with one or more children at 3.09%, compared to those without children (0.75%).[80]

Modelling impact of vaccination of 5-11 year olds on case numbers in New Zealand

The Ministry is undertaking ongoing internal modelling studies. The model considers vaccination of 5 to 11-year-olds in a subset of the scenarios. Assuming roughly 50% uptake in this group and the same vaccine effectiveness as in older age groups, preliminary analysis suggests that vaccination of 5-11 year-olds could substantially decrease transmission, resulting in half as many cases, hospitalisations and deaths.

Non-pharmaceutical interventions for the prevention of COVID-19 in children

Given that aerosol transmission is a key mechanism for spread of SARS-CoV-2, there is increasing focus on the need for strategies such as optimising ventilation, air quality and mask wearing. OzSAGE (a multidisciplinary group of experts in Australia) recommends the following strategies to help protect children from SARS-CoV-2 infection:[81]

- Vaccinating eligible children, their parents and teachers as soon as possible
- Ensuring access to safe indoor air through ventilation and filtration
- Using high quality masks for children and teachers in schools
- Providing families flexible learning options so they can make their own decisions about their children attending school in-person.

The ECDC [62] recommends the following measures to prevent the spread of infection in schools (adapted to levels of community SARS-CoV-2 transmission as well as to the education setting and age group):

- Physical distancing (by cohorting, ensuring physical distance in the classroom, reducing class sizes, staggering arrival and break times, and holding classes outdoors)
- Improved ventilation
- Promotion of 'stay-at-home' when sick policies
- Promotion of respiratory etiquette
- Regular hand-washing
- Use of masks when feasible.

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In addition, testing strategies for educational settings aiming at timely testing of symptomatic cases are recommended to ensure isolation of cases and tracing and quarantine of their contacts.[8] The ECDC notes that the decision to close schools to control the COVID-19 pandemic should be used as a last resort, given the negative physical, mental and educational impacts on children and the economic impact on society more broadly[6]: "While a measure of last resort, school closures can contribute to a reduction in SARS-CoV-2 transmission, but are by themselves insufficient to prevent community transmission of COVID-19 in the absence of other non-pharmaceutical interventions and the expansion of vaccination coverage. The effectiveness of school closures appears to have declined in the second wave as compared to the first wave of the COVID-19 pandemic, possibly in part due to better hygiene measures in school settings."

Evidence from the United States shows wearing masks in classrooms may reduce the chance of transmission. After adjusting for potential described confounders, the odds of a school-associated COVID-19 outbreak in schools without a mask requirement were 3.5 times higher than those in schools with an early mask requirement (OR = 3.5; 95% CI = 1.8–6.9).[82] Another MMWR analysis indicated that increases in paediatric COVID-19 case rates during the start of the 2021–22 school year were smaller in U.S. counties with school mask requirements than in those without school mask requirements.[83]

A recent systematic review has investigated the effectiveness of public health measures in reducing the incidence of COVID-19, SARS-CoV-2 transmission, and COVID-19 mortality, focussing only on empirical studies.[84] They noted two studies [85, 86] that assessed the effectiveness of school closures on incidence of COVID-19 or COVID-19 mortality. Both were rated at moderate risk of bias.[84] One of these studies was a US population-based time series analysis conducted in 2020, and it found that school closure was temporally associated with decreased COVID-19 incidence (adjusted relative change per week, –62%) and mortality (adjusted relative change per week, –58%).[86] States that closed schools earlier, when the cumulative incidence of COVID-19 was low, had the largest relative reduction in incidence and mortality. However, some of the reduction could have been related to other concurrent pharmaceutical interventions.[87] On the other hand, time series analyses to evaluate the effectiveness of school closure in Japan found no effect on the incidence of COVID-19.[85]

The systematic review identified three studies investigating the impact of school closures on transmission, all rated at moderate risk of bias.[84] The review notes that two natural experiments from the US reported a reduction in transmission (i.e., reproductive number); One study reported a reduction of 13% (relative risk 0.87, 95% CI 0.86 - 0.89) and another reported a 10% reduction(0.90, 0.86 to 0.93). It also cites a Swedish study that reported an association between school closures and a small increase in confirmed SARS-CoV-2 infections in parents (odds ratio 1.17, 95% CI 1.03 to 1.32), but observed that teachers in lower secondary schools were twice as likely to become infected than teachers in upper secondary schools (odds ratio 2.01, 95% CI 1.52 to 2.67).

Another study experimentally evaluated the impact of ventilation on aerosol dynamics and distribution, along with the effective filtration efficiency (EFE) of four different mask types, with and without mask fitters, in a classroom setting.[88] They reported that infection probability estimates indicate that ventilation alone is not able to achieve probabilities <0.01 (1%). The use of moderate to high EFE masks reduces infection probability, by >5× in some cases. Reductions provided by ventilation and masks are synergistic and multiplicative.

A retrospective cohort study from the US investigated the effectiveness of 3 versus 6 ft of physical distancing for controlling spread among primary and secondary students and staff.[89] Student case rates

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were similar in the 242 districts with ≥ 3 versus ≥ 6 ft of physical distancing between students (IRR, 0.891; 95% confidence interval, .594-1.335); results were similar after adjustment for community incidence (adjusted IRR, 0.904; .616-1.325). Cases among school staff in districts with ≥ 3 versus ≥ 6 ft of physical distancing were also similar (IRR, 1.015, 95% confidence interval, .754-1.365).

A recent study used epidemiological models to simulate the spread of SARS-CoV-2 among students, teachers, and staff in both primary and secondary schools and applied these to better understand the risks of reopening schools and to explore the effectiveness of different mitigation strategies.[90] They reported that the risk of school outbreaks increases as community prevalence increases, and that secondary schools pose greater control challenges than primary schools. The models indicate that a number of measures can help substantially: dividing students into multiple cohorts who attend school on an alternating basis, frequently testing teachers and students, and vaccinating teachers and staff. The authors emphasise that basic transmission control strategies such as mask use, social distancing, and ventilation remain essential.[90]

Prior to COVID-19 vaccines being available for children, UNICEF and WHO developed guidance on how to minimise transmission in schools and keep schools open.[4] These recommendations are still applicable, even with vaccines now being available. The CDC recommends layering multiple prevention strategies, including: promoting vaccination; consistent and correct use of masks; physical distancing; screening for prompt identification of cases; improved ventilation; handwashing and respiratory etiquette; staying home when sick and getting tested; contact tracing in combination with isolation and quarantine; and routine cleaning with disinfection under certain conditions.[65] Studies of SARS-CoV-2 transmission in schools that consistently implemented layered prevention strategies have shown success in limiting transmission in schools, even when testing of close contacts has been incomplete. [65] In June 2020 the Harvard School of Public Health published "Healthy Schools Risk Reduction Strategies for Reopening Schools" which outlined a range of mitigation strategies under the themes of healthy classrooms, healthy buildings, healthy policies, healthy schedules and healthy activities.[91]

The Pfizer COVID-19 vaccine for 5-11 year olds

A phase 3 randomised control trial was conducted to assess the safety, immunogenicity and efficacy of two doses of the Pfizer Comirnaty (BNT162b2) vaccine ('the Pfizer vaccine') administered 21 days apart in children aged 6 months to 11 years, with findings thus far published for 5-11-year-olds.[92]

During the phase 1 study from 24 March through 14 April 2021, a total of 48 children 5-to-11 years of age received 10 μ g, 20 μ g, or 30 μ g of the Pfizer vaccine (16 children at each dose level). For the phase 1 trial, a total of 50 children 5 to 11 years of age were screened for inclusion at four US sites, and 48 received escalating doses of the Pfizer vaccine. Half the children were male, 79% were White, 6% were Black, 10% were Asian, and 8% were Hispanic or Latinx. The mean age was 7.9 years. Based on reactogenicity and immunogenicity, a dose level of 10 μ g was selected for further study.[92]

In the phase 2/3 trial, participants were randomly assigned in a 2:1 ratio to receive two doses of either the Pfizer vaccine at 10ug or placebo. A total of 2268 children were randomly assigned to receive the Pfizer vaccine (1517 children) or placebo (751 children). At data cut-off, the median follow-up was 2.3 months.[92] The trial was run across 81 sites in the US, Spain, Finland and Poland. Overall, 52% were male, 79% were White, 6% were Black, 6% were Asian, and 21% were Hispanic or Latinx. The mean age was 8.2 years; 20% of children had coexisting conditions (including 12% with obesity and approximately 8% with



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asthma), and 9% were SARS-CoV-2—positive at baseline. Apart from younger age and a lower percentage of Black and Hispanic or Latinx 5-to-11-year-olds (6% and 18%, respectively) than 16-to-25-year-olds (12% and 36%, respectively), demographic characteristics were similar among the 5-to-11-year-old and 16-to-25-year-old Pfizer recipients who were included in the immunobridging subset.[92]

Children with no or stable pre-existing conditions were eligible to participate, except those with an immunocompromising or immunodeficiency disorder, those with a history of MIS-C, or those receiving immunosuppressive therapy (including cytotoxic agents and systemic glucocorticoids). In addition, in the phase 1 study, children with a previous clinical or virologic COVID-19 diagnosis were excluded.[92]

Safety and reactogenicity

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Safety evaluations included assessment of reactogenicity events reported by a parent or guardian using an electronic diary for 7 days after each dose. Data on unsolicited adverse events, including confirmed diagnoses of myocarditis or pericarditis, were collected from the first dose through 1 month after the second dose. Data on serious adverse events will be collected from the first dose through 6 months after the second dose. [92]

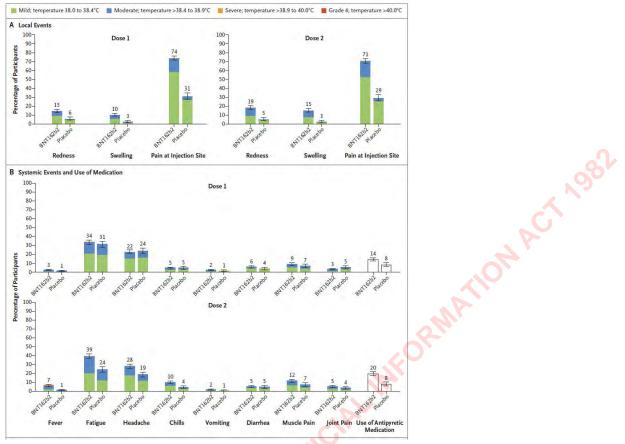
In the 5-to-11-year-olds, as in other age groups, the Pfizer vaccine had a favourable safety profile, with side effects generally comparable to those observed in 16 - 25-year-olds who received standard 30 μ g doses.[93] Most local reactions were mild to moderate, lasting 1-2 days. Injection-site pain was the most common local reaction, occurring in 71-74% of Pfizer recipients. Fatigue and headache were the most frequently reported systemic events. In general, systemic events were reported more after the second dose than first dose (see Figure 2). As compared with adults and adolescents in the pivotal trial, 5-to-11-year-olds reported a higher incidence of injection-site redness (15 to 19%, vs. 5 to 7%) and swelling (10 to 15%, vs. 5 to 8%), but a generally lower incidence of systemic events, including fever (3 to 7%, vs. 1 to 20%) and chills (5 to 10%, vs. 6 to 42%).[92, 94, 95]

Figure 2: Local Reactions and Systemic Events Reported in the Phase 2–3 Trial (5-11 year olds) within 7 Days of Injection of Pfizer or Placebo.[92]



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No vaccine-related serious adverse events were noted in the clinical trial; however, the trial was too small to detect rare side effects such as myocarditis or thrombosis with thrombocytopaenia. The trial was therefore not powered to detect any rare unanticipated adverse events in this age group. [96] From the first dose through one month after the second dose, adverse events were reported by 10.9% of Pfizer recipients and 9.2% of placebo recipients. Slightly more Pfizer recipients (3.0%) than placebo recipients (2.1%) reported adverse events that were considered by the investigators to be related to the vaccine or placebo. Severe adverse events were reported in 0.1% of Pfizer recipients and 0.1% of placebo recipients. Three serious adverse events in two participants were reported by the cut-off date; all three (postinjury abdominal pain and pancreatitis in a placebo recipient and arm fracture in a Pfizer recipient) were considered to be unrelated to the vaccine or placebo. No deaths or adverse events leading to withdrawal were reported. Lymphadenopathy was reported in 10 Pfizer recipients (0.9%) and 1 placebo recipient (0.1%). No myocarditis, pericarditis, hypersensitivity, or anaphylaxis in Pfizer recipients was reported. Four rashes in Pfizer recipients (observed on the arm, torso, face, or body, with no consistent pattern) were considered to be related to vaccination; the rashes were mild and self-limiting, and onset was typically 7 days or more after vaccination.[92]

Immunogenicity and Efficacy

For all participants in the phase 1 and for a subset of participants in phase 2/3, blood samples were collected for immunogenicity assessments, which included determination of SARS-CoV-2 neutralisation titres. Serum samples collected from 5-to-11-year-olds and 16-to-25-year-olds were assayed in parallel to ensure comparability of titres.[92]

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Immune responses one month after the second dose of the Pfizer vaccine were immunologically bridged to those in 16-to-25-year-olds from the pivotal trial of two 30 μ g doses of Pfizer. Children aged 5-11 receiving two 10 μ g doses had a similar, statistically non-inferior, neutralising antibody responses with a geometric mean titre (GMT) of 1,197.6 (95% CI: 1,106.1, 1,296.6) vs 1,146.5 (95% CI: 1,045.5, 1,257.2) for ages 16-25.[93] One month after the second dose, the geometric mean ratio (GMR) of SARS-CoV-2 neutralising titres in 5-to-11-year-olds to those in 16-to-25-year-olds was 1.04 (95% CI, 0.93 to 1.18), a ratio meeting the prespecified immunogenicity success criterion (lower bound of two-sided 95% CI,>0.67; GMR point estimate, \geq 0.8).[92, 93] One month after the second dose, the GMR of SARS-CoV-2 neutralising titres in 5-to-11-year-olds to those in 16-to-25-year-olds was 1.04 (95% CI, 0.93 to 1.18), a ratio meeting the prespecified immunogenicity success criterion (lower bound of two-sided 95% CI,>0.67; GMR point estimate, \geq 0.8).[92]

Vaccine efficacy against symptomatic NAAT-confirmed COVID-19 at 7 days or more after the second dose was assessed. COVID-19 with onset 7 days or more after the second dose was reported in three recipients of the Pfizer vaccine and in 16 placebo recipients, producing a vaccine efficacy or 90.7% (95% CI, 67.7 to 98.3).[92] No cases of severe COVID-19 or MIS-C were reported.

Data are not yet available on the real world effectiveness of the vaccine to protect against hospitalisation or infection in this age group, but are expected in coming months.[96]

Real-world rollout

In October 2021, the Global Advisory Committee on Vaccine Safety (GACVS) concluded that in all age groups the benefits of mRNA COVID-19 vaccines in reducing hospitalisations and deaths due to COVID-19 outweigh the risks.[4] The Advisory Committee on Immunization Practices (ACIP) made an interim recommendation for use of the Pfizer vaccine in children aged 5-11 years in the United States for prevention of COVID-19.[3, 97] This was unanimously supported by the Committee. In making this recommendation, ACIP considered the importance of COVID-19 as a public health problem, as well as benefits and harms, parents' values and preferences, acceptability, feasibility, resource use, and equity for use of the vaccine among children.[3, 97]

ACIP conducted a systematic review of published and unpublished evidence for benefits and harms. Key conclusions from ACIP included:

"ACIP determined that use of the Pfizer-BioNTech COVID-19 vaccine among children is a reasonable and efficient allocation of resources. To expand COVID-19 vaccine access, additional considerations should be given to demographic groups that have experienced disproportionate COVID-19 morbidity and mortality, as well as those with barriers to routine health care (e.g., members of certain racial/ethnic groups and those living in a rural or frontier area, experiencing homelessness, with a disability, or lacking health insurance). Children from racial and ethnic minority groups have experienced a disproportionally high incidence of COVID-19 as well as secondary impacts of the COVID-19 pandemic such as reduced in-person learning (12). Providing rapid and equitable access to COVID-19 vaccines for children will necessitate increasing the enrollment of pediatric health care providers into the COVID-19 vaccination program, using the broad geographic accessibility of pharmacies, and expanding school-focused strategies to ensure vaccination opportunities for a diverse population, as well as engagement with community leaders, pediatric health care providers, and parents or guardians."[3]

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These equity related comments have high relevance for New Zealand.

The US FDA approved a modified formulation of the Pfizer vaccine (10 µg each dose, administered 3 weeks apart) for children aged 5-11 on 29 October 2021.[98] On 2 November, CDC recommended the use of the vaccine in this age group.[99] The White House announced on 18 November that 2.6 million children received the vaccine.[100] From December 14, children aged 5-11 will need to show proof of at least one dose of COVID-19 vaccine to participate in indoor activities in New York City. As of 12 December, almost 5.4 million children aged 5-11 in the US had received at least one dose and almost 2.5 million children had received their second dose. [101] Other countries including Canada, Israel, UAE, Costa Rica, Singapore, Malaysia, Bahrain, Slovakia, Saudi Arabia, Australia and Kuwait have authorised use of the Pfizer vaccine in children aged 5-11 years. Data are yet to be reported from any of these countries.

On 25 November, the European Medicines Agency recommended granting approval for children aged 5 to 11. On 1 December 2021 the European Centre for Disease Prevention and Control published interim public health considerations for COVID-19 vaccination of children aged 5-11 years.[36]

In Australia, on 5 December the Therapeutic Goods Administration (TGA) provisionally approved the Pfizer vaccine as safe and effective for use among this age group.[102] On 10 December 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) recommended use of this vaccine in 5-11 year-olds.[96] The Australian Government will start rolling out the Pfizer vaccine to 5 to 11-year-olds from early January 2022.

Regulators in the UK and New Zealand are reviewing the data for 5-11 year-olds and are yet to approve the vaccine for this age group.

Dosing intervals

The US has recommended a 3 week interval between doses as in the clinical trials. There are no data available about extending the interval of the paediatric formulation of the Pfizer vaccine, however Canada is recommending a minimum 8 week interval. [103] Similarly, in Australia, the schedule recommended by ATAGI for this age group is 2 doses, 8 weeks apart. In special cicrumstances the interval may be shortened to a minimum of 3 weeks. [96] Data from older age groups has showed that an extended dosing interval may improve immunogenicity and the effectiveness after the second vaccine, and may also reduce the risk of myocarditis and pericarditis after vaccination. [96]

Data are also very limited on extended dosing intervals for the Pfizer vaccine in adults and the impact on vaccine efficacy and safety. However, emerging data suggests that the immune response is likely improved somewhat by extending the dosing interval. This is consistent with basic principles of vaccinology and immunology, that suggests that immune responses are generally better with longer intervals.

Several countries have been using extended intervals, ranging from approximately 6-16 weeks for the Pfizer vaccine for their general populations, including England, Canada, and several countries in Europe. A study of 750 participants aged 50-89 years in the UK found higher protection following extended schedules. GMTs at 14-34 days were 6703 (95%CI, 5887-7633), higher than those receiving Pfizer 19-29 days apart (694; 540 - 893). Higher two-dose vaccine efficacy was also observed with >6 week intervals between Pfizer doses compared to the authorised 3-week schedule, including ≥80 year-olds.[104] Another study from Canada found efficacy was significantly higher against both infection and hospitalisation with longer 7-8-week vs. manufacturer-specified 3-4-week interval between doses.[105] With both studies however it's

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unclear whether this results in more durable protection, as waning protection, at least against infection, seems to be similar across different interval periods used. The studies have also had small sample sizes.

There may also be a connection between shorter intervals and increased reactogenicity or adverse events. One study found reactogenicity after a late second dose (given at 44-45 weeks post-first dose) or a third dose was lower than reactogenicity after a first dose.[106] Considering the increased risk of serious adverse events such as myocarditis in younger age groups, there could be an argument for an extended dosing interval. However, is without direct evidence that an extended dosing interval reduces the risk of myocarditis. Relevant to operational considerations, a pre-print paper has shown a statistically significant increase in myocarditis occurrence following the second dose of the Pfizer vaccine if the second dose was given at a shorter interval of less than 30 days between doses.[107] However, the study was limited to those aged 12 and over.

Coadministration

There is yet to be specific recommendations in the New Zealand setting for the coadministration of COVID-19 vaccines in children, or the possibility of the COVID-19 vaccine being combined in a formulation with other vaccines.

There are limited clinical trial, observational, or laboratory data on the safety and immunogenicity associated with the coadministration of the Pfizer COVID-19 vaccine and other vaccines in all populations. Based on first principles, there is the potential for a reduced immune response when two different types of vaccine are administered together or within several days of each other. However, there are no additional safety concerns associated with coadministration, over and above each vaccine's individual safety profile. Given that the catch-up campaigns for MMR, HPV, and Boostrix are largely among younger age groups, and that these individuals are likely to have a robust immune response, younger age groups are less likely to be adversely impacted by coadministration of vaccines. Younger age groups have lower vaccination rates compared to others. Any obstacles to accessing and completing vaccinations should be removed and steps should be taken to encourage completion of the recommended vaccine schedules. In general, the risk of reduced immune protection from coadministration of the Pfizer COVID-19 vaccine and other vaccines is low in younger age groups, while the public health benefit gained from higher vaccine coverage is substantial.

In New Zealand adults, CV TAG earlier recommended either dose of the Pfizer vaccine can be administered at any time before, after or simultaneously with other Schedule vaccines (in separate syringes, at separate sites), including MMR, influenza, HPV, Tdap and meningococcal vaccines, and this has been included within the Immunisation Handbook. The only exception is the live herpes zoster vaccine for which, spacing of at least 7 days is recommended before or after the Pfizer vaccine.[108]

The CDC has stated that COVID-19 vaccines 'may be administered without regard to timing of other vaccines, which includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day'.[109] The American Medical Association states it is considered best practice to administer all the vaccines someone is eligible for in the same visit as it helps ensure that people are up to date with their vaccinations, though there are some exceptions, such as children with asplenia, complement component deficiency or HIV infection.[110] They also state that for those children who need two doses of the influenza vaccine, they should receive their first dose early as the second dose cannot be given until four weeks later but the circulation of influenza can fluctuate at different times.

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In Australia, ATAGI has said that the paediatric Pfizer COVID-19 vaccine can be co-administered with other vaccines, though parents and guardians should be aware that this may be associated with an increase in mild-moderate adverse events. [96] Health Canada recommends that if possible, children shouldn't receive the Pfizer vaccine within 14 days of other vaccines, such as the flu vaccine. This is a precaution to monitor any side effects from the COVID-19 vaccine or another vaccine. [103]

Number needed to treat

The number needed to treat (NNT) for a vaccine is interpreted as the average number of people who need to be vaccinated to prevent one additional adverse outcome from the disease. It is calculated as 1/(incidence in unvaccinated – incidence in vaccinated).

It is important to note that the NNT is not a fixed value for any one vaccine, outcome or population. It will vary with baseline risk (incidence in unvaccinated), which for infectious diseases can fluctuate with factors such as control measures in place (e.g. border controls, lockdowns, masks) and season. Although the simplest calculations of NNT can be performed using trial data, it should be noted that trial data are likely to overestimate the NNT. This is because trials are often "completed" relatively early which may appear to reduce the background risk (and increase the NNT). The NNTs for Pfizer vaccine trials are shown in Table 2.

Table 2: Numbers Needed to Treat, Pfizer COVID-19 vaccine trials

Trial	NNT confirmed COVID-19	NNT severe disease/ hospitalisation	NNT death	Notes
Pfizer phase 3 COVID-19 vaccine trial, adults (16 years and over)	141 Vacc: 8/21,720 Plac: 162/21,728	2716 Vacc: 1/21,720 Plac: 9/21,728	Not calculable (no cases in either group)	To October 9 th 2020 [94]
	30 Vacc: 77/23,153* Plac: 850/23,153*	723 Vacc: 0/23,153* Plac: 32/23,153*	N/A (not reported)	To March 13 th 2021[111]
Pfizer phase 3 COVID-19 vaccine trial, adolescents (12-15 years)	71 Vacc: 0/1131 Plac: 16/1129	N/A (not reported)	Not calculable (no cases in either group)	58% had at least 2 months of follow-up after their second vaccine dose[95]
Pfizer phase 3 COVID-19 vaccine trial, children (5- 11 years)	51 Vacc: 3/1517 Plac: 16/751	Not calculable (no cases in either group)	Not calculable (no cases in either group)	Median 2.3 months follow up. All recruited early to mid June 2021[92]

^{*} Denominators per group not reported but groups previously very closely balanced

It is challenging to present a fair comparisonof NNTs across childhood vaccines. This is because baseline incidence of these infectious disease can vary substantially over time period, and the length of time that the population is observed for. Table 3 presents NNTs for a range of scenarios, with worked examples for measles vaccine and COVID-19 in children. To make these comparisons as fair as possible, it is assumed that in a hypothetical, completely unvaccinated population of children, each virus is allowed to circulate freely

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until the herd immunity threshold is reached. Because of this, the baseline risk for COVID-19 outcomes is substantially higher than in the Phase 3 trials reported in Table 2, and the NNTs therefore lower. Additionally, for the calculations around NNTs for COVID-19 in children, there are many uncertainties around numbers used to calculate these estimates, including R0 in children, and the proportion of infected children who go on to die. However, in these examples, the NNTs for COVID-19 vaccine for each outcome are generally around 5 times that for measles vaccine.

Table 3: Number needed to treat with different percentage of population with outcome with no vaccination, and vaccines of different efficacy

		Number Needed to Treat to Prevent One Occurrence of the Outcome								
		Percenta	ge of pop	oulation wi	th outcor	me of int	erest in a	bsence (of vaccine	
	100%	75%	50%	10%	5%	1%	.75%	.5%	.1%	.01%
95% effective vaccine	1.1	1.4	2.1	11	21	105	140	211	1053	10526
80% effective vaccine	1.3	1.7	2.5	13	25	125	167	250	1250	12500
50% effective vaccine	2	2.7	4	20	40	200	267	400	2000	20000

Worked examples:

<u>Measles in children:</u> With no vaccination, around 92-94% of the population will become infected (usually in childhood), based on R0 of 12-15. With vaccine efficacy of 95%, NNT would be just over 1 to prevent 1 case of measles. The NNT to prevent 1 hospitalisation would be just over 4 (based on around 1 in 4 cases needing hospitalisation), and just over 1000 to prevent one measles death (based on around 1 per thousand).

Covid-19 in children: It should be noted there are many uncertainties around these estimates. With no vaccination, and assuming R0 of 6, around 83% of the population would become infected at some point (possibly fewer if R0 lower in children resulting in higher NNTs, possibly higher if natural infection doesn't prevent re-infection allowing on going circulation). With vaccine efficacy of 95%, NNT would be around 2.5 to prevent 1 symptomatic case (based on around 50% of cases in children being symptomatic [5]). The NNT would be around 30 to prevent 1 hospitalisation (based on 1 in 25 of cases in 6-11 year olds being severe [6]), and 5000 to prevent 1 death (based on 1 in 4000 cases dying: 4% of cases being severe and 0.6% of severe cases dying.[112])

Risks and benefits of vaccinating 5-11 year olds in Aotearoa New Zealand

The decision to vaccinate children requires very careful weighing of the known and potential risks and benefits. The balance of risks and benefits of COVID-19 vaccination in children is more complex than in adults as the relative harms from vaccination and disease are less well established in this age group.[35]

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The balance of direct benefits over potential vaccine risks (such as rare cases of myocarditis) is more limited in this age group compared to older individuals.[96]

Risks

Careful consideration must be given to the incidence of severe adverse events in this age group. The risk of myocarditis (or other rare, serious adverse events) in children has not yet been determined, nor has the long-term safety of the vaccine.[4] This is a new class of vaccine and it cannot be assumed that the responses of young children will be the same as older children or adults. Some adverse events in other age groups have only become apparent following widerspread rollout, and the trials in young children (around 2,200 children) are too small to be able to detect rare side effects. Vaccination may have mild side effects in children, including fatigue resulting in absences from school. Given COVID-19 is generally mild and rarely severe, this risk of adverse events must be balanced. Within several months, millions of children in the US will have been vaccinated, which will provide much more information about safety as well as potential impact on community transmission. An option could be to wait for further real world data before making a final decision. The efficacy of vaccines against MIS-C and long COVID are still unknown, and therefore vaccines may not protect them against these conditions.

ATAGI states that the risk of myocarditis or pericarditis after mRNA COVID-19 vaccination in children aged 5-11 years is not yet known but appears to be rare based on preliminary data from US surveillance networks.[96] Paediatric cardiologists have noted that myocarditis after the vaccine is rarer and usually milder than the cardiac complications from COVID-19, including those from multisystem inflammatory syndrome (MIS-C).[113] In a US CDC report, myocarditis was reported up to 37 times more often in unvaccinated children less than 16 years old with COVID-19.[36]

Vaccination status and the potential for mandates also has inherent risk as it may be that this is a cause for exclusion (whether vaccinated or unvaccinated), and those who are unvaccinated may not be able to fully participate in some environments (even if not required by law). This is likely to inequitably impact communities who are already experiencing disadvantage and where current vaccine coverage is poor. Given parental consent is required for vaccination in this group, there may be some reluctance by some parents to vaccinate children who would like to be vaccinated. Importantly, the mode of delivery for vaccination in this age group will need to be equitable, noting that in-school models of vaccine delivery have been used in the past and been a success. This will not reach some children in this age group, and consideration will need to be given to those in isolated communities, undertaking distance learning, or home-schooled.

In terms of risks beyond individual level factors, the role of children in transmission still requires further evidence. It is possible that a national rollout in the 5-11 year old age group would not significantly reduce overall levels of infection. Most children who get COVID-19 do so from a household exposure, so high coverage in adults and older children is a good strategy for protecting children. Given that vaccinated and unvaccinated people can have similar peak viral loads during infection and transmission of the Delta variant in households occurs equally as often from vaccinated and unvaccinated individuals, [114] vaccination of this age group may have little impact on transmission in households in the context of high community transmission. However, there have been few studies that have specifically looked at the ability of children with breakthrough infections to transmit.

The WHO states that before considering implementing primary vaccination series in adolescents and children, it is important to attain high coverage of primary vaccination in highest risk subgroups, such as

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older adults or peoeple with comorbidities (taking into account booster doses as needed based on evidence of waning and optimizing vaccination impact).[4] As a matter of global equity, as long as many parts of the world are facing extreme vaccine shortages, countries that have achieved high vaccine coverage in their high-risk populations should prioritise global sharing of COVID-19 vaccines through the COVAX facility before proceeding to vaccination of children and adolescents who are at low risk for severe disease.[4]

There is also the risk that rolling out the Pfizer vaccine in this age group will further negatively impact the national immunisation schedule for children, where vaccination rates for MMR, HPV and Boostrix are falling and campaigns have been impacted by COVID-19 and lockdowns. There is a danger that rolling out an additional vaccine will further derail catch-up campaigns that are currently underway through the diverting of public health resources, increasing the public health risk of outbreaks. Vaccination rates are lowest among Māori and Pacific, and therefore there are equity concerns that there will be greater risk in these populations. If unanticipated safety issues were to emerge with wider use of the Pfizer vaccine, this could also impact trust in the national immmunisation programme generally.

Benefits

The direct health benefit of vaccinating children and adolescents is lower compared with adults, due to the lower incidence of severe COVID-19 and deaths.[4] However, the risk of hospitalisation and death from COVID-19 is similar or even higher than that for other diseases for which vaccines are routinely given. In addition, if a high proportion of children are infected, even a very low rate of severe illness might translate to a high absolute number of cases.[35]

The benefits of vaccinating children in this age group are that it will help protect those who are immunocompromised, those who are very young or otherwise unable to be vaccinated, and provide protection for the vulnerable in multi-generational households. It will be very important for equity, as currently many of New Zealand's COVID-19 cases are in children and in disadvantaged communities. In high-income countries, children from deprived and ethnic minority groups are more frequently infected with SARS-CoV-2 which might be due to a greater likelihood of living with unvaccinated adults or in multigenerational and overcrowded households.[35] They may also have more severe outcomes associated with infection.[35]

While the role of children in transmission may be smaller, given the vaccine reduces the risk of infection, it will reduce the risk of children introducing COVID-19 into the home and exposing family members, who might then need to stand down from education and work. This is particularly important in households with several children. Having ongoing exposures and consecutive isolation periods may result in children having to isolate for a significant period of time.

Vaccination also brings wider benefits through the avoidance of isolation, quarantine, school closures and other indirect harms of lockdowns. School attendance is critical to the well-being and life prospects of children and to parental participation in the economy. [4] Vaccinating school-aged children may help minimise school disruptions by reducing the number of infections at school and the number of children required to miss school because of quarantine requirements. [4] In addition, some children are reliant on meals provided at schools, as food insecurity is increasingly common, particularly in low decile schools. Allowing schools to remain open will allow these programmes to continue. In an educational setting, vaccination may mean that other measures which have been challenging to implement can be reduced, such as social distancing and the wearing of masks. Vaccination will also help protect teaching staff and their whānau at home who may not be eligible to be vaccinated. From a wellbeing perspective, vaccination

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will help maintain normality in the education system and keep learning in a structured classroom environment. This will help contribute to normal routines and a sense of stability for children after nearly two years of disruption, will mean a reduced need to subject children to testing which can be quite invasive, and will help make children feel more involved in the 'team of five million' messaging that has underpinned New Zealand's response to the pandemic.

Although severe or fatal COVID-19 is rare in the 5-11 age group, some children (e.g. those with certain comorbidities) are substantially more vulnerable. These groups could be considered for accelerated access to the appropriately dosed Pfizer vaccine. In their case, the risk of harm from vaccination is estimated to be lower than the risk of harm from COVID-19. [35]

Another advantage of vaccinating children is the possibility of decreasing transmission and thus reducing severe cases in adults and the risk of new virus variants emerging. [35] If vaccinating 5-11 year olds also reduces cases in other age groups, this might also lower the likelihood of increased restriction settings and lockdowns and minimise disruption to young people's lives.

However, it is possible that without introducing vaccines to this age group, there may be a series of rolling outbreaks in Māori and Pacific tamariki, resulting in significant impacts on their whānau and communities with isolations required for multiple children within families in succession, which could continue for an extended period of time. However, it is worth noting that isolation period length does not vary depending on vaccination status.

It is important to note the te ao Māori view of tamariki is not just as individual entities, as they have very strong links to whānau and communities and consider them inextricably interlinked. This has important implications if vaccination was to be offered to this age group. Older family members may be more likely to take up the opportunity to get vaccinated as a whānau, in settings familiar to them, such as those offered by Māori health providers or iwi/hapu-led vaccine initiatives. It is likely that the lower rates of vaccination in Māori are not due to hesitancy so much as inadequate access to the vaccine and culturally appropriate care and messaging.

In addition, whilst there may be some concerns about the effect of extending the vaccination programme to 5-11 year olds on other vaccination programmes, this operational consideration could be better seen as an opportunity to improve the system going forward, rather than a reason to recommend against vaccinating 5-11 year olds for SARS-CoV-2. There is potential for a COVID-19 vaccination roll-out in 5-11-year olds to be used to also catch children up on other childhood immunisations, assuming that coadministration of vaccines can occur.

Concerns regarding possible stigmatisation and exclusions could be addressed in other ways, and not necessarily influence the decision to use. For example, there could be a policy decision that children cannot be denied access to locations/events on the basis of vaccination status, which could be operationalised by not issuing vaccine certificates for this age group.

Next Steps

A memo based on this RfA and CV-TAG discussions will be written and shared with CV TAG for approval.



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In the development of this work, the following parties have been consulted with: Intelligence and Surveillance team, Science and Insights

CV-TAG and invited guests, including Māori paediatricians

Resources used:	ast the same of th	
Ministry of Health Policies and Procedures	⊠ Yes □ No	
External Health Scientific organisations	⊠ Yes □ No	
Existing database of RFAs	⊠ Yes □ No	
Internal Ministry of Health Advice	□ Yes □ No	
External Expert Advice	⊠ Yes □ No	
Literature Review	⊠ Yes □ No	

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